Clinical Research Coordinator Level 2 Programme

Course Description

The Clinical Research Coordinator (CRC) Level 2 Programme builds on a CRC's fundamental competencies in clinical trials and examines the complexities of investigator-initiated trials and multi-center clinical research studies. The programme is designed to empower CRCs with project management skills and the ability to coordinate investigator-initiated clinical research studies with reasonable degree of proficiency across a range of study designs. Application of skills will be reinforced through classroom discussion, case scenarios and practice-based activities.

Learning Outcomes

- Define sponsor responsibilities in an investigator-initiated study
- Apply project management concepts to manage time, resources and quality issues
- Coordinate and perform secretariat duties for multi-site project meetings
- Develop study documents such as data collection tools
- Manage research materials, biological specimens and site logistic matters
- Implement the operational workflow and quality systems for the research study
- Explain the IRB and regulatory requirements for sponsors
- Track project status and completion of study procedures
- Develop the ability to anticipate and mitigate potential risks or non-compliance
- Highlight key concepts for the preparation and conduct of study monitoring and development of a study monitoring plan

Who Should Attend

- Senior CRCs,
- CRCs who are carrying out job responsibilities equivalent of a Senior CRC, and
- CRCs who are progressing towards Senior CRC job grade

Entry Requirements

All requirements must be fulfilled:

- At least 2 years of experience in coordinating clinical research studies;
- Has experience in subject recruitment, informed consent and/or subject follow-up; and
- Has basic understanding of clinical research, such as IRB requirements, ICH Good Clinical Practice, source documentation, essential documents, safety reporting and management of investigational product.

CRCs, who do not possess a comprehensive fundamental knowledge in clinical trials, may wish to attend the CRC Level 1 Programme prior to applying for the CRC Level 2 Programme.

Course Duration

- Approximately 3 weeks / 6 days (every Thursday and Friday), 9:00 am to 6:00 pm
- 1 run in a year – July intake
  ** Please refer to the SCRI Website for the class dates of the upcoming intake.*

Note: Information is accurate at time of print and is subject to changes without prior notice.

Course Location

The programme will be conducted either in physical or virtual classroom.

** Please refer to the SCRI Website for more information on the venue of the upcoming intake.*

Course Outline

Day One • Responsibilities of Sponsor PI in Investigator-initiated Multi-centre Trial • Fundamentals of Project Management • Quality Management Systems	**Day Two** • Study Design and Protocol Review • Apply Project Management Knowledge on Site Feasibility • Research Grants Management • Research Agreements and Insurance • Project Organisation Structure & Process
Day Three • Resource Management • Study Budget • Data Collection & Management • Develop Study Documents	**Day Four** • Study Template Design • IRB, Regulatory & HBRA • IM and SIV, Training of Study Personnel
Day Five • Management of Clinical Research Materials • Management of Biological Specimens • Safety Monitoring • Recruitment Strategies	**Day Six** • Conduct Study Monitoring • Project Management During Study • Be Audit/Inspection Ready • Site Readiness for Closure

**Kindly note that the course outline may be subjected to changes without prior notice.*

Technical Requirements

This is only applicable if the programme is conducted virtually.

It is mandatory to fulfil **ALL** the following minimum technical requirements:

1. Use of PC or Laptop to access the Zoom virtual class for better learning experience as you need to refer to the training handouts while attending the class.
2. Stable internet connection (3G or 4G/LTE), with minimum bandwidth of 600kbps is recommended. You can check your Internet bandwidth using www.speedtest.net or http://bandwidthplace.com/.
3. Supported browser versions:
    - Windows: IE11+, Edge 12+, Firefox 27+, Chrome30+
    - Mac: Safari 7+, Firefox 27+, Chrome30+
    - Linux: Firefox 27+, Chrome 30+
4. Headphone (preferred) or speaker to listen in (built-in / USB plug-in / wireless Bluetooth)
5. Microphone for class discussion (built-in / USB plug-in / wireless Bluetooth)
6. Webcam (built-in / USB plug-in). It is compulsory to turn on the camera for the duration of the Zoom virtual class for attendance authentication.

Registration Period

- July Intake: 15 February to 1 April

Note: Information is accurate at time of print and is subject to changes without prior notice.

Application Procedure

To register for the CRC Level 2 Programme, applicants and their supervisors must complete the following electronic registration forms below.

Registration Form	**Registration Form (Section C)**
[To be completed by Applicant]	[To be completed by Supervisor / Reporting Officer]
https://form.gov.sg/61d3af356c60da00123c0264	https://form.gov.sg/61d3f77f2efd780012420c86

Registration is on a first-come first-served basis and priority will be given to CRCs core-funded under the NMRC CRC programme. Priority will also be given to CRCs from Singapore's public healthcare institutes under Ministry of Health Holdings.

Course Fees

Full Price	$3500.00 *(inclusive of 7% GST)*
CRCs from Singapore's Public Healthcare Institutes under MOH Holdings (After 90% subsidy)	$350.00 *(inclusive of 7% GST)*

Qualification

Participants who successfully completed all modules of this programme with at least 75% class attendance will receive a Certificate of Completion (CRC Level 2 Programme) from SCRI Academy.

Enquiries

For enquiries, please contact scriacademy@scri.cris.sg.