<table>
<thead>
<tr>
<th>Requires Amendment</th>
<th>Does NOT require Amendment if there is NO change in Assessments BUT may require an Amendment for Subject Notification and /or Revised Consent</th>
<th>Requires Reportable Event submitted to IRB within 72 hours</th>
</tr>
</thead>
</table>
| □ Planned changes that impact participant safety or data integrity  
  * Examples include: dispensing study drug without performing safety lab or procedure  
  * failure to capture endpoint assessment data  
  * If these changes impact risk/benefit, a revised consent should be submitted that addresses these issues for reconsenting existing subjects and enrolling future subjects | □ Conducting research visits outside of study window in a timeframe that does not impact safety or data integrity  
  ✗ Document as a minor deviation and retain in study records, and submit copy at the time of next continuing review if applicable  
  ✗ If PI plans to permanently adjust the study window moving forward, they should submit an amendment | □ Changes to protocols to prevent immediate hazard to research participants already enrolled in study. |
| □ Changes that involve protocol modifications to any of the following  
  ✷ Study procedures and/or assessments  
    * Examples include: study visit now conducted remotely but physical exam or vital will no longer be performed, or  
    * performing procedure or assessment at other location (e.g. private physician office)  
  ✷ Addition or removal of study visits  
  ✷ Study drug dispensing  
    e.g. ship drug directly to study participant  
  ✷ Planned data safety monitoring  
    * If these changes do not impact risk/benefit you may consider using COVID change notification for existing subjects but may require a revised consent for future subjects | □ Only change is conducting protocol assessments remotely  
  No change in any assessments or timing  
  ✗ For existing subjects, consider using the COVID Change Notification. Submit to IRB as amendment for approval  
  ✗ For future subjects, submit amendment to revise consent to address remote practices | |
<table>
<thead>
<tr>
<th>Use of an electronic digital signature on a consent form</th>
<th>Use of Remote Consent process</th>
</tr>
</thead>
<tbody>
<tr>
<td>* If using remote consent <em>and</em> an electronic digital signature, an Amendment is required</td>
<td></td>
</tr>
</tbody>
</table>