

## APPENDIX A: Operational Checklist for Offsite Conduct of Clinical Research

PLAN ELEMENT	PLAN SPECIFICS
<b>Physical Distance Plan</b> <input data-bbox="354 331 451 415" type="checkbox"/>	<ul style="list-style-type: none"> <li>• Provide details on the provision of physical distance that is consistent with the current recommendations.</li> <li>• Establish maximum occupancy for offsite space.</li> <li>• Establish workspace markings (distances) where appropriate.</li> <li>• Provide separate sections/discussion for specialized/shared equipment that need their own personnel distance guidelines and markings.</li> </ul>
<b>Offsite Logistics Plan</b> <input data-bbox="354 573 451 657" type="checkbox"/>	<ul style="list-style-type: none"> <li>• The PI is responsible for creating a system whereby it is known in near real-time who is offsite and when they are conducting offsite in-person visits.</li> <li>• A list of all personnel who are allowed to conduct offsite in-person visits. If cohorts are utilized, the cohort groups may be provided.</li> <li>• Work (visit) hours for in-person visits should be stated.</li> <li>• Logistics for special shared equipment, if varied from established practice (e.g. how to reserve) should be explained.</li> </ul>
<b>Personnel Responsibilities</b> <input data-bbox="354 762 451 846" type="checkbox"/>	<ul style="list-style-type: none"> <li>• State responsibilities of study personnel and how they will know their roles.</li> <li>• Document standard safety rules and point to relevant existing guidance.</li> </ul>
<b>Cleaning Plan</b> <input data-bbox="354 909 451 993" type="checkbox"/>	<ul style="list-style-type: none"> <li>• Provide a plan for how the offsite location will be cleaned/sanitized.</li> <li>• PIs and personnel are advised that given the desire to maximize physical distancing, additional cleaning duties are expected of personnel. Areas to be considered: vehicle used in transport, touch spots, research equipment, among others.</li> </ul>
<b>Human Research Protection Plan</b> <input data-bbox="354 1161 451 1245" type="checkbox"/>	<ul style="list-style-type: none"> <li>• Explain steps to be taken to ensure that participants are protected against COVID-19 exposure.</li> <li>• Explain how you intend to manage research participants who test positive for COVID-19.</li> <li>• Ensure participants receive information regarding potential COVID-19 exposure risk by having them read and sign a COVID addendum to the consent form</li> <li>• If the project involves community-based research techniques such as data collection and/or interviews, describe updated safety procedures.</li> </ul>
<b>Research Biospecimen Plan</b> <input data-bbox="354 1423 451 1507" type="checkbox"/>	<ul style="list-style-type: none"> <li>• Explain steps to be taken to ensure safety in handling research specimens.</li> <li>• If the study involves collection and/or handling of COVID-19 specimens, describe the safety procedures to be implemented.</li> <li>• Ensure all staff have completed relevant safety training, e.g. Safe Shipping of Biohazards</li> </ul>
<b>PPE, Materials and Supplies Plan</b> <input data-bbox="354 1612 451 1696" type="checkbox"/>	<ul style="list-style-type: none"> <li>• Define needs for appropriate PPE and cleaning materials.</li> <li>• Document materials required before study launch.</li> <li>• State how the lab/study is procuring necessary PPE and/or specific cleaning materials.</li> <li>• Indicate if support is needed and specify for what PPE or other materials</li> </ul>
<b>Transportation Plan</b> <input data-bbox="354 1728 451 1812" type="checkbox"/>	<ul style="list-style-type: none"> <li>• How staff, equipment, PPE, and disinfection supplies will travel off site</li> <li>• How will specimens be handled and returned to campus</li> </ul>