AUSTRALIAN ICH GCP (Including Teletrials)
SOP 60 Appendix 1
Example Initiation Check-List

ACTIVITY	COMPLETE
Ensure the Site Initiation Meeting is scheduled and all relevant staff are able to attend - (Investigator, Clinical Research Coordinator, Sponsor or CRA, Pharmacist, other relevant people such as laboratory staff). It is usual for the Sponsor to confirm the initiation by letter	
Review Investigational Product overview and background	
Review with investigator and relevant staff their understanding of the protocol, study procedures, randomisation procedures, un-blinding procedures, sampling handling procedures and study timelines	
Review that site resources are adequate to conduct the trial	
Review with investigator and relevant staff Safety Reporting procedures and principles of Good Clinical Practice (ICH-GCP), including informed consent procedures, investigator responsibilities, record keeping, ethics and governance reporting.	
Review contents of Site Master File to ensure it complies to Australian ICH GCP	
Review source documentation location for Satellite sites	
Complete site signature and delegation of responsibilities log	
Review investigational product shipment records	