**STUDY INITIATION CHECKLIST**

|  |  |
| --- | --- |
| STUDY TITLE |  |
| PROTOCOL NUMBER |  |
| SITE, SITE NUMBER |  |
| SPONSOR NAME |  |
| PRINCIPAL INVESTIGATOR NAME |  |
| MONITOR NAME |  |
| DATE |  |
| METHOD OF VISIT | On-Site  Teleconference  Other, specify: |

List personnel in attendance from site, below. Attach attendance sheet.

|  |  |
| --- | --- |
| NAME, TITLE | ROLE |
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Verify each document or activity required below. Attach any supporting documentation.

| NO. | DOCUMENT OR ACTIVITY (DISCUSSED/VERIFIED) | YES | NO | N/A | COMMENTS |
| --- | --- | --- | --- | --- | --- |
| 1 | Staff CVs signed/dated |  |  |  |  |
| 2 | Staff trained on protocol |  |  |  |  |
| 3 | Staff trained on data entry |  |  |  |  |
| 4 | Check required number of forms delivered to site (i.e. consent forms, case forms). |  |  |  |  |
| 5 | Sponsor and site have agreed to study contract and budget. |  |  |  |  |
| 6 | Indemnity/insurance completed for site. |  |  |  |  |
| 7 | EC/IRB approval granted for study. |  |  |  |  |
| 8 | Staffing allocation complete. |  |  |  |  |
| 9 | Specific staff responsibilities discussed with staff |  |  |  |  |
| 10 | Staff trained in GCP. |  |  |  |  |
| 11 | Required facilities are available/functional. |  |  |  |  |
| 12 | Materials/equipment for study available/received. |  |  |  |  |
| 13 | Investigator’s file prepared |  |  |  |  |
| 14 | Final contract and budget signed and filed. |  |  |  |  |
| 15 | e-CRF accessible (if applicable) |  |  |  |  |
| 16 |  |  |  |  |  |
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| *Name of Monitor (Print)* | | |
|  |  |
| *Monitor Signature* | *Date* |

|  |  |  |
| --- | --- | --- |
|  | | |
| *Name of Principal Investigator (Print)* | | |
|  |  |
| *Principal Investigator Signature* | *Date* |

**Disclaimer:** It is considered best practice for all research projects to have a Study Initiation Checklist. This template is provided for informational purposes only and does not constitute legal or compliance advice. Users are responsible for determining the necessary information to meet their specific objectives and for ensuring compliance with local requirements.