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

<table>
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<tr>
<th>PLAN ELEMENT</th>
<th>PLAN SPECIFICS</th>
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| Physical Distance Plan      | • Provide details on the provision of physical distance that is consistent with the current recommendations.  
                                 • Establish maximum occupancy for offsite space.  
                                 • Establish workspace markings (distances) where appropriate.  
                                 • Provide separate sections/discussion for specialized/shared equipment that need their own personnel distance guidelines and markings. |
| Offsite Logistics Plan      | • 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.  
                                 • A list of all personnel who are allowed to conduct offsite in-person visits. If cohorts are utilized, the cohort groups may be provided.  
                                 • Work (visit) hours for in-person visits should be stated.  
                                 • Logistics for special shared equipment, if varied from established practice (e.g. how to reserve) should be explained. |
| Personnel Responsibilities  | • State responsibilities of study personnel and how they will know their roles.  
                                 • Document standard safety rules and point to relevant existing guidance. |
| Cleaning Plan               | • Provide a plan for how the offsite location will be cleaned/sanitized.  
                                 • 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. |
| Human Research Protection Plan | • Explain steps to be taken to ensure that participants are protected against COVID-19 exposure.  
                                 • Explain how you intend to manage research participants who test positive for COVID-19.  
                                 • Ensure participants receive information regarding potential COVID-19 exposure risk by having them read and sign a COVID addendum to the consent form  
                                 • If the project involves community-based research techniques such as data collection and/or interviews, describe updated safety procedures. |
| Research Biospecimen Plan   | • Explain steps to be taken to ensure safety in handling research specimens.  
                                 • If the study involves collection and/or handling of COVID-19 specimens, describe the safety procedures to be implemented.  
                                 • Ensure all staff have completed relevant safety training, e.g. Safe Shipping of Biohazards |
| PPE, Materials and Supplies Plan | • Define needs for appropriate PPE and cleaning materials.  
                                 • Document materials required before study launch.  
                                 • State how the lab/study is procuring necessary PPE and/or specific cleaning materials.  
                                 • Indicate if support is needed and specify for what PPE or other materials |
| Transportation Plan         | • How staff, equipment, PPE, and disinfection supplies will travel off site  
                                 • How will specimens be handled and returned to campus |