OCSO CRS Close-out Checklist

CTU/CRS Name:		CTU/CRS ID:	
CRS Leader:		OCSO PO:	

Instructions: Consult with assigned OCSO Program Officer (PO) and appropriate Network Leadership and Operations Center for CRS close-out procedures. Complete the checklist with appropriate dates as you complete the steps in the checklist. When all close-out procedures have been finalized, sign this checklist and return it to your OCSO PO to ensure that all requirements have been met. In some instances the site will be required to verify the disposition of all study products and specimens in lieu of a final close-out monitoring visit. Upon receipt, the OCSO PO will review and notify you when the close-out has been completed.

Review of Investigator Responsibilities: Sites must comply with DAIDS, FDA, and local institutional guidelines regarding storage of clinical trial records. When local and/or institutional requirements exceed DAIDS and FDA requirements, the local/institutional requirements must be followed. Guidance on document storage and destruction is available in the DAIDS policy on record retention at: https://www.niaid.nih.gov/research/daids-clinical-site-implementation-operations

Item	Requirement	Date Completed *List date or indicate if not applicable (N/A)*	Comments
General			
1	Develop and submit a transition plan for closure to your OCSO PO with timelines.		
2	Designate a point of contact at the CRS for any future contact by NIAID seeking access to study records, clinical records, or specimens. *Include name and complete contact information as well as location of record storage in the comments field.*		
3	Notify all study staff and CAB members of the site closure.		
Clinical/Regulatory			
4	Resolve outstanding issues in the CSM.		
5	Deregister all protocols with the Protocol Registration Office. *List the protocols in the comments.*		

Item	Requirement	Date Completed *List date or indicate if not applicable (N/A)*	Comments
6	Notify the Institutional Review Board (IRB)/Ethics Committee (EC) in writing of the study closure, site closure, and patient disposition. File the notification document with Essential Documents. *List each protocol, the date the letter was sent to the IRB, and the date the IRB approved the termination in the comments or attach a separate document.*		
7	Resolve all data management queries.		
8	Create a status spreadsheet of all participants currently still on study with relevant details and provide to your OCSO PO. Confirm that all participants have completed the final study visit or have been transferred to another CRS. *Transfer options and procedures must be discussed with Network(s)*		
9	Enter all serious adverse events (SAEs) and Expedited Adverse Events (EAEs), (including those reported 60 days after discontinuation of study drug) in the DAIDS Adverse Event Reporting System (DAERS) and confirm they have been reconciled.		
10	Ship (if applicable) or store all CRFs. *Note: The CRSs may send CRFs to the CTU for storage.*		
11	Store all files and confidential participant information (including Essential Documents and Regulatory Files) according to DAIDS policies and procedures for record storage in order to protect data with personal identifiers. *https://www.niaid.nih.gov/research/daids-clinical-site-implementation-operations* _ *Describe in the comments or attach the storage plan.*		

Item	Requirement	Date Completed *List date or indicate if not applicable (N/A)*	Comments
12	Account for all study specimens stored at the site per clinical trial group or protocol team requirements. *Describe specimen shipment status (i.e., number of specimens, destination) in the comments or attach a document.*		
Pharmacy			
13	Perform study product accountability for all protocols.		
14	Reconcile study product accountability logs.		
15	Return all study product(s) to the NIAID Clinical Research Products Management Center (CRPMC) or other source, **OR** dipose of them per PAB/CRPMC directions. *Indicate the final disposition of all study product in the comments or attach a separate document.*		
16	Retain the final study product disposition documentation in the Essential Documents per pharmacy guidelines.		
17	Store pharmacy records according to the DAIDS record retention policy. *Note: CRSs may send records to the CTU for storage.* *Describe in the comments or attach the storage plan.*		
18	Resolve all outstanding pharmacy issues in the CSM.		

Signatures

	Printed or Typed Name	Signature	Date
Completed by: ***Person who completed the form***			
CRS Leader:			
Reviewed by: ***OCSO Program Officer***			