**Study Title:
IRB #**

**PI:
Sponsor:**

|  |  |  |
| --- | --- | --- |
| **Task** | **Date completed and initials** | **Comments** |
| **Closeout Visit**[ ] Letter of closure from sponsor received[ ]  Closeout visit scheduled with monitor/sponsor representative and study team members |  |  |
| **Regulatory Documents**[ ]  Verified as complete[ ]  Notes to file included when appropriate[ ]  All correspondence with IRB and sponsor filed[ ]  Delegation of authority log finalized |  |  |
| **CRF/Source data**[ ]  Verified as complete[ ]  Corrections properly documented and explained, as necessary[ ]  Copy of any eCRFs received from sponsor |  |  |
| **Adverse Events**[ ]  Events ongoing at study closeout visit followed to resolution[ ]  Sponsor reporting requirements completed[ ]  IRB reporting requirements completed |  |  |
| **Data Queries** [ ]  All queries have been addressed[[1]](#footnote-1)[ ]  Documentation completed for data discrepancies and queries unable to be resolved |  |  |
| **Emory Sponsor**[ ]  Final report obtained from sites, as applicable[ ]  IDE Final report submitted to FDA[ ]  Final report and request to withdraw IND submitted to FDA  |  |  |
| **Investigational Product**[ ]  Accountability records completed[ ]  Investigational product and other supplies returned/destroyed according to sponsor/CRO instructions and documented  |  |  |
| **Study Equipment**[ ]  All equipment provided by outside vendors returned |  |  |
| **Specimens/Samples**[ ]  Submitted to laboratory for analysis or storage[ ]  Logs completed |  |  |
| **IRB**[ ]  Final study report submitted[ ]  Acknowledgement received & filed[ ]  IRB acknowledgement forwarded to sponsor |  |  |
| **Financial Obligations**[ ]  Subject payments/reimbursements processed[ ]  Receipts, documentation of payments filed[ ]  Final accounting completed & reports submitted as required[ ]  Accounts closed as appropriate |  |  |
| **VA studies**[ ]  VA close-out form submitted[[2]](#footnote-2) |  |  |
| **Websites, if applicable**[ ]  Trial status updated at clinicaltrials.gov [ ]  Emory Healthcare website updated  |  |  |
| **Documents Storage**[ ]  Study files prepared for long-term storage[[3]](#footnote-3)[ ]  Inventory completed |  | Site for long term storage\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Date records archived to storage \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

1. If queries are answered with de-identified data, study can be closed. [↑](#footnote-ref-1)
2. Form can be found at <http://www.atlanta.va.gov/Docs/Closeout_Summary_for_Human_Subjects_Research.docx> [↑](#footnote-ref-2)
3. Reference Emory policy for document storage: <http://records.emory.edu/retention-schedules/categories/research.html>. For VA studies, check their specific retention schedule. [↑](#footnote-ref-3)