COVID-19 Prioritization Checklist for Intervention/Therapeutic Clinical Trials

Scores are on an NIH scale: *1 (Exceptional) to 9 (Poor)*

Principal Investigator: _____

Study Title: _____

Scientific Rationale (10%)	• Does treatment target SARS-CoV-2 proteins? • Is there evidence of preclinical efficacy? • Is there evidence of safety in human studies?	
Significance (10%)	• If the study accrued its target, would the results meaningfully affect clinical care for COVID-19 or contribute to generalizable knowledge? • Is there a new or innovative clinical trial hypothesis that would shape prioritization over other studies?	
Research Plan /Study Design (20%)	• Is the rationale for sample size reasonable? • Are procedures clearly-specified and well-justified? • Is the mechanism-of-action distinct from other trials at Johns Hopkins? • Are study endpoints reasonable/easily ascertained? • Are study procedures overly burdensome to clinical care or likely to present undue infection risk to study personnel?	
Operational Feasibility /Safety (10%)	• Are there enough prospective participants? • What are the competing trials with similar eligibility criteria? • Are there competing trials with a similar approach/mechanism? How briskly have they accrued study subjects? • Is the timeline for study completion realistic? • Is there sufficient funding for the study and is the budget realistic? • Is there a sufficient quantity of study drug? • Has an FDA IND/waiver been secured?	
Experience of Investigators (10%)	• Does the Principal Investigator (PI) or Co-Investigator (Co-I) have experience with infectious disease or critical care? • Does PI or Co-I have experience in clinical trials? • Does the PI or Co-I have experience consenting or treating hospitalized/intensive care unit subjects?	
Study Subject /Institutional Considerations (10%)	• What is level of burden on patient and family? • What is anticipated burden on patient care team? • What is burden on research team? • What is burden on support systems (laboratories)?	
Safety (10%)	• Is there adequate protection for patients? Is informed consent appropriate? • Does the potential benefit to subject and importance of the result justify the risks? • Does the potential benefit to subject and importance of the result justify the risks to the care team and to the study team? • Does the potential benefit to subject and importance of the result justify the risks to the community?	
Overall Impact (10%)	• What is the likely impact of the study on COVID-19 at Johns Hopkins and the world?	