STUDY INITIATION CHECKLIST

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STUDY TITLE						
PROTOCOL NUMBER						
SITE, SITE NUMBER						
SPONSOR NAME						
PRINCIPAL INVESTIGATOR NAME						
MONITOR NAME						
DATE						
METHOD OF VISIT	☐ On-Site ☐ Teleconference ☐ Other, specify:					
List personnel in attendance from site, below. Attach attendance sheet.						
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Verify each document or activity required below. Attach any supporting documentation.

NO.	DOCUMENT OR ACTIVITY (DISCUSSED/VERIFIED)	YES	NO	N/A	COMMENTS
1	Staff CVs signed/dated				
2	Staff trained on protocol				
3	Staff read investigator brochure for product				
4	Check required number of forms delivered to site (i.e. consent forms, case forms).				
5	Sponsor and site have agreed to study contract and budget.				
6	Indemnity/insurance completed for site.				
7	EC/IRB approval granted for study.				
8	Staffing allocation complete.				
9	Specific staff responsibilities discussed with staff				
10	Staff trained in GCP.				
11	Required facilities are available/functional.				
12	Investigational product stored appropriately.				
13	Materials/equipment for study available/received.				
14	Investigator's file prepared				
15	Final contract and budget signed and filed.				
16	Interactive Voice Response Systems (IVRS) available (if applicable)				
17	e-case forms available (if applicable)				
18	Drug shipment received (if applicable)				
19	Other supplies received (if applicable)				

Name of Monitor (Print)	
Monitor Signature	Date
Name of Principal Investigator (Print)	
Principal Investigator Signature	Date

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