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| University of Pittsburgh |
| **STUDY CLOSEOUT CHECKLIST** |
| **Study Title**:  | **IRB #**:  |
| **Principal Investigator**:  | **Closure Date**:  |

**PURPOSE**: This document provides a *general* checklist for site personnel to utilize for study closure. Other tasks may be required by external entities (e.g., funding agency) or of local study teams leading a multi-institutional study.

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| **Case Report Forms and Source Documents** |
| **No.** | **Task** | **Assigned Staff** | **Date Completed** | **Comments** |
| 1 | Confirm source documentation is present and complete for all subjects  |   |   |   |
| 2 | Confirm all case report forms (paper/electronic) were completed, signed, and dated as applicable |   |   |   |
| 3 | Confirm all queries were resolved |  |  |  |

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| **Data Management** |
| *Note: If the site is using a Data Coordinating Center (DCC), tasks 4-8 will be assigned to the DCC.* |
| **No.** | **Task** | **Assigned Staff** | **Date Completed** | **Comments** |
| 4 | Confirm all relevant data is entered into the database  |  |  |  |
| 5 | Confirm all data entered in the database was validated with source documentation  |  |  |  |
| 6 | Confirm all queries were issued, returned, and resolved |  |  |  |
| 7 | Once all queries are resolved, clean and perform a quality check of the database |  |  |  |
| 8 | Perform database lock  |  |  |  |

| **Investigator Site Files** |
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| **No.** | **Task** | **Assigned Staff** | **Date Completed** | **Comments** |
| 9 | Confirm signed consent documents are filed for all subjects |   |   |   |
| 10 | Confirm all regulatory file documents are present, including, but not limited to: * Approved protocols and amendments
* Approved consent documents
* IRB approval correspondence
* Study team licenses, CVs, training certificates
* Laboratory and Pharmacy documentation
* Manual of Procedures (MOP)
* Standard Operating Procedures (SOPs)
 |   |   |   |
| 11 | Confirm the completeness of the following logs as applicable: * Subject Screening and Enrollment Log
* Monitoring Visit Log
* Delegation of Responsibilities Log
* Telephone Log
* Training Log
* Subject Code List
* Randomization Log
* Investigational Product Accountability Log: Stock Record and Subject Record
* Specimen Tracking Log
* Freezer/Refrigerator Temperature Logs
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| 12 | If study was terminated early, confirm notification of study termination was sent to all enrolled subjects as appropriate |  |  |  |
| 13 | Before final report to the IRB, confirm protocol deviations were documented and reported to the IRB as appropriate |  |  |  |
| 14 | Before final report to the IRB, confirm access to identifiable data is no longer needed for data analysis and reporting (e.g., manuscript presentation / Clinicaltrials.gov)  |  |  |  |
| 15 | Confirm reporting of study closure to the IRB and file study closure confirmation in the investigator site files  |  |  |  |
| 16 | Confirm record retention requirements and notify sponsor when study files will be transferred to long term off-site storage |  |  |  |

| **Event Reporting and Reconciliation** |
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| **No.** | **Task** | **Assigned Staff** | **Date Completed** | **Comments** |
| 17 | Confirm all adverse events, serious adverse events, and unanticipated problems were documented and reported to the appropriate parties per protocol requirements |   |   |   |
| 18 | Confirm all required follow-up documentation was retrieved, communicated to appropriate parties, and is present in the study files |   |   |   |

| **Investigational Product** |
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| **No.** | **Task** | **Assigned Staff** | **Date Completed** | **Comments** |
| 19 | Contact investigational drug services (IDS) to terminate study as applicable |   |   |   |
| 20 | Confirm investigational product (IP) disposition forms and accountability records are complete and present for all subjects who received the IP  |   |   |   |
| 21 | Confirm final disposition of IP was completed per MOP, site pharmacy protocol, supplier, and sponsor requirements |  |  |  |

| **Collected Laboratory Specimens** |
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| **No.** | **Task** | **Assigned Staff** | **Date Completed** | **Comments** |
| 22 | Confirm all specimens were either analyzed or stored for future use |   |   |   |
| 23 | Confirm specimens collected for future use were adequately processed, labeled/de-identified, and stored |   |   |   |
| 24 | Confirm destruction (per institutional policies) of specimens not identified for future analysis |  |  |  |

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| **Report and Supplies** |
| **No.** | **Task** | **Assigned Staff** | **Date Completed** | **Comments** |
| 25 | Confirm [ClinicalTrials.gov](https://www.clinicaltrials.gov/) was updated and results reported per regulations (for questions, contact CTgov@pitt.edu)  |   |  |   |
| 26 | Confirm final disposition of study supplies and any equipment provided for the study  |  |  |  |
| 27 | Once all documents are checked, prepare study files for on-site storage and then long-term storage as per organizational policy |  |  |  |

**TO BE SIGNED AT STUDY CLOSURE**: I attest that the above information is accurate and complete.

Principal Investigator Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_