

## Human Subject Research Coronavirus Phased Contingency Plan:

Guidance for Studies \*\*\*may be modified\*\*\* V4 4/3/2020

[International Sites](#) should follow this plan subject to local health authority and local IRB direction – see [more here](#).

	<b>Example Triggering Criteria</b>	<b>Changes to Research</b>
<b>Phase 0</b>	Potential, but no immediate threat of spread to local researchers and employees	<b>Develop contingency plans</b>
<b>Phase 1</b>	Regional community spread; no to minimal local cases	<b>Same as Phase 0</b> <b>Screen participants for potential infectious risk</b> <b>Cease sponsor on-site monitoring visits</b> <b>IRBs will implement triage procedures to prioritize reviews to manage workload</b>
<b>Phase 2</b>	Local community spread; High absenteeism; Sporadic institutional closures	<b>Same as Phase 1</b> <b>Defer enrolling new participants except for Tier 1 and limited Tier 2 studies.</b> <b>Implement tiered procedures for enrollment/research procedures:</b> Tier 1: allowable* Tier 2: must be strongly justified* Tier 3: direct participant contact should be paused

<b>Phase 3</b>	Massive regional disruption Widespread institutional closures	<p><i>Updated and effective on 4/3/2020</i></p> <p><b>Tier 1:</b></p> <p>Tier 1 studies must cease any in-person visits specifically for research purposes that require subjects to travel from out of state where the Governor of that state has issued a no travel order.</p> <p>All other in-person interactions may only continue for Tier 1 studies if the PI presents a compelling justification to continue these interactions and the petition to continue is approved by the IRB. Studies at the Sidney Kimmel Cancer Center or JH-ACH must seek the approval to continue in-person activities from their respective review committees.</p> <p>Requests for new enrollment in this Tier must continue to be submitted to the IRB, SKCCC or JH-ACH review committee as previously established.</p> <hr/> <p><b>Tier 2:</b></p> <p>Tier 2 studies must cease all in-person interactions. The IRB will no longer consider requests to continue in-person activities for this Tier. Data collection that does not require in-person participant interaction (e.g. telephone or online) may continue.</p> <p><b>No new enrollment is permitted for Tier 2 studies.</b></p> <hr/> <p><b>Tier 3:</b></p> <p>Tier 3 studies must not enroll new participants in studies requiring in-person interaction nor continue to conduct in-person visits. Data collection that does not require in-person participant interaction (e.g. telephone or online) may continue.</p>
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