* Record all protocol deviations that occur at a study site (primary and satellite). It is required for both observational and interventional clinical research studies.
* Site staff may prepare a Protocol deviation form, but **each deviation should be signed and dated by the PI.**
* This Form is to be kept in the Study Master File (SMF) and Satellite Site Study File (SSSF) for the relevant site.
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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 |
| **F –** Serious Adverse Event Reporting/Unanticipated Adverse Device Effect | **G –** Randomization Procedures/Study Drug Dosing | **H –** Visit Schedule/Interval | **I –** Efficacy Ratings | **J –** Other, please specify |

|  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **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 |  |  |
|  |  |  |  |  |  | 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 |  |  |
|  |  |  |  |  |  | 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 |  |  |
|  |  |  |  |  |  | Yes  No | Yes  No |  | Yes  No |  |  |
|  |  |  |  |  |  | Yes  No | Yes  No |  | Yes  No |  |  |