Requires Amendment	Does NOT require Amendment if there is NO change in Assessments BUT may require an Amendment for Subject Notification and /or Revised Consent	Requires Reportable Event submitted to IRB within 72 hours
☐ **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 ☐ **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	☐ **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** ☐ **Only change is conducting protocol assessments remotely** No change in any assessments or timing ↳ Document as a minor deviation and retain in study records, and submit copy at the time of next continuing review if applicable ↳ 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	☐ **Changes to protocols to prevent immediate hazard to research participants already enrolled in study.**

☐ **Use of an electronic digital signature on a consent form**	☐ **Use of Remote Consent process** * If using remote consent and an electronic digital signature, an Amendment is required	