Summary: Site Initiation for MCRI-Sponsored Trials

Why is this required?

The Site Initiation process will ensure that participating site staff have been trained in the protocol and trial-specific procedures and to ensure the clinical trial is performed in accordance with GCP and local laws.

Who is responsible for completing the Site Initiation?

The Sponsor-Investigator for any MCRI Sponsored Clinical Trial is responsible for ensuring all trial site staff are trained to complete clinical trial processes in accordance with the Protocol, GCP, and all relevant local laws and regulatory requirements prior to commencing recruitment at the site.

The Sponsor-Investigator may delegate specific Site Initiation tasks to members of the Central Trial Coordinating Team.

When does the 'Site Initiation' process occur?

Site Initiation commences after ethics approval has been obtained for the site.

Site Initiation concludes when the Site Initiation Visit has occurred, the Green Light Approval form has been completed and the Central Coordinating Team sends a Notification of Site Activation Letter to the site. Only once the participating site has received this letter may they begin recruitment.

Helpful Resources

- MCTC145-SOP: Regulatory Green Light Approval for Clinical Trial Site Activation
- MCTC034-Regulatory Green Light Approval Form
- MCTC140-Template: Essential Document Request letter
- MCTC122-Template: Site Initiation Booking letter
- MCTC132-Template: Site Initiation Meeting Agenda
- MCTC136-Template: Site Initiation Attendance Log
- MCTC142-Template: Site initiation Follow Up Report
- MCTC141-Template: Site Initiation Follow Up Letter
- MCTC016-Template: Notification of Site Activation letter

Key Actions

Planning

- HREC approval received covering the site
- Governance approval received at the site
- CTRA fully executed
- All site-specific Essential Documents have been received and filed in SIF.
- Section 1 of MCTC034: Regulatory Green Light Approval completed

Preparation

- Master Site Initiation presentation (i.e. PowerPoint slide set) adapted to site, including:
  - Protocol Review + Clinical Background,
  - Trial Operations and Logistics, and
  - Trial Database training
- Date of Site Initiation Visit confirmed in writing
- Clinical Trial supplies delivered to Site
- Monitor training completed (if applicable)

Site Initiation Visit (SIV)

The Site PI must be present at the Site Initiation Visit – otherwise, it should be rescheduled.

- Site Initiation Presentation reviewed with all key participating site staff
- Confirmed Site PI plan for training of staff unable to attend the SIV
- Site staff have signed the SIV Attendance Log
- Collect outstanding Essential Documents from Site (i.e. Delegation Log, Training Log etc)

IMP Trials

- Reviewed Trial Drug Procedures with relevant participating site staff (usually pharmacy staff)
- Section 3 of MCTC034 Regulatory Green Light Approval completed
- Ship trial drug to site (if required)

Post Site Initiation Visit

- Section 2 of MCTC034 Regulatory Green Light Approval completed
- SI Follow Up Report filed in corresponding sites SIF
- Site Initiation Follow Up Letter with critical findings sent to site and filed in corresponding sites SIF
- Notification of Site Activation Letter sent to site
- Site given access to Trial Database

Find Out More

Review the full SOP for Site Initiation for MCRI-Sponsored Trials [MCTC139] on the CRDO Launching Pad under 'Management'.

Please contact mctc@mcri.edu.au if you have any questions.