STUDY CLOSEOUT CHECKLIST

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| --- | --- | --- | --- | --- |
| Date of Closeout: | |  | | |
| Sponsor: | |  | | |
| Protocol: | |  |  |
| Sponsor Contact: | | Name: | Phone: |
|  | | Title: | Fax: |
| ❑ | Visit Date Confirmed, if applicable | | | |
| ❑ | Site attendees available and confirmed | | | |
| ❑ | Meeting room booked, if applicable | | | |
| ❑ | Applicable departments aware of visit (N.B. pharmacy), if applicable | | | |
| ❑ | Study files reviewed for completeness | | | |
| ❑ | CRFs completed and available for review along with associated source documents | | | |
| ❑ | All previous data queries resolved | | | |
| ❑ | Arrangements made for return of all study-related items and loaned equipment | | | |
| ❑ | Arrangements made for return or destruction of investigational product | | | |
| Items Discussed With Sponsor: | | | | |
| ❑ | Patient follow-up | | | |
| ❑ | Record retention and storage | | | |
| ❑ | Publication plans | | | |
| ❑ | Anticipated timing of final report | | | |
| ❑ | Final payment(s) | | | |
| ❑ | Plans for inspections or audits | | | |
| ❑ | Feedback on site performance | | | |
| Follow-Up: | | | | |
| ❑ | REB notified of study closure | | | |
| ❑ | Relevant departments/staff notified of study completion/closure | | | |
| ❑ | Closeout summary letter received from the sponsor | | | |
| ❑ | All data queries resolved or closed | | | |
| ❑ | Final payment received | | | |
| ❑ | Study files complete and ready for archiving | | | |
| Comments: | | | | |

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|  |  |  |  |  |
| Signature of Person Completing Form |  | Name |  | Date |