IRB Protocol No: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date of the Visit: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Study Protocol Title: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Study Protocol Number: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Principal Investigator: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Sponsor: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Total # of Expected Subjects: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Total Subjects Enrolled: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

|  |  |  |  |
| --- | --- | --- | --- |
|  | Yes | No | Comments |
| Are site facilities appropriate? |  |  |  |
| Are Informed Consents recent? |  |  |  |
| Any adverse events found? |  |  |  |
| Any protocol noncompliance/deviation? |  |  |  |
| Are all Case Record Forms up to date? |  |  |  |
| Are storage date and investigating products locked? |  |  |  |
| Are participants well protected? |  |  |  |
| Any outstanding tasks or results of visits? |  |  |  |

Duration of visit: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Time start: \_\_\_\_\_\_\_\_\_\_\_\_\_\_ Time end:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name of IRB member/representatives: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Completed by: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_