COVID-19: A Motivating Force to Reimagine Clinical research
South Carolina Clinical & Translational Research (SCTR) Institute
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Overview
The emergence of SARS-CoV-2 and the subsequent COVID-19 pandemic forced the country to enact extreme measures to limit virus transmission. Academic health institutions implemented measures for the protection of patients and families, staff, and trainees. These included physical distancing, enforced by limiting visitors and non-essential personnel, to support infection control measures as well as to conserve limited protective equipment supply and medication stores. At the same time, the scientific community was developing research questions to understand the disease mechanism and course, identify new and repurpose existing therapeutics, and engineer and test vaccines.

MUSC leveraged its CTSA program to implement safety measures in a manner to limit an adverse effect on clinical research (e.g. continue research remotely) and to prioritize COVID-19 research opportunities. Building on a coordinated and collaborative management model (depicted below) the South Carolina Clinical and Translational Research Institute partnered with investigators, research leadership, research regulatory and compliance offices, and informatics to implement tactics for remote and virtual trials and to fast-track research study review and start-up.

Utilization & Impact
Numerous study teams have sought consultations through SPARCRequest© for implementing virtual approaches including teleconsult, remote study visits and monitor access, and investigational product management. A resource website centralizes guidance and tools and has received nearly 1,400 unique pageviews since going live in April 2020.

Resources

Remote & Virtual Trial Resources

Remote Trials

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Impact
Studies spanned observational to interventional approaches and supported all phases of the translational research continuum
• ~$24 Million - COVID-19 study contract awards in the 16th months
• 21 days - COVID-19 vaccine study contract executed & IRB approval
• 300 patients enrolled EAP Convalescent Plasma treatment study
• Highest enrolling site in AZ vaccine trial & 3rd highest enrolling site-Tocilizumab in Patients with Moderate to Severe COVID-19 Pneumonia
• 140 patients contributed to COVID-19 Biorepository; 6,260 specimens collected; 10 projects supported to date
• Fast tracked COVID study start up (receipt of documents to executed contract) from average 131 days to average 16.5 days (range: 13 – 20 days)