

AUSTRALIAN ICH GCP (Including Teletrials) SOP 130 Appendix 1 Example Close Out Check-List

ACTIVITY	COMPLETE
Ensure all protocol required data has been collected	
Finalise accountability and disposition of investigational product (medicine/device)	
Verify that all study files are complete	
Discuss overall study conduct at the site	
Collect final signatures for any delegation or training logs or reports	
Discuss archiving of original data and documents	
Dispose of or return any remaining trial specific supplies including biological samples	
Formally close the site	
Notify the HREC and /or Governance Office that the study has been closed, and study materials returned/destroyed/archived.	