



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
REB/IEC Approval	Y <input type="checkbox"/> N/A <input type="checkbox"/>	Approval Date:
Protocol	Y <input type="checkbox"/> N/A <input type="checkbox"/>	Version Number or Date:
Informed Consent Form (ICF)	Y <input type="checkbox"/> N/A <input type="checkbox"/>	Version Number or Date:
Recruitment/Study Information #1	Y <input type="checkbox"/> N/A <input type="checkbox"/>	Version Number or Date:
Other: _____	Y <input type="checkbox"/> N/A <input type="checkbox"/>	Version Number or Date:
REB/IEC Membership List	Y <input type="checkbox"/> N/A <input type="checkbox"/>	Dated:
Recent (<i>within 2 years</i>) signed & dated CVs		
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:
Current Medical Licenses or Registration <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
Administrative Documents		
Delegation of Authority Signature Log	Y <input type="checkbox"/> N/A <input type="checkbox"/>	
Signed Protocol Signature Page	Y <input type="checkbox"/> N/A <input type="checkbox"/>	Date signed:
Final Fully Executed Contract	Y <input type="checkbox"/> N/A <input type="checkbox"/>	Final Date signed:
Lab Certification/Accreditation (Local or Central)		
Lab:		Expiry Date:
Lab:		Expiry Date:
Training Logs / Certificates		
Good Clinical Practice (GCP)	Y <input type="checkbox"/> N/A <input type="checkbox"/>	Expiry Date:
Training: Transportation of Dangerous Goods (if applicable)	Y <input type="checkbox"/> N/A <input type="checkbox"/>	Expiry Date:
Documented protocol training (Investigator's meeting sign in sheet, training log)	Y <input type="checkbox"/> N/A <input type="checkbox"/>	
If your study is a regulated clinical trial under Health Canada, you should also have the following documents on file		
REBA Form	Y <input type="checkbox"/> N/A <input type="checkbox"/>	Date signed:
QIU Form	Y <input type="checkbox"/> N/A <input type="checkbox"/>	Date signed:
CTSI Form (sometimes this is held with the sponsor only)	Y <input type="checkbox"/> N/A <input type="checkbox"/>	Study Commencement Date:
Training: Division 5	Y <input type="checkbox"/> N/A <input type="checkbox"/>	Expiry Date:
Training: Other _____	Y <input type="checkbox"/> N/A <input type="checkbox"/>	Expiry Date: