|  |  |  |  |
| --- | --- | --- | --- |
| **AE/Con Med Review** | If yes, record on AE or Con meds form |  | Comments |
| New AE: | Yes | No |  |
| New Con Meds: | Yes | No |  |
| Existing AE update: | Yes | No |  |
| Existing Con Med update: | Yes | No |  |

|  |
| --- |
| **Subject Questionnaires / Patient Report Outcomes (PROs) completed?** |
| *<<enter questionnaire name here>>*  *<<enter questionnaire name here>>* |

|  |
| --- |
| **Clinician assessments completed?** |
| *<<enter assessment name here>>*  *<<enter assessment name here>>* |

|  |  |
| --- | --- |
| **Vital Signs** | **Time: Performed by:** |
| Blood pressure: | \_\_\_\_\_\_\_/\_\_\_\_\_\_\_ mmHg R or L arm |
| Heart Rate: | \_\_\_\_\_\_ bpm |
| Respiratory Rate: | \_\_\_\_\_\_ bpm |
| Oral Temperature: | \_\_\_\_\_\_ Fahrenheit |

|  |  |
| --- | --- |
| **Required study procedures completed** |  |
| <<List procedure>> | Yes  No: reason:\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| <<List procedure>> | Yes  No: reason:\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| <<List procedure>> | Yes  No: reason:\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| <<List procedure>> | Yes  No: reason:\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Were required labs collected? | Yes  No: reason:\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| PK samples | Pre-dose PK **Time**:  Time subject dosed **Time**:  xx min post dose PK **Time**:  x hours post dose PK **Time:**  x hours post dose PK **Time:** |
| Urine Pregnancy Test  Lot #:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Exp: \_\_\_\_\_\_\_\_\_\_\_\_ | Yes  No  NA\_\_\_\_\_\_\_  Results:  Negative  Positive  Read by:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **Study Drug** |  |
| Were drug bottles/packages from previous dispensing visit returned? | Yes No |
| Was drug compliance assessed? | Yes No |
| Was study drug dispensed? | Yes No |
| Was dose administered at visit? | Yes No  Time Administered: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Completed by:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Dosing Instructions reviewed with verbalized subject understanding? | Yes No  Completed by:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |