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| [University of Pittsburgh](https://officeofsponsoredprograms.cmail20.com/t/j-l-ethhhjd-iuajjtduu-t/) | |
| **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 |  |  |  |
| 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](mailto: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: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_