Site Initiation Visit Checklist

Protocol #:	
Name of the Investigational Product:	
Sponsor:	
Protocol #:	
Site Name:	
Principal Investigator:	
Clinical Research Associate:	
Date:	

Document /Activity	**Yes**	**No**	**NA**	**Comments**
Signed and dated curriculum vitae are available for clinical trial site staff	☐	☐	☐	
Clinical trials team familiarise themselves with the protocol?	☐	☐	☐	
Clinical trials team familiarise themselves with the investigational product by reading the Investigator's Brochure (IB)	☐	☐	☐	
Clinical Trial Research Agreement (CTRA) and clinical trial budget with the sponsor has been executed.	☐	☐	☐	
Indemnity including insurance certificate is available for clinical trial site.	☐	☐	☐	
Ensure Human Research Ethics Committee (HREC) and Research Governance Office (RGO) approval in place	☐	☐	☐	

Adequate study staff is available for the Site Initiation Visit (SIV)	☐	☐	☐	
Discuss and determine the particular responsibilities of the staff in the clinical trial team on the Delegation of Responsibilities Log	☐	☐	☐	
All clinical trials team GCP trained	☐	☐	☐	
Facilities that are required are available and functional	☐	☐	☐	
Ensure materials and documents for the clinical trial have been received and securely stored including Investigational Product	☐	☐	☐	
Prepare and maintain Investigator Site File (ISF)	☐	☐	☐	
Study Supplies & Miscellaneous				
IVRS related information available	☐	☐	☐	
eCRF information received	☐	☐	☐	
Drug shipment received	☐	☐	☐	
Other supplies received	☐	☐	☐	

Investigator's Name (print)	Signature	Date