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| --- |
| **GENERAL INSTRUCTIONS** – delete this box from the completed form. Red text represents instructions to you – to be deleted from the final version.  **NOTE: This form is designed to be an example of a Schedule of Events. Update it as necessary for your specific study.**   * This template tool includes procedure and visit information as an example only. Study teams should delete all non-relevant information. * Study teams should review this carefully and make all adjustments as necessary for their study requirements. The format and inclusion of rows or columns is only meant to provide study teams with examples of how to build this table. * At the study team’s discretion, a Schedule of Events can only include participant-facing activities or can also include study-management tasks. For example, data entry or specimen shipping can be included on this Events table. * Events or procedures can be as detailed as makes sense for the study. For example, specifically naming Case Report Forms to be completed at each visit might be useful to ensure data entry occurs correctly. Another example might be a study that only collects specific vital signs depending on the visit could also add that information to this Events Table with a row for each specific vital sign. * A good Schedule of Events is one that provides enough detail that somebody could tell what needs to be done at each point in the study but does not overwhelm or crowd the page. * A Schedule of Events that is written for a protocol can also be used for consents with editing to remove non-participant-facing steps and language editing so that it is able to be understood in lay language. * This schedule of events table can be used in a protocol (if using [IRB template](https://www.bumc.bu.edu/irb/inspir-ii/irb-templates/), Section 18 Appendix) or Manual of Procedures or other study document. * This Schedule of Events must be updated if a protocol amendment changes the timing of an event or anything else on this schedule. |

| **Procedures** | **Screening** | **Baseline** | **Visit 1** | **Visit 2** | **Visit 3** | **Visit 4** | **Visit 5** | **Visit 6** | **Visit 7** | **Visit 8** | **Visit 9** | **Visit 10** | **As Needed Only** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| ***Visit Window*** | *Not*  *Applicable* | *Not*  *Applicable* | *+/- 2 days* | *+/- 2 days* | *+/- 2 days* | *+/- 2 days* | *+/- 2 days* | *-/+ 2 days* |  |  |  |  |  |
| Brief Screening Agreement | X |  |  |  |  |  |  |  |  |  |  |  |  |
| Screening Questionnaire | X |  |  |  |  |  |  |  |  |  |  |  |  |
| Informed Consent |  | X |  |  |  |  |  |  |  |  |  |  |  |
| Eligibility Review and Confirmation |  | X |  |  |  |  |  |  |  |  |  |  |  |
| Infusion |  |  | X | X | X | X |  |  |  |  |  |  |  |
| Blood Draw |  | X | X |  |  |  | X | X |  |  |  |  |  |
| Urine Collection |  | X | X |  |  |  | X | X |  |  |  |  |  |
| Vital Signs |  | X | X | X | X | X | X | X |  | X |  | X |  |
| Symptom Checklist |  | X | X | X | X | X | X | X | X | X |  |  |  |
| Sleep Quality Questionnaire |  | X | X |  |  | X |  | X | X | X |  |  |  |
| Medical Record Review Only |  |  |  |  |  |  |  |  |  |  | X | X |  |
| **Data Entry Only** | **Screening** | **Baseline** | **Visit 1** | **Visit 2** | **Visit 3** | **Visit 4** | **Visit 5** | **Visit 6** | **Visit 7** | **Visit 8** | **Visit 9** | **Visit 10** | **As Needed Only** |
| Eligibility Form |  | X |  |  |  |  |  |  |  |  |  |  |  |
| Study Drug Data Form |  |  | X | X | X | X |  |  |  |  |  |  |  |
| Vital Sign Form |  | X | X | X | X | X | X | X |  | X |  |  |  |
| Lab Results Form |  | X | X |  |  |  | X | X |  |  |  |  |  |
| Symptom Checklist |  | X | X | X | X | X | X | X | X | X |  |  |  |
| Sleep Quality |  | X | X |  |  | X |  | X | X | X |  |  |  |
| Long-Term Status Form |  |  |  |  |  |  |  |  |  |  |  | X |  |
| Protocol Deviation  *Assessment, Reporting,*  *Data Entry* |  |  |  |  |  |  |  |  |  |  |  |  | X |
| Adverse Event  *Assessment, Reporting,*  *Data Entry* |  |  |  |  |  |  |  |  |  |  |  |  | X |

|  |  |  |  |
| --- | --- | --- | --- |
| **Visit Name** | **Target Timeline** | **Window** | **Notes or Comments** |
| Screening | Not Applicable | Not Applicable |  |
| Baseline | Within 30 days of screening | | Study “clock” starts at baseline – this is considered Day 0 |
| Visit 1 | 7 days after Baseline | -/+ 2 days | First infusion |
| Visit 2 | 7 days after Visit 1 | -/+ 2 days | Visit 2-5 are all based on time after the previous infusion |
| Visit 3 | 7 days after Visit 2 | -/+ 2 days |
| Visit 4 | 7 days after Visit 3 | -/+ 2 days |
| Visit 5 | 7 days after Visit 4 | -/+ 2 days | Safety Visit, 7 days after last infusion |
| Visit 6 | 30 days after Visit 4 | -/+ 2 days | Safety Visit, 30 days after last infusion |
| Visit 7 | 90 days after Visit 4 | -/+ 7 days | Safety Visit, 90 days after last infusion |
| Visit 8 | 1 years after Visit 4 | -/+ 15 days | Final Participant Visit, 1 year after last infusion |
| Visit 9 | 2 years after Visit 4 | -/+ 15 days | Long-Term Status Review, medical record data review only |
| Visit 10 | 3 years after Visit 4 | -/+ 15 days | Long-Term Status Review, medical record data review only |