|  |  |  |  |
| --- | --- | --- | --- |
| **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 TestLot #:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Exp: \_\_\_\_\_\_\_\_\_\_\_\_ | [ ]  Yes [ ]  No [ ]  NA\_\_\_\_\_\_\_Results: [ ]  Negative [ ]  PositiveRead 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 [ ] NoTime Administered: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Completed by:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Dosing Instructions reviewed with verbalized subject understanding? | [ ] Yes [ ] NoCompleted by:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |