



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
<i>[Add additional rows in each section as necessary]</i>		
1. REB/IEC Approvals <i>[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]</i>	Y <input type="checkbox"/> N <input type="checkbox"/> N/A <input type="checkbox"/>	Approval Date: Renewal Due Date:
Protocol [Vx.x, dd-mmm-yyyy]	Y <input type="checkbox"/> N <input type="checkbox"/> N/A <input type="checkbox"/>	
ICF [Vx.x, dd-mmm-yyyy]	Y <input type="checkbox"/> N <input type="checkbox"/> N/A <input type="checkbox"/>	
[Recruitment/Study Information #1] [vx.x, dd-mmm-yyyy]	Y <input type="checkbox"/> N <input type="checkbox"/> N/A <input type="checkbox"/>	
[Recruitment/Study Information #2] [Vx.x, dd-mmm-yyyy]	Y <input type="checkbox"/> N <input type="checkbox"/> N/A <input type="checkbox"/>	
2. REB/IEC Approved Informed Consent Form(s) on institutional letterhead <i>[Include all consents/versions/languages approved for the Study.]</i>	Y <input type="checkbox"/> N <input type="checkbox"/> N/A <input type="checkbox"/>	
3. REB/IEC Membership List	Y <input type="checkbox"/> N <input type="checkbox"/> N/A <input type="checkbox"/>	Dated:
4. REBA Form or equivalent <i>[Original at site; copy to Sponsor/SI or CTN]</i>	Y <input type="checkbox"/> N <input type="checkbox"/> N/A <input type="checkbox"/>	Date signed:
5. QIU Form <i>[Original at site; copy to Sponsor/SI or CTN]</i>	Y <input type="checkbox"/> N <input type="checkbox"/> N/A <input type="checkbox"/>	Date signed:
6. CTSI Form <i>[Original at site; copy to Sponsor/SI or CTN]</i>	Y <input type="checkbox"/> N <input type="checkbox"/> N/A <input type="checkbox"/>	Study Commencement Date:
7. Financial disclosure of [qualified investigator / site investigator]	Y <input type="checkbox"/> N <input type="checkbox"/> N/A <input type="checkbox"/>	
8. Site Personnel Information Sheet	Y <input type="checkbox"/> N <input type="checkbox"/> N/A <input type="checkbox"/>	
9. Delegation of Authority Log <i>[Original at site; copy to Sponsor/SI or CTN]</i>	Y <input type="checkbox"/> N <input type="checkbox"/> N/A <input type="checkbox"/>	
10. Recent (within 2 years) CVs <i>[All Investigators/Sub-Investigators and other pertinent personnel]</i> <i>[All CVs MUST be signed and dated on the front page]</i>		
Name:	Y <input type="checkbox"/> N <input type="checkbox"/> N/A <input type="checkbox"/>	Date signed:
Name:	Y <input type="checkbox"/> N <input type="checkbox"/> N/A <input type="checkbox"/>	Date signed:



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



I confirm that the above documentation/information has been received, verified and is complete:
(Project Management personnel)

Name and Title: _____

Signature: _____

Date: _____
dd-mmm-yyyy