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| **This document must be used in conjunction with the Post Approval Submission Form or HRP-213 (Modification Form)** | | | | | |
| **IRB Number:** | | |  | | |
| **Protocol Name:** | | |  | | |
| **Principal Investigator Name:** | | |  | | |
| **Using the table below, please summarize the modifications included in the submission.** | | | | | |
| **Document**  **Type** | **Section** | **Page #** | | **Modification/Amendment/Change** | **Rationale for Change** |
| *Example: Main ICF* | *Risk Section* | *16-18* | | *Added additional common risks of fatigue, nausea, and diarrhea.* | *Updated IB risks section (Page 113 Table 44) identified these as new risks/risks with increased frequency* |
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