Study Close-Out Checklist

This form is adapted from:
https://www.nidcr.nih.gov/research/toolkit/Documents/Study_Close_Out_Checklist_approved_v20.docx

Tool:	Study Close-Out Checklist
Purpose:	This document provides a checklist for study personnel to ensure that all necessary aspects of study closure and archival have been addressed.
Audience/User:	Investigators and Study Coordinators may use this template as a starting point for customizing a protocol/study specific checklist for site closure activities.
Details:	Prior to considering a study closed or archived, necessary steps must be completed to ensure all aspects of study components have been addressed. This checklist provides a reference point for closure status.
Best Practice Recommendations:	Review this template and customize it to the specific needs and requirements of the study. Close-Out activities may be updated as needed. Remove or mark as "not applicable" those elements that are not required.

Study Close-Out Checklist

No.	*Task*	*Owner*	*Date Completed*	*Comments*
Case Report Forms (CRFs)/Source Documents				
1	Confirm that appropriate source documentation is present for all subjects			
2	Paper Studies: Confirm that all CRFs have been completed, collected, and the proper legible copies are present in study files Electronic Data Capture (EDC) Studies: Confirm that all electronic CRFs have been completed and submitted to the Data Coordinating Center (DCC), as applicable			
3	Paper Studies: Confirm that all data clarification forms (DCFs) and queries issued to date have been submitted to the DCC , appropriately resolved, signed and dated by the investigator, and that signed and dated queries are filed with the corresponding CRF page or subject Electronic Data Collection (EDC) Studies: Confirm that all electronic queries issued to date have been appropriately resolved, reviewed by the CRA/SC/DM as appropriate, and closed, where applicable			
4	EDC Studies: Ensure that all CRF pages requiring signature have been electronically signed and dated by the investigator			
Data Management				
Note: If the site is using a Data Coordinating Center (DCC), tasks 5-8 will be owned by the DCC.				
5	Confirm all data is entered into the database			
6	Ensure all queries have been issued, returned, and resolved			
7	Once all queries have been resolved, clean and QC the database			
8	Perform database lock			
Adverse Event, Unanticipated Problem, and Serious Adverse Event Reporting/Reconciliation				
9	Ensure that all AEs, UPs, and SAEs have been captured, followed, and resolved per protocol, and reported to the appropriate parties (Sponsor, IRB, and FDA, if applicable) according to protocol reporting requirements			
10	Confirm that all required follow-up documentation has been retrieved, communicated to appropriate parties, and is present in the study files			

Investigator Site Files				
11	Confirm that signed consent forms are on file for all subjects			
12	Reconcile study files with Trial Master File (TMF) list. For studies where the TMF is maintained at the lead site or by another DCC, ensure all required documents are present, including collection of all required documents from all Investigator Site Files, where appropriate. These can include, but are not limited to: • protocols and amendments • approved consent document templates • IRB approvals • study team licenses • study certification documentation and CVs • laboratory documentation • Manual of Procedures (MOP) • Standard Operating Procedures (SOPs)			
13	Ensure reporting of study closure to the IRB and receipt/filing of study closure confirmation in the investigator site files			
14	If study was terminated early, confirm notification of study termination has been sent to all enrolled subjects as appropriate*			
15	Confirm that all protocol deviations have been noted in source documentation and reported to the IRB as appropriate			
16	Consider appropriate storage of Quality Management (QM) reports / metrics			
17	Confirm sponsor and institutional requirements for record retention and notify sponsor when study files will be transferred to long term off-site storage			
Ensure the completeness of the following logs:				
18	Pre-Screening Log (*if applicable)*			
19	Subject Screening and Enrollment Log			
20	Monitoring Visit Log *(if applicable)*			
21	Delegation of Responsibilities Log			
22	Telephone Log			
23	Training Log			
24	Subject Code List			
25	Randomization Log *(if applicable)*			
26	Investigational Product Accountability Log: Stock Record *(if applicable)*			
27	Investigational Product Accountability Log: Subject Record *(if applicable)*			
28	Specimen Tracking Log *(if applicable)*			
29	Freezer/Refrigerator Temperature Logs *(if applicable)*			

Investigational Product				
30	Confirm that investigational product disposition forms and accountability records are complete and present for all subjects receiving study drug			
31	Confirm final disposition of investigational product was completed per MOP, site pharmacy protocol, supplier, and sponsor requirements			
Collected Laboratory Specimens (Samples)				
32	Confirm that all specimens have either been analyzed or stored for future use			
33	Ensure that specimens collected for future use have been adequately processed, labeled/de-identified, and stored			
34	Confirm site process for identification and disposition of future use specimens connected to subjects who withdraw consent or do not consent for their specimens to be saved			
35	Confirm destruction, per institutional policies, of specimens not identified for future analysis			
Analysis, Manuscripts, and Submissions/Publications				
36	Data analysis complete			
37	Primary manuscript finalized			
38	Results submitted to ClinicalTrials.gov Intramural Studies: Confirm that notification has been made to the Office of Protocol Services (OPS) for change in study status and update to ClinicalTrials.gov Extramural Studies: Confirm that the appropriate party has updated ClinicalTrials.gov with the update in study status			
39	Confirm final disposition of study supplies and any equipment provided for the study: <insert study-specific items>			