Intern Learning Areas & Responsibilities:
2023 SKILLED Clinical Trial Study Coordinator Internship

The Victorian Comprehensive Cancer Centre Alliance (VCCC Alliance) is once again offering SKILLED Clinical Trial Study Coordinator Internships to suitable applicants across Victoria. The Study Coordinator (SC) Internship provides an opportunity for graduates with a PhD or Master's degree in science or a healthcare discipline to develop their skills and experience towards a future career in clinical trials.

Internship placements will commence on 20th February 2023 and are available at metropolitan Melbourne sites.

This placement is advertised on the VCCC Alliance website, including social media platforms and closes **at 9am Friday 2nd December 2022**. Applications via email to **Chris.Packer@unimelb.edu.au**

Applicants who are successful in gaining one of these highly sought-after placements, will participate in a practical internship that provides supervised training and experiential learning based at either a Melbourne Metropolitan or Victorian Regional clinical trials site. Placements are structured to enhance future job readiness and employment opportunities in the health sector.

During the placement, SC Interns will learn about and gain supervised experience in the duties and accountabilities of the study coordinator role.

2023 SKILLED Study Coordinator Internship Program

Integrated and Supervised Onsite Training: Learning Areas and Responsibilities

The following information outlines the key areas of learning, learning activities and the responsibilities the intern will undertake during their internship program. SC Interns are supported by a host site supervisor who will provide coaching support, direction, and guidance throughout the internship program. Each Intern will also be supervised by and learn from experienced onsite clinical trial staff.

Internship Program Summary

The Study Coordinator (SC) Intern will complete an initial one-week induction program, conducted by the VCCC Alliance, followed by a structured 39-week onsite placement which integrates formalised learning and practical supervised experiential learning. During this program, the SC Intern will learn and then assist with the coordination of clinical trials as part of their host site placement. They will learn how to ensure all clinical trials are managed according to the International Conference for Harmonization (ICH) guidelines for Good Clinical Practice (GCP) to ensure the safety and protection of trial participants and the integrity of trial data subsequently collected.

Reporting

The SC Intern will report to and follow the directions of the nominated host site supervisor.

Immunisation Risk Category Description

Category A: Position involving direct patient contact, potential for exposure to blood, body fluid, human tissue specimens during course of a normal working day.
(Use of Personal Protective Equipment will be a requirement and training will be provided)
https://www2.health.vic.gov.au/public-health/immunisation/adults/vaccination-workplace/vaccination-healthcare-workers

Intern Key Relationships:

Placement Site, Internal Key Contacts:

Research participants & their caregivers, senior medical staff, principal and co-investigators, multidisciplinary team members and clinical trial unit staff

Other, likely external contacts:

Clinical trial sponsor representatives from pharmaceutical companies and collaborative groups, Cancer Trials Australia, Research nurses and data managers at other hospitals, laboratories and diagnostic imaging centres.

Key Learning and Practice Areas and Intern Responsibilities:

All learning and practice areas listed will be undertaken under the direct or indirect supervision of onsite experienced trial staff.

Learning and Practice Area: Patient Screening and Registration

The Intern will learn about and gain experience in:

- Ensuring that for all potentially eligible patients are identified for clinical trials and that informed consent is obtained where appropriate and in accordance with GCP standards.
- Ensuring that all consenting patients are screened for eligibility and deemed eligible, in accordance with the trial protocol, and are registered or randomised as required without deviation.
- Meeting planned accrual targets.
- Liaising with clinicians and other health professionals to assist in the identification of eligible patients.
- Ensuring that the relevant departments/interns are aware of upcoming and current trials by the appropriate dissemination of information.
- Ensuring all eligible patients have signed the appropriate consent forms, having been duly informed of all relevant information by the Investigator and Study Coordinator.
- Learning how to be actively involved in the informed consent process and how to ensure informed consent is obtained according to standard hospital practice, ICH GCP and the NHMRC National Statement on Ethical Conduct in Research Involving Humans.

- Ensuring all consenting clinical trial participants are screened for eligibility in accordance with the protocol.

