|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Protocol Name and IRB #** | | | | | | |
| **Data Collection Event** | **Pre-Enrollment** | **Enrollment** | **Week 1** | **Week 2** | **Week 3** | **Week 4** |
| Inclusion/Exclusion | X | X (confirm) |  |  |  |  |
| ICF Documentation |  | X |  |  |  |  |
| Medical History |  |  | X |  |  |  |
| Medical History Update |  |  |  |  |  | X |
| Concomitant Medications |  |  | X |  |  |  |
| Physical Exam |  |  | X |  |  | X |
| Vital Signs/Measurements |  |  | X |  |  | X |
| Telephone Contact |  |  | X | X | X |  |
| Research Sample Tracking Log |  |  | X | X | X | X |
| Drug Accountability Log |  |  | X | X | X | X |
| Protocol Deviation/Unanticipated Problem Log (PRN) |  |  |  |  |  |  |
| Serious Adverse Event Assessment |  |  | X | X | X | X |
| Subject Off Study\*\* |  |  |  |  |  | X |
| Etc. |  |  |  |  |  |  |

\*Complete prior to week 4 if early termination