Clinical Trial Assistant Internship
Cancer Clinical Trials
Border Medical Oncology Research Unit
Albury/Wodonga

<table>
<thead>
<tr>
<th>Internship title:</th>
<th>Clinical Trial Assistant Hons or Masters Intern, Cancer Clinical Trials Border Medical Oncology Research Unit – Albury/Wodonga</th>
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<tbody>
<tr>
<td>Reports To:</td>
<td>Direct</td>
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<tr>
<td></td>
<td>Indirect</td>
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<tr>
<td>Internship timeframe &amp; location:</td>
<td>Intern – Full Time, 40 weeks</td>
</tr>
<tr>
<td>Commencement Date</td>
<td>22 February 2021</td>
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<td></td>
<td>There will be a 2-week induction process commencing on 22 February 2021, held at the Victorian Comprehensive Cancer Centre (VCCC) in partnership with Parkville Cancer Clinical Trial Unit (PCCTU), prior to the intern commencing ‘on-site’ supervised training at their host site.</td>
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<tr>
<td>Key Relationships</td>
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<tr>
<td>Internal</td>
<td>• Research participants &amp; their caregivers</td>
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<td></td>
<td>• Senior medical staff, principal and co-investigators</td>
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<td></td>
<td>• Multidisciplinary team members</td>
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<td></td>
<td>• Host site staff</td>
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<td>• Pharmacy team staff</td>
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<td>• Internal stakeholders, as relevant to conducting trials, i.e. same day services, inpatient wards, outpatient pathology</td>
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<td></td>
<td>• Internal human research ethics committee (HREC)</td>
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<tr>
<td>External</td>
<td>• Interns participating in the VCCC SKILLED program</td>
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<td>• Clinical trial sponsor representatives from pharmaceutical companies and collaborative groups</td>
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<td></td>
<td>• Cancer Trials Australia</td>
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<td></td>
<td>• Research nurses and data managers at other hospitals</td>
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<td></td>
<td>• External laboratories and diagnostic imaging centres</td>
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<tr>
<td>Immunisation Risk Category</td>
<td>Category A: Internship involving direct patient contact, potential for exposure to blood, body fluid, human tissue specimens during course of a normal working day.</td>
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<tr>
<td>Remuneration</td>
<td>The intern will be remunerated as an intern/trainee</td>
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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 post graduate level scientists including pharmacy with the skills to become clinical trial assistants (CTAs), 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 Clinical Trial Assistant Intern will assist with the administrative support for both the Clinical Trial and Pharmacy teams which includes database/s, clinical trial management system support. The Clinical Trial Assistant Intern will also be responsible for maintaining appropriate regulatory documents and ensuring regulatory compliance in the conduct of clinical trials. 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.

During the internship, interns will be assessed using a competency framework to assess their learning and will, when required, receive host site support and assistance to apply their learnings. The SKILLED Clinical Trial Assistant Competency Framework can be viewed on the VCCC website.

https://www.viccompcancerctr.org/opportunities/

The objective of the internship is to provide a professional and practical level of job specific training to create job-ready Clinical Trial Assistants to build capacity and support the VCCC and collaborating partners to achieve continued excellence in service provision.

KEY RESPONSIBILITIES:

The Clinical Trial Assistant Intern will assist in the following key areas under direct and indirect supervision of the host site’s Clinical Trial and Pharmacy Unit staff and managers.

<table>
<thead>
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<th>Demonstrated by:</th>
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<tbody>
<tr>
<td><strong>1. Administrative Support</strong></td>
<td>Refer to competencies in Clinical Trial Assistant Competency Framework</td>
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</table>
| • Administratively assist clinical trial unit and pharmacy team staff with the day to day running of multiple clinical trials and pharmacy support, as needed. Use initiative and judgement to interpret the needs and priorities within the teams to ensure the provision of timely and effective administrative support. | a. Resources/financial management, and  
b. Data collection and documentation from A Study Management Competency |
• Work to ensure all allocated trial related tasks are met in the designated timelines, in an organised manner and in accordance with ICH GCP.
• Maintain regulatory files in accordance with ICH GCP and Unit’s Standard Operating Procedures.
• Conduct electronic and hard copy filing in a timely manner and in accordance to regulatory requirements.
• Coordinate onsite monitoring visits, as required
• Actively co-ordinate financial processes in compliance with institutional policies and regulatory guidelines.
• Develop and implement tools to oversee and facilitate patient reimbursement.

2. Database/s and Clinical Trial Management System Support

• Provide support and act as a resource to Unit staff in the use of the VELOS clinical trial management system
• Provide support to Unit staff in the entry of data into relevant unit database/s
• Undertake appropriate training where required to allow access to appropriate databases
• Ensure all requests for data entry are responded to and completed within allocated timelines
• Work with attention to detail to ensure all data entered is accurate and verifiable against source data

Refer to competencies in Clinical Trial Assistant Competency Framework

a. Data Collection and Documentation from A Study Management Competency

3. Laboratory Operations

• Ensures accurate sourcing, tracking and processing of biological samples safely and carefully within the trial environment

Refer to competencies in the Clinical Trial Assistant Competency Framework

Handling biological samples from B Laboratory Operations competency

4. Interaction with Participants

Refer to competencies in Clinical Trial Assistant Competency Framework
- Ensures patient comprehension and safety during initial and ongoing clinical trial informed consent discussions

**5. Regulatory Management**

- Ensures adherence to ethical practices and regulations during the conduct of clinical trials to protect the rights and well-being of patients and the collection of quality data

<table>
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<tr>
<th>Informed consent process from C. Interaction with Participants Competency</th>
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<tr>
<td>a. Ethics and regulation compliance from D Regulatory Management competency</td>
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**6. Participates as integral member of the Clinical Trials and Pharmacy Unit teams**

- 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 a wide range of people at different levels to ensure people are informed and kept up to date as relevant.
- Accepts and provides constructive feedback for continuous development
- Maintains confidentiality and displays discretion in dealing with fellow staff and patients

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<tr>
<td>a. Clinical trial related communications/coordination from A Study Management competency</td>
</tr>
<tr>
<td>b. Informed consent process from C Interaction with Participants Competency</td>
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</table>

**7. Commits to professional education and development**

- Demonstrates a commitment to undertake the necessary professional education required of the Clinical Trial Assistant Intern role.
- Follows instruction and undertakes training 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.
- Meet critical deadlines while maintaining consistent high standards
- Utilise organisational and forward planning

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<tr>
<td>a. Professional Development from E Professional Skills Competency</td>
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tools

- Maintain appropriate workload planning and tracking tools

### 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:**

- Able to commence internship orientation from 22 February to 5 March 2021 in Parkville
- Willing to relocate to Albury Wodonga or surrounding area for the duration of the internship (following orientation) for a period of 38 weeks
- 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

- An Honours or Masters degree in pharmacy

Special Requirements

To be eligible for consideration, applicants must:

- be available to commence on 22 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.

Acknowledgement

The SKILLED Clinical Trials Internships program is part of the MTPConnect Researcher Exchange and Development within Industry (REDI) initiative funded through the Australian Government's Medical Research Future Fund.