

Human Subjects Research Phases Table

Research Protocols & Study Designs:	Research Phases*			
	Phase 1 15-20% restriction to only essential & critical capacity	Phase 2 20-50% more relaxed degree of access	Phase 3 50-70% normal operations	Phase 4 return to full research operations
Research with significant direct therapeutic benefits to the participant and risk of viral exposure can be minimized.	Allowed	Allowed	Allowed	Allowed
Research for which pausing could cause harm to participants.	Allowed	Allowed	Allowed	Allowed
Research that is conducted remotely regardless of potential for direct benefit.	Allowed	Allowed	Allowed	Allowed
COVID-19 Research – observational or interventional with special precautions in place.	Allowed	Allowed	Allowed	Allowed
Protocols that provide moderate potential benefit for an individual’s health or wellbeing over time which, if unavailable, may pose a long-term risk to the research participant (screening, diagnostic, palliative care).	Not allowed	Allowed	Allowed	Allowed
Research where all in-person interaction occurs concurrent with clinical or other interactions at the facility. For instance, a patient already on site for a clinic visit or a student already on campus for an academic purpose. In addition, research personnel must be willing and able to conduct interaction in accordance with safety guidelines.	Not allowed	Allowed	Allowed	Allowed
Protocols comparing standard treatments or practice guidelines which, if stopped, the potential societal benefit of the science would be significantly and adversely impacted. Must be measured against risk of participant exposure to COVID-19.	Not allowed	Not allowed	Allowed	Allowed
Non-essential or observational in-person research where facility occupancy allows physical distancing and risk mitigated to a minimal risk level.	Not allowed	Not allowed	Allowed	Allowed
Non-essential, in-person research in which risk cannot be mitigated to minimal risk levels.	Not Allowed	Not Allowed	Not Allowed	Allowed

***Research activities that are labeled as “Allowed” must be able to meet and consistently follow all applicable safety guidelines in order to resume/start.**