

Requires Amendment	Does <u>NOT</u> 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
<p><input type="checkbox"/> Planned changes that impact participant safety or data integrity</p> <p><i>Examples include:</i></p> <ul style="list-style-type: none"> • dispensing study drug without performing safety lab or procedure • failure to capture endpoint assessment data <p>* If these changes impact risk/benefit, a revised consent should be submitted that addresses these issues for reconsenting existing subjects and enrolling future subjects</p> <p><input type="checkbox"/> Changes that involve protocol modifications to any of the following</p> <ul style="list-style-type: none"> ■ Study procedures and/or assessments <p><i>Examples include:</i></p> <ul style="list-style-type: none"> • study visit now conducted remotely but physical exam or vital will no longer be performed, <i>or</i> • performing procedure or assessment at other location (e.g. private physician office) <ul style="list-style-type: none"> ■ Addition or removal of study visits ■ Study drug dispensing <p>e.g. ship drug directly to study participant</p> <ul style="list-style-type: none"> ■ Planned data safety monitoring <p>* 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</p>	<p><input type="checkbox"/> Conducting research visits outside of study window in a timeframe that does not impact safety or data integrity</p> <ul style="list-style-type: none"> ↳ 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 <p><input type="checkbox"/> Only change is conducting protocol assessments remotely</p> <p>No change in any assessments or timing</p> <ul style="list-style-type: none"> ↳ 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 	<p><input type="checkbox"/> Changes to protocols to prevent immediate hazard to research participants <u>already enrolled in study.</u></p>

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