Learning and Practice Area: Assisting in Clinical Trial Coordination

The Intern will learn about and gain experience in:

- The types of unit/departmental meetings that occur and participate in those meetings that act to inform the team and the Intern of upcoming and current trial activity.
- Attending start-up meetings for clinical trials and other relevant projects and, if necessary and when learned, take part in reminding investigators of the requirements for these meetings.
- Learning how to assist in the planning and conduct of meetings.
- Ensuring that all relevant interns are informed of and invited to attend study site initiation meetings.
- Ensuring that the clinical trial is coordinated as per the protocol and in accordance with the ICH guidelines for good clinical practice (GCP).
- Assisting in the care of the patient and their family/carer by maintaining a patient-focused approach, communicating in plain terms and respectfully
- Ensuring that all trial-related investigations, procedures and treatments are performed by the appropriately trained and experienced staff and as per the trial protocol.
- Learning how to ensure the protocol/project requirements are met and maintain the interest and support of trial participants and other colleagues.
- Learning how to ensure all trials are coordinated as per the protocol and according to ICH GCP.
- As SC, learn how to ensure that all interns participating in the care of clinical trial participants have the appropriate experience and are trained in the protocol and in their trial-specific responsibilities in accordance with GCP.
- Learning about the delegation of trial authority and how to ensure the Principle Investigator for each trial has appropriately completed and signed the delegation of authority log for all staff participating in the trial.
- Participating in patient reviews and clinic visits.
- Learning how to and gaining experience in assisting in arranging patient trial tests and procedures.
- Learning how to assist with patient assessments which fall within the scope of the Study Coordinator role.

Learning and Practice Area: Data Collection/Data Entry of Case Record Forms

The Intern will learn about and gain experience in:

- How to use and access relevant systems/databases.
- Learning how to ensure that all registered patients are appropriately documented on the appropriate systems
- Attending clinics and patient visits to learn how to and gain experience in collecting appropriate data.
- Ensuring all case report forms (paper or electronic) are completed and dispatched to the appropriate authorities within established timeframes.
- Ensuring all data recorded in case report forms (CRF's) can be tracked to verifiable source data.
- Learning about data entry requirements and entering accurate data into relevant clinical trial unit

database/s within allocated timelines.

- Understanding confidentiality and privacy requirements of data handled.
- Ensuring all data entered is accurate and verifiable against source data.
- Applying learnings gained throughout the internship to achieve high standards in the quality if clinical trial data entered, ensuring there are no breaches of patient, sponsor or departmental confidentiality.

Learning and Practice Area: Organisation, Problem Solving and Prioritisation Skills

The Intern will gain practical experience in the necessities of being organised and able to prioritise and problem solve in an active clinical trial unit environment by:

- Learning about activity timelines and deadlines and about the priorities required in a clinical trials unit and how to apply those priorities.
- Being aware of the clinical trial units and requirements to meet critical deadlines whilst maintaining consistently high standards
- Utilising excellent organisational and forward planning skills within the scope of the internship Maintaining appropriate task and activity planning and utilization of tracking tools education.
- Preserving high standards in quality clinical trial data entered by the intern.

Intern Responsibilities

Successfully selected Study Coordinator Interns will be required to:

- Comply with Requirements of the National Safety & Quality Health Service Standards
- Comply with all Clinical Trial Unit (CTU) site Policies and Procedures.
- Demonstrate and role model CTU site values.
- Complete and maintain all mandatory training relevant to the host site and the internship
- Contribute to a safe and healthy working environment and utilise personal protective equipment as required.
- Report any unsafe practices through the incident reporting system provided.
- Promote a no blame culture of safety and wellbeing.
- Maintain knowledge of onsite emergency procedures and location of emergency equipment.
- Take all reasonable steps to prevent bullying, discrimination and harassment throughout the placement.
- Report any incidents of bullying, discrimination or harassment experienced or observed.
- Observe child safe principles and expectations for appropriate behaviour toward and in the company of children.
- Be able to travel between sites, if necessary, for the internship placement and training as required (COVID-19 restrictions permitting).

General Conditions:

All Clinical Trial Units/host sites strongly support clinical trial participants in expressing their wishes and values. Sites have a zero tolerance of child abuse, and all allegations and safety concerns will be treated very seriously. For more information refer to Site's Child Safe Policy.

VCCC Alliance

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All Clinical Trial Units/host sites are an equal opportunity employer and committed to providing interns a placement environment which is free from bullying, harassment, or discrimination. All sites are a smoke-free environment.

Host sites reserves the right to modify learning areas, activities, practice areas and responsibilities as required, and the intern will be consulted if and when this occurs.