## Study Coordinator Post-Doctorate Internship, Cancer Clinical Trials

<table>
<thead>
<tr>
<th>Internship title:</th>
<th>Study Coordinator Post-Doctorate Intern, Cancer Clinical Trials</th>
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<tr>
<td><strong>Reports To:</strong></td>
<td>Direct Host Site Manager or Supervisor (confirmed upon placement)</td>
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<td>Indirect VCCC Clinical Trials Workforce Development Manager</td>
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<td><strong>Internship timeframe &amp; location:</strong></td>
<td>Intern – Full Time Maximum Term Contract, 40 weeks Location: To be confirmed upon selection</td>
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<td><strong>Commencement Date</strong></td>
<td>1st February 2021</td>
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<td>There will be a 2-week induction process commencing on 1 Feb 2021, held at the Victorian Comprehensive Cancer Centre (VCCC) in partnership with Parkville Cancer Clinical Trial Unit (PCCTU), prior to the intern commencing ‘on-the-job’ supervised training at their host site.</td>
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**Key Relationships**

**Internal**
- Research participants & their caregivers
- Senior medical staff, principal and co-investigators
- Multidisciplinary team members
- Host site staff
- Internal stakeholders, as relevant to conducting trials, i.e. same day services, inpatient wards, outpatient pathology
- Internal human research ethics committee (HREC)

**External**
- Interns participating in the VCCC SKILLED program
- Clinical trial sponsor representatives from pharmaceutical companies and collaborative groups
- Cancer Trials Australia
- Research nurses and data managers at other hospitals
- External laboratories and diagnostic imaging centres

**Immunisation Risk Category**
**Category A:** Internship involving direct patient contact, potential for exposure to blood, body fluid, human tissue specimens during course of a normal working day.

**Remuneration**
The intern will be remunerated as an intern/trainee

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### Introduction

This internship is offered as a part of the SKILLED Clinical Trials Internship Program (SKILLED program). The SKILLED program has been developed by the Victorian Comprehensive Cancer Centre in collaboration with its alliance partners and other metropolitan and regional clinical trial units across Victoria. The program aims to
increase the numbers of scientists, including post-graduate and post-doctoral level scientists with the skills to become study coordinators (SCs), entering the clinical trials sector, trained and job ready.

About the VCCC
The VCCC’s multi-site, multi-disciplinary model brings together the complementary strengths of Peter MacCallum Cancer Centre, Melbourne Health (including The Royal Melbourne Hospital), The University of Melbourne, The Walter and Eliza Hall Institute of Medical Research, The Royal Women’s Hospital, The Royal Children’s Hospital, Western Health, St Vincent’s Hospital Melbourne (including St Vincent’s Institute), Austin Health (including the Olivia Newton-John Cancer Research Institute and Austin Lifesciences) and Murdoch Children’s Research Institute, along with a growing list of Victorian regional health care providers.

Internship Overview
The Study Coordinator Intern will assist with the coordination of clinical trials, as a member of their host site’s team. The Intern will receive training to ensure that 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 and confidentiality of trial data subsequently collected.

The ongoing objective of the internship is to provide a professional and practical level of job specific training to create job-ready Study Coordinators to support the VCCC and collaborating partners to achieve continued excellence in service provision by ensuring that evidence-based evaluation is the basis for clinical practice.

KEY RESPONSIBILITIES:
The Study Coordinator Intern will assist in the following key areas under direct and indirect supervision of the host site’s clinical trial staff/managers.

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<thead>
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<th>Key Responsibilities</th>
<th>Demonstrated by:</th>
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<tbody>
<tr>
<td>1. Assists with Patient screening and registration to:</td>
<td>• Where required, all eligible patients have signed the appropriate consent forms having been duly informed of all relevant information by the Investigator and Study Coordinator.</td>
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<tr>
<td>• Ensure that all potentially eligible patients identified for clinical trials, and that informed consent is obtained where appropriate and according to GCP.</td>
<td>• Informed consent is obtained according to standard hospital practice, ICH GCP and the NHMRC National Statement on Ethical Conduct in Research Involving Humans and be actively involved in the ongoing informed consent process.</td>
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<td>• Ensure that all consenting patients are screened for eligibility as per the protocol and are registered/randomised as required.</td>
<td>• All consenting clinical trial participants are screened for eligibility as per the protocol.</td>
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<td>• Meet planned accrual targets</td>
<td>• All participants deemed eligible for the trial are registered/randomized as per protocol and without deviation.</td>
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<td>o Liaise with clinicians and other health professionals to assist in the identification of eligible patients.</td>
<td>• All relevant unit/departmental meetings have been attended (to ensure the intern is informed of and informs the team of upcoming / current trial activity).</td>
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<td>• Ensure that the relevant departments/staff are aware of upcoming/current trials by the appropriate dissemination of information.</td>
<td>• All relevant clinical staff are informed of and invited to attend study site initiation meetings.</td>
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### 2. Assists in Clinical Trial Coordination to ensure that:
- the clinical trial is coordinated as per protocol and as per the ICH guidelines for good clinical practice.
- relevant assistance is provided to support the care of the patient and their family by maintaining a patient focused approach at all times.
- all trial related investigations, procedures and treatments are performed by the appropriately trained and experienced staff and as per the trial protocol.
- the protocol/project requirements are met and maintain the interest and support of participants and other colleagues.
- All trials are coordinated as per the protocol and according to ICH GCP.
- All staff 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.
- The Principal Investigator for each trial has appropriately completed and signed the delegation of authority log for all staff participating in the trial.
- Attends start-up meetings for the clinical trials and other relevant projects and, if necessary, reminds investigators of the requirement for these meetings.
- Assisting the planning and conduct of meetings as required.
- Participates in patient reviews and clinic visits.
- Assists in arranging patient trial tests and procedures.
- Assists with patient assessments which fall within the scope of the study co-ordinator.

