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 |