CRAFT Satellite Site Supervision Plan

Background

In the CRAFT model[1], a trial site cluster consists of a primary site that is conducting the clinical trial and a series of satellite sites organized in a hub-and-spoke model. This increases access to trials for eligible remote patient(s) for whom participation in the full scope of trial visits at the primary site would be a barrier to enrollment. The Qualified Investigator at the primary site maintains the responsibilities set forth in ICH GCP E6 R(2) for the Trial Master File and the conduct of research in compliance with applicable regulatory guidelines for data quality, integrity and for patient safety.

The Satellite Site Supervision plan has been developed to capture the supervision of clinical trial activities that are delegated to a Satellite Site. This template is intended to be customized for *each* identified Satellite Site, prior to the start of study activities at the site.

Aims

- To serve as a detailed record of Primary Site trial supervision responsibilities for all aspects of patient visits planned at the Satellite Site location.
- To ensure that Satellite Site team members have the required knowledge of CGP, ethical conduct of research, patient confidentiality and trial-specific procedures to be able to manage the participants throughout the trial.
- To ensure mechanisms (e.g. communication plan, reporting procedures) are in place to manage unexpected study-related issues, including adverse events, to acceptable resolution.

Complementary documents and processes

- Study protocol
- Study Delegation Log
- Institutional SOPs
    - Documentation of Investigational Site Staff Qualifications, Training Records and Adequacy of Resources
    - Communication with Research Ethics Board (REB), Institutional Research Governance, Sponsor and Insurer
    - Protocol and Investigational Brochure (IB) Development
    - Participant Informed Consent Process and Documentation
    - Case Report Forms, Source Documents, Record Keeping and Archiving
    - Safety Data Monitoring and Reporting Requirements for Clinical Trials
    - Handling and Shipping of Biological Substances in Clinical Trials
    - Standard Operating Procedure (SOP) Creation, Implementation and Revision
    - Protocol Deviation Documentation, Reporting and Investigations
    - The Study Site Master File and Essential Documents
    - Investigator Responsibilities
    - Participant Recruitment and Screening
    - Vendor Qualification and Surveillance
    - Management of Investigational Product
    - Site Initiation and Close Out
    - Equipment Calibration and Maintenance

[1] Canadian Remote Access Framework for clinical Trials, CRAFT : https://3ctn.ca/files/canadian-remote-access-framework-for-clinical-trials-craft

Site Supervision Plan - Approvals

Study Title: _____

Primary Site: _____

Qualified Investigator: _____

Signature:_____ **Date:**_____

Satellite Site: _____

Satellite Site sub-Investigator: _____

Signature:_____ **Date:**_____

Sponsor: _____

Sponsor Representative:_____

Signature:_____ **Date:**_____

Document History

Date	Activity or Change	Approved by:

Site Supervision Plan - Responsibilities Matrix

Clinical Trial Activity	Plan Detail	Responsible Person(s)	
		Primary Site	Satellite Site
Satellite Site Startup and Closure			
Master Research Agreement, Statement of Work – review and execution			
Local REB - submissions & correspondence			
Institutional department approvals, as required (e.g. pharmacy, imaging, pathology, procurement, etc.)			
Amendments			
Satellite site close out			
[Insert additional activities and/or adapt, as required]			
Communications			
Trial team meeting (specify)			
Reporting and management of protocol amendments, process changes, changes to site personnel, etc.			
Correspondence between trial sponsor and satellite site (e.g. study notifications, monitoring, etc.)			
[Insert additional activities and/or adapt, as required]			
Clinical Trial Team Training			
Training and documentation of applicable GCP, TCP2 content for clinicians listed on the study delegation log			
Protocol training and documentation as required for planned trial-related procedures			
[Insert additional activities and/or adapt, as required]			
Participant Enrollment and Case Management			
Study candidate screening and eligibility assessment			
Participant consent process			
Participant enrollment, randomization			

Clinical Trial Activity	Plan Detail	Responsible Person(s)	
		Primary Site	Satellite Site
Participant's contact for the trial			
Scheduling trial visits, booking tests / procedures			
Source data collection and reporting			
Collection of participant-reported source data (e.g. surveys, assessments)			
Adverse Event management and reporting requirements			
Unblinding (as applicable)			
Protocol Deviations			
[Insert additional activities and/or adapt, as required]			
Investigational Product/Study Intervention			
Procurement, distribution, storage (as applicable)			
IP accountability, reconciliation, disposition			
[Insert additional activities and/or adapt, as required]			
Budget Management			
Scheduled payments to satellite sites			
Reimbursement for participants' out-of-pocket costs			
[Insert additional activities and/or adapt, as required]			
Other Delegated Trial Activities			
[Insert additional activities and/or adapt, as required]			