



## 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/A	APPROVAL DATE / DETAILS / COMMENTS
<b>REB/IEC Approval</b>	Y <input type="checkbox"/> N/A <input type="checkbox"/>	Approval Date:
<b>Protocol</b>	Y <input type="checkbox"/> N/A <input type="checkbox"/>	Version Number or Date:
<b>Informed Consent Form (ICF)</b>	Y <input type="checkbox"/> N/A <input type="checkbox"/>	Version Number or Date:
<b>Recruitment/Study Information #1</b>	Y <input type="checkbox"/> N/A <input type="checkbox"/>	Version Number or Date:
<b>Other: _____</b>	Y <input type="checkbox"/> N/A <input type="checkbox"/>	Version Number or Date:
<b>REB/IEC Membership List</b>	Y <input type="checkbox"/> N/A <input type="checkbox"/>	Dated:
<b>Recent (<i>within 2 years</i>) signed &amp; dated CVs</b>		
Name:	Y <input type="checkbox"/> N/A <input type="checkbox"/>	Date signed:
Name:	Y <input type="checkbox"/> N/A <input type="checkbox"/>	Date signed:
Name:	Y <input type="checkbox"/> N/A <input type="checkbox"/>	Date signed:
Name:	Y <input type="checkbox"/> N/A <input type="checkbox"/>	Date signed:
<b>Current Medical Licenses or Registration</b> <i>All Investigators/Sub-Investigators and other pertinent personnel</i>		
Name:	Y <input type="checkbox"/> N/A <input type="checkbox"/>	Expiry Date:
Name:	Y <input type="checkbox"/> N/A <input type="checkbox"/>	Expiry Date:
Name:	Y <input type="checkbox"/> N/A <input type="checkbox"/>	Expiry Date:



DOCUMENT / ACTIVITY	RECEIVED Y / N/A	APPROVAL DATE / DETAILS / COMMENTS
<b>Administrative Documents</b>		
<b>Delegation of Authority Signature Log</b>	Y <input type="checkbox"/> N/A <input type="checkbox"/>	
<b>Signed Protocol Signature Page</b>	Y <input type="checkbox"/> N/A <input type="checkbox"/>	Date signed:
<b>Final Fully Executed Contract</b>	Y <input type="checkbox"/> N/A <input type="checkbox"/>	Final Date signed:
<b>Lab Certification/Accreditation (Local or Central)</b>		
<b>Lab:</b>		Expiry Date:
<b>Lab:</b>		Expiry Date:
<b>Training Logs / Certificates</b>		
<b>Good Clinical Practice (GCP)</b>	Y <input type="checkbox"/> N/A <input type="checkbox"/>	Expiry Date:
<b>Training: Transportation of Dangerous Goods (if applicable)</b>	Y <input type="checkbox"/> N/A <input type="checkbox"/>	Expiry Date:
<b>Documented protocol training (Investigator's meeting sign in sheet, training log)</b>	Y <input type="checkbox"/> N/A <input type="checkbox"/>	
<b>If your study is a regulated clinical trial under Health Canada, you should also have the following documents on file</b>		
<b>REBA Form</b>	Y <input type="checkbox"/> N/A <input type="checkbox"/>	Date signed:
<b>QIU Form</b>	Y <input type="checkbox"/> N/A <input type="checkbox"/>	Date signed:
<b>CTSI Form (sometimes this is held with the sponsor only)</b>	Y <input type="checkbox"/> N/A <input type="checkbox"/>	Study Commencement Date:
<b>Training: Division 5</b>	Y <input type="checkbox"/> N/A <input type="checkbox"/>	Expiry Date:
<b>Training: Other _____</b>	Y <input type="checkbox"/> N/A <input type="checkbox"/>	Expiry Date: