STUDY START-UP CHECKLIST

The following activities / documents should be in place before starting the study. If you are acting as the study Principal Investigator/Sponsor Investigator, you must have this information from all of the study sites. Modified from CTN SOPPM 13: Site Start-up Checklist

DOCUMENT / ACTIVITY	RECEIVED Y / N / N/A	APPROVAL DATE / DETAILS / COMMENTS
[Add additional rows in each section as necessary]		
1. REB/IEC Approvals ***[List all documents / versions (protocol, consents, etc.) approved. If a document date of approval is different than date noted for overall approval, note the date in the last column. Ensure approval includes investigator/site details]***	Y ☐ N ☐ N/A ☐	Approval Date: Renewal Due Date:
Protocol [Vx.x, dd-mmm-yyyy]	Y ☐ N ☐ N/A ☐	
ICF [Vx.x, dd-mmm-yyyy]	Y ☐ N ☐ N/A ☐	
[Recruitment/Study Information #1] [vx.x, dd-mmm-yyyy]	Y ☐ N ☐ N/A ☐	
[Recruitment/Study Information #2] [Vx.x, dd-mmm-yyyy]	Y ☐ N ☐ N/A ☐	
2. REB/IEC Approved Informed Consent Form(s) on institutional letterhead ***[Include all consents/versions/languages approved for the Study.]***	Y ☐ N ☐ N/A ☐	
3. REB/IEC Membership List	Y ☐ N ☐ N/A ☐	Dated:
4. REBA Form ***[Original at site; copy to Sponsor/SI or CTN]*** ***[Or equivalent with a letter or Note to File from site if REB/IEC does not complete REBA form]***	Y ☐ N ☐ N/A ☐	Date signed:
5. QIU Form ***[Original at site; copy to Sponsor/SI or CTN]***	Y ☐ N ☐ N/A ☐	Date signed:
6. CTSI Form ***[Original at site; copy to Sponsor/SI or CTN]***	Y ☐ N ☐ N/A ☐	Study Commencement Date:
7. Financial disclosure of [qualified investigator / site investigator]	Y ☐ N ☐ N/A ☐	
8. Site Personnel Information Sheet	Y ☐ N ☐ N/A ☐	
9. Delegation of Authority Log ***[Original at site; copy to Sponsor/SI or CTN]***	Y ☐ N ☐ N/A ☐	
10. Recent (within 2 years) CVs ***[All Investigators/Sub-Investigators and other pertinent personnel]*** ***[All CVs MUST be signed and dated on the front page]***		
Name:	Y ☐ N ☐ N/A ☐	Date signed:
Name:	Y ☐ N ☐ N/A ☐	Date signed:

DOCUMENT / ACTIVITY	RECEIVED Y / N / N/A	APPROVAL DATE / DETAILS / COMMENTS
11. Current Medical/Professional Licenses ***[All Investigators/Sub-Investigators and other pertinent personnel with formal relevant clinical training – MDs, nurses, PTs, OTs, pharmacists, etc.]***		
Name:	Y ☐ N ☐ N/A ☐	Expiry Date:
Name:	Y ☐ N ☐ N/A ☐	Expiry Date:
12. **Training Logs / Certificates** ***[Logs / Certificates to be included as applicable: Original at site; copy to Sponsor/SI or CTN]***	Y ☐ N ☐ N/A ☐	
13. Final Contract or Roles & Responsibilities document	Y ☐ N ☐ N/A ☐	Date signed:
14. Signed Protocol Signature Page ***[Original at site; copy to Sponsor/SI or CTN]***	Y ☐ N ☐ N/A ☐	Date signed:
15. Laboratory Reference Ranges of all Labs		
Lab:	Y ☐ N ☐ N/A ☐	Date Valid:
Lab:	Y ☐ N ☐ N/A ☐	Date Valid:
16. Laboratory Certifications of all labs used		
Lab:	Y ☐ N ☐ N/A ☐	Expiry Date:
Lab:	Y ☐ N ☐ N/A ☐	Expiry Date:
17. Pharmacy Certifications		
Pharmacy:	Y ☐ N ☐ N/A ☐	Expiry Date:
Pharmacy:	Y ☐ N ☐ N/A ☐	Expiry Date:
18. Confirmation of Investigational Product Shipping Address:		
Contact Name: **Shipping Address:** **Phone Number:**	Y ☐ N ☐ N/A ☐	
Contact Name: **Shipping Address:** **Phone Number:**	Y ☐ N ☐ N/A ☐	