This document contains examples for a Schedule of Events to be included in the consent form and one that may be included in the protocol or provided as a standalone SOE.

## Visit Schedule for Consent Form

Study PI:

Contact Info:

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Visit Schedule** | | | | | | | |
| **Study Activity** | Screening Visit | Visit # / Timepoint | Visit # / Timepoint | Visit # / Timepoint | Visit # / Timepoint | End of Sudy Visit / W 14 | **Comments** |
| Consent Signed | X |  |  |  |  |  |  |
| Medical History | X |  |  |  |  |  |  |
| Physical Exam | X |  | X | X | X | X |  |
| Blood collection for lab tests | X |  | X |  | X |  |  |
| Side Effects Assessments | X | X | X | X | X | X |  |
| Study Medication – Pill Count | X | X | X | X | X | X | Bring your study medication to these appointments |
| Medications/Vitamins/Supplements |  |  |  |  |  |  |  |
| Time for each visit | 2 hrs | 1 hr | 1 hr | 30 min | 1 hr | 2 hr |  |

1. Name the study activity in terms the participant will understand. Blood collection for lab tests vs. CBC w/Diff.
2. Enter the visit or visit number.
3. Include the timepoint for the visit: Month 1. Include timepoint window, as applicable)
4. If the visit is virtual or via phone, label as such: Phone Visit Day 7.

## Schedule of Events for Protocol

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Schedule Of Events** | | | | | | | | | |
| **Study Activity** | **Timepoint** | | |  |  |  | **Comments (Optional)** | **Footnotes** |  |
|  | Screening (D0) | Treatment (D14 +/- 3d) | Follow Up: Week 2 | Follow Up: Month 1 | Follow Up: Month 2 | Follow Up: Month 3 |  |  | |
| Consent Signed | X |  |  |  |  |  |  |  | |
| Inclusion / Exclusion Criteria | X |  |  |  |  |  |  |  | |
| Physical Exam | X |  | X | X | X | X |  | Height only at Screening visit. | |
| CBC w/ Differential | X |  |  | X | X | X |  |  | |
| Pregnancy Test | X | X |  |  |  |  |  | Women of child-bearing potential only. | |
| Adverse Events | X | X | X | X | X | X |  |  | |
| Concomitant Medications | X | X | X | X | X | X |  |  | |

Study Activity:

List procedure name, and protocol reference (pg. #, section, etc.)

Timepoint:

1. Enter the timepoint name. Ex. Pre-screening, Screening, Baseline, Week 1 Day 7.
2. If a visit occurs in Treatment or Follow Up, add preface. Ex. Treatment: Week 1 Day 7
3. Indicate visit windows. Ex. +/-3D
4. If treatment occurs in cycles, indicate the cycle number(s).

Footnotes:

May be added in the table or listed below.

Footnotes should begin with an explanation of any abbreviations used in the table.