**Investigator Name:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ **Protocol/IRB Number:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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| **Protocol Deviation Types\*** | | | | | | | | | |
| A – Consent Procedures D – Laboratory Assessments/Procedures G – Randomization Procedures/Study Drug Dosing  B – Inclusion/Exclusion Criteria E – Study Procedures H – Visit Schedule  C – Concomitant Medication F – SAE/UP Event/Effect I – Other | | | | | | | | | |
| **Deviation No. (ex: 1, 2, 3, etc.)** | **Subject ID** | **Date of Deviation** | **Date Identified** | **Deviation Description** | **Dev. Type\*** | **Resulted in Adverse Event (Y/N)** | **Did Subject Continue in Study (Y/N)** | **IRB Reportable (Y/N)** | **IRB Reported Date** |
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