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* Deviation Code: (A-J) See codes below—**enter the appropriate deviation code from the list**.

|  |
| --- |
| **Deviation Codes:** |
| **A –** Consent Procedures | **B –** Inclusion/Exclusion Criteria | **C –** Concomitant Medication/Therapy | **D –** Laboratory Assessments/Procedures | **E –** Study Procedures |
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|  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Reference Number** | **Subject ID** | **Deviation Code****(see above)** | **Date of deviation****(dd/mmm/yyyy)** | **Date identified****(dd/mmm/yyyy)** | **Description** | **Did the deviation result in an adverse event (AE)?****Y/N** | **Did the subject continue on the study?****Y/N** | **Date of withdrawal****(dd/mmm/yyyy)** | **Ethics reporting requirements?****Y/N** | **Date reported to ethics****(dd/mmm/yyyy)** | **PI signature and date** |
|  |  |  |  |  |  | [ ]  Yes [ ]  No | [ ]  Yes [ ]  No |  | [ ]  Yes [ ]  No |  |  |
|  |  |  |  |  |  | [ ]  Yes [ ]  No | [ ]  Yes [ ]  No |  | [ ]  Yes [ ]  No |  |  |
|  |  |  |  |  |  | [ ]  Yes [ ]  No | [ ]  Yes [ ]  No |  | [ ]  Yes [ ]  No |  |  |
|  |  |  |  |  |  | [ ]  Yes [ ]  No | [ ]  Yes [ ]  No |  | [ ]  Yes [ ]  No |  |  |
|  |  |  |  |  |  | [ ]  Yes [ ]  No | [ ]  Yes [ ]  No |  | [ ]  Yes [ ]  No |  |  |
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|  |  |  |  |  |  | [ ]  Yes [ ]  No | [ ]  Yes [ ]  No |  | [ ]  Yes [ ]  No |  |  |
|  |  |  |  |  |  | [ ]  Yes [ ]  No | [ ]  Yes [ ]  No |  | [ ]  Yes [ ]  No |  |  |
|  |  |  |  |  |  | [ ]  Yes [ ]  No | [ ]  Yes [ ]  No |  | [ ]  Yes [ ]  No |  |  |
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|  |  |  |  |  |  | [ ]  Yes [ ]  No | [ ]  Yes [ ]  No |  | [ ]  Yes [ ]  No |  |  |
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|  |  |  |  |  |  | [ ]  Yes [ ]  No | [ ]  Yes [ ]  No |  | [ ]  Yes [ ]  No |  |  |