Sponsor/Sponsor-Investigator (SI) – Study Roles and Responsibilities Checklist

Document Version #:	
Version Date:	DD-MMM-YYYY

Study Title:	
Protocol No. :	
Version No. :	

Role	Name, Title, and Organization	Signature and Date
Checklist Preparation		
Study Sponsor or SI		
*Sponsor Representative		
‡Study Manager/Collaborator		
Chief Clinical Research Officer		

[Note to template: include Sponsor Representative, Study Manager/Collaborator, as applicable]
*The lead Investigator will be considered the Sponsor Representative when an institution is the Sponsor
‡[Post-Doctoral Fellow (PDF) Name], a Post-Doctoral Fellow under the supervision of [PDF Supervisor], submitted this study under the CTN Pilot Study Program. The contract for this study will be between [PDF Supervisor], the study Sponsor-Investigator, and the CTN. For the purpose of this document, [PDF Name], is referred to as the Study Manager/Collaborator.

Study Team

Role	Assigned Personnel	Email
Sponsor/SI		
Medical Monitor		
Study Project Management (external)		
CTN Project Management		
CTN Regulatory Affairs		
CTN Data Management		
CTN Programming		
CTN Research Assistant		
CTN Communications		
CTN Statistics		
CTN Study Monitor		
Other (specify)		

Summary of Responsibilities:

[Note to template: There should only be one party assigned to an activity/task per line. If the activity/task is shared, the activity/task should be separated in lower level activities/tasks so that assignment is clear. For any activities/tasks that don't apply, list n/a under Sponsor/SI]

Activities/Tasks	Sponsor/SI	CTN	Comments
Financial Management			
CTN / [Sponsor or SI] Contract			
Other Contracts			
Budget Management			
Funding			
Pass-through Costs			
Study Start Up			
Protocol Development			
Informed Consent Form(s) Template Development			
Study-wide Recruitment Material (poster, letter, etc.) Development			
Regulatory Agency(ies) Submission(s) and Updates			
Clinical Trial Registration and Updates			
Study Management			
Site Selection			
Main Point of Contact with Sites			
Site Management			
Site Initiation/Training			
Study Drug			
• Supply			
• Labelling			

Activities/Tasks	Sponsor/SI	CTN	Comments
• Management			
• Release			
Study Supplies			
Study Manual(s) and Materials Development			
Trial Master File ☐ Florence eBinders™ ☐ Paper-based ☐ Hybrid (Florence eBinders™ and paper-based)			
• Set-up			
• Maintenance			
• Archiving			
Monitoring Plan and Execution			
Risk Management			
• Risk Register			
Protocol Deviation Management			
Serious Adverse Event Reporting			
• Regulatory Agency(ies)			
• Site investigators / study sites			
Unblinding			
Communications/Community Awareness			
Vendor Management			

Activities/Tasks	Sponsor/SI	CTN	Comments
Archiving			
Auditing (if applicable)			
Data Management			
Data Management Plan Preparation			
Data Collection Worksheet/Case Report Form Development			
Edit Check Plan Preparation			
Database Development			
Data Validation Plan Preparation			
Database User Manual and Entry Guidelines Preparation			
Database Training			
Query Management			
Randomization			
Randomization System Development			
Randomization Procedures			
Statistics			
Randomization and Blinding Design			
Manual / Emergency Manual Randomization			
Statistical Analysis Plan Preparation			
Interim Analysis			
Final Analysis			

Activities/Tasks	Sponsor/SI	CTN	Comments
Final Report			
Data and Safety Monitoring Committee			
Data and Safety Monitoring Committee Management			
DSMC Report			
Other (e.g., publications)			
Publications, conference abstracts/ presentations, and KT activities**			

** For CTN studies, the Sponsor/SI must acknowledge CTN support when completing any type of publication and/or presentation. The Sponsor must inform the CTN about all presentations, publications and KT activities, as the CTN is required to report these activities to its funder (CIHR) on an annual basis.