### 3. Assists in Data Collection and Entry – Case Record Forms
- All registered patients are appropriately documented on the appropriate systems.
- Attends clinics and patient visits to collect appropriate data.
- All case report forms (paper or electronic) are completed and dispatched to the appropriate authorities within established timeframes.
- All data recorded in CRF’s can be tracked to verifiable source data.
- Good relationships have been developed with trial sponsor representatives, trial organisers or other relevant personnel.
- No breaches of patient, sponsor or departmental confidentiality have been committed.
- All data entry is completed in a timely fashion per trial and sponsor requirements.

### 4. Commits to professional education and development
- Demonstrates a commitment to undertake the necessary professional education required of the Study Coordinator Intern role.
- Follows instruction and undertakes training in order to acquire the knowledge and skills needed to implement new study protocols from a variety of clinical specialties.
- In conjunction with Manager, proactively identifies areas that require additional knowledge and works towards meeting the learning objectives set.
- Undertakes mandatory training requirements as defined by host site policy.

### 5. Participates as integral member of the Clinical Trials or Research Team
- Participates appropriately in quality activities.
- Participates in Unit and Team Meetings.
- Assists in planning activities.
- Supports colleagues and shares workload when capacity allows.
- Shares knowledge and actively communicates to ensure people are informed and kept up to date as relevant.
Conduct Requirements

While host sites may have specific expectations, they will inform the intern of upon placement, all host sites expect that interns will:

- Demonstrate and role model the host sites values.
- Comply with all the host site’s Policies and Procedures.
- Comply with the Requirements of the National Safety & Quality Health Service Standards.
- Comply with all requirements, regulations, policies and procedures regarding the management of confidential and sensitive information.
- Complete and maintain all mandatory training relevant to area of practice.
- Participate in staff development processes as required.
- Contribute to a safe and healthy working environment.
- Report unsafe work practices using the incident reporting system.
- Promote a no blame culture of safety and wellbeing.
- Maintain working knowledge of emergency procedures and location of emergency equipment.
- Be respectful of others and take all reasonable steps to prevent bullying, discrimination and harassment in the workplace.

The host site strongly supports patients in expressing their wishes and values. Clinical staff are encouraged to engage in Advance Care Planning (ACP) discussions with patients.

The host site is an equal opportunity employer and is committed to providing for its employees a work environment which is free from harassment or discrimination.

The host site is a smoke-free environment.

Key Selection Criteria:

Essential:

- 2 years of cancer-related experience
- Excellent written and oral communication skills
- Personal confidence, empathy and initiative required to deal with patients and their families from diverse backgrounds and experiences
- Proven problem-solving skills with the ability to learn new processes and systems quickly
- Excellent organisational skills and ability to prioritise effectively
- Meticulous with excellent attention to detail
- Able to work independently, while able to contribute effectively in a team setting
- Cooperative and supportive collegiate approach with the ability to gain the support of others
- Commitment to excellence in customer service and patient care
- Discrete and meticulous in managing the security of confidential and sensitive information
Qualifications

- Post-doctoral PhD in relevant scientific discipline

Special Requirements

To be eligible for consideration, applicants must:

- be available to commence on 1st February 2021
- be based in Victoria as this program is funded by the Victorian Department of Health and Human Services
- be an Australian citizen or hold permanent residency status

Equity & Inclusion:

All host sites are equal opportunity employers who are committed to providing a workplace free from all forms of unlawful discrimination, harassment, bullying, vilification and victimisation.