

**STUDY SITE VISIT**

**REPORT FORM**

  **Form 8**

|  |  |  |  |
| --- | --- | --- | --- |
| **IRB Ref. No.** |  | **Date of the Visit:** |  |

|  |  |
| --- | --- |
| **Study Title:** |  |

|  |  |  |  |
| --- | --- | --- | --- |
| **Principal****Investigator:** |  | **Phone:** |  |

|  |  |  |  |
| --- | --- | --- | --- |
| Sponsor  |  | Site |  |

|  |  |  |  |
| --- | --- | --- | --- |
| **Reason for****Site visit** |  | **Persons****interviewed** |  |

|  |  |  |  |
| --- | --- | --- | --- |
| Total number of expected subjects: |  | Total subjects enrolled: |  |

|  |  |  |  |
| --- | --- | --- | --- |
|  | **YES** | **NO** | **COMMENTS** |
| **Are site facilities appropriate?** |  |  |  |
| **Is confidentiality of documents maintained (e.g cabinets with lock****and keys)?** |  |  |  |
| **Are the test articles property kept and maintained?** |  |  |  |
| **Are informed Consent Forms computers?** |  |  |  |
| **Are approved ICF versions used?** |  |  |  |
| **Are copies of the approved version of the protocol documents****Kept in the site?** |  |  |  |
| **Are files of all communication with the IRB found in the site?** |  |  |  |
| **Does the site keep copies of all communication with the IRB in the sites?** |  |  |  |
| **Are copies of adverse event reports kept?** |  |  |  |
| **Are investigator function properly delegated to qualified research personnel?** |  |  |  |
| **Is there appropriate documentation of qualification of personnel?** |  |  |  |
| **Are all Case Record Forms up to date?** |  |  |  |
| **Are copies of protocol deviation/ violation reports kept in the****site?** |  |  |  |
| **Is there evidence of appropriate corrective action taken as recommended by the IRB?** |  |  |  |

|  |  |  |
| --- | --- | --- |
|  | Summary of findings:  |  |
|  | Recommendation: |  |
|  |  |  |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Duration of visit: (hours)** |  | **Starting form:** |  | **Finish:** |  |
|  |
| **Name of IRB Member Visitors:** |  |
|  |
| **Reported by:**  |  | **DATE:** |   |
| **Signature**  |  |  |
|  |