Section 1.To be filled up by the Principal Investigator. Documents relevant to the Site Visit should be submitted together with this form

SJDIRB Reference Code		**Date of Submission**	DD Month YYYY
Protocol Code		**SJREB Code**	
Protocol Title			
Principal Investigator			
Sponsor/CRO			
Approval Date	DD Month YYYY	**Date of Visit**	DD Month YYYY
Total number of expected subjects		**Total subjects enrolled**	

Indicators	Yes	No	Comments
Are site facilities appropriate?			
Are informed consents recent?			
Participant or LAR signed consent			
Any adverse events found?			
Any protocol non-compliance/violation?			
Are all Case Report Forms up to date?			
Are storage of data and investigational products locked?			
How well are participants protected?			
Any outstanding tasks or results of visit?			

Comments

Site Visit Membe	Signature	Date

Section 2: FOR SJDIRB USE ONLY (To be filled by the Primary Reviewer)

Decision Points	Recommendation
○ Recommend further action ○ Request additional information	1. . 2. . 3. .

SIte Visit leader	**Signature**	**Date**

SJDIRB Final Action	
Final Decision	**Recommendation/Comments**
○ Recommend further action 1. ○ Request additional information	(e.g. Proceed with the recommendation of the reviewer or full board meeting last _____)

SJDIRB Officer	Name	Signature	Date
Board/Panel Secretary			
Chair/Panel Lead			

Site Visit Checklist & Program

Activity	Date	Officer-In-Charge	Objective	Reference Documents	Remarks
Site Visit Notification			Inform the Principal Investigator (PI) of the upcoming site visit, its purpose, and the tentative schedule.		
Pre-Visit Meeting			Discuss the audit plan, assign roles and responsibilities, and review relevant documents.	Sponsor Audit Report, ICF, Study Protocol	
Site Visit Proper					
• **Opening Meeting**			Introduce the audit team, explain the audit process, and address any initial questions from the site staff.		
• **Document Review**			Verify that essential documents are complete, accurate, and current.	ICFs, Study Protocol, Regulatory Documents, Source Documents, Participant Files	
• **Recruitment Process Review**			Assess the recruitment process to ensure compliance with the approved protocol and ethical guidelines.	Recruitment Materials, Screening Logs, Eligibility Criteria	
• **Patient Interviews**			Interview a sample of study participants to assess their understanding of the study and the informed consent process.	Informed Consent Forms (ICFs)	
• **Source Data Verification**			Verify the accuracy and completeness of the data collected.	Case Report Forms (CRFs), Source Documents	
• **Sponsor Audit Findings Validation**			Review the sponsor's audit findings and the site's corrective actions to ensure their adequacy and effectiveness.	Sponsor Audit Report, Site Corrective Action Plan	
• **Facilities Inspection**			Inspect the study site facilities to ensure they are appropriate for the conduct of the study.		
• **Closing Meeting**			Summarize the preliminary audit findings and discuss any significant observations with the site staff.		
Audit Report Preparation			Prepare a comprehensive audit report documenting the audit findings, conclusions, and recommendations.		
IRB Review and Follow-up			Review the audit report and determine any necessary follow-up actions.	Audit Report	