

# Grampians Health Clinical Trials Unit Site CV

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All requests and enquiries regarding use and availability of this publication should be directed to:

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## Site background

Established in 2004, the Grampians Health Ballarat Clinical Trials Unit has grown to become the largest and most comprehensive clinical research facility in Western Victoria.

As a cornerstone of Grampians Health, formed in 2021 through the strategic amalgamation of four key health services, our unit serves a vast catchment of over 250,000 people across 48,000 square kilometres, representing 17% of regional Victoria's population. Our state-of-the-art facility currently manages an impressive portfolio of over 100 active studies, encompassing phase I through IV clinical trials.

Our success is driven by a team of seasoned professionals, including 20 principal investigators and 11 study coordinators, collectively bringing over 50 years of specialised experience to every project.

Key strengths of our unit include:

- Experienced leadership: a dedicated clinical trials manager and assistant to oversee operations, ensuring seamless study execution.
- Cutting-edge technology: we employ advanced electronic management systems for trial documentation, including BOSSnet and ARIA for remote monitoring capabilities.
- Rigorous compliance: all research staff are ICH-GCP and IATA certified, adhering to the highest industry standards.
- Comprehensive infrastructure: our facility features Site-Docs for electronic ISF management, an Ethical Review Manager, and robust Standard Operating Procedures.

Grampians Health Ballarat Clinical Trials Unit is committed to fostering innovation and delivering high-quality, ethically sound research. Our integration within the larger Grampians Health network allows us to leverage extensive resources and expertise, positioning us as an ideal partner for companies seeking to conduct clinical trials in a dynamic regional setting.

With our proven track record, state-of-the-art facilities, and dedication