**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)