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
1	Research with significant direct therapeutic benefits to the participant and risk of vital exposure can be minimized.	Allowed	Allowed	Allowed	Allowed
2	Research for which pausing could cause harm to participants.	Allowed	Allowed	Allowed	Allowed
3	Research that is conducted remotely **regardless of potential for direct benefit.**	Allowed	Allowed	Allowed	Allowed
4	COVID-19 Research – observational or interventional with special precautions in place.	Allowed	Allowed	Allowed	Allowed
5	Protocols that provide 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
6	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
7	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
8	Research that does not provide direct benefit to individual human subjects but that provide societal/community benefit.	Not Allowed	Not Allowed	Allowed	Allowed
9	In-person research in which transmission risks cannot be fully controlled by the research teams (e.g., research in public settings or participants' homes, etc.)	Not Allowed	Not Allowed	Not Allowed	Requires Pre-approval from the Office of the Vice President for Research

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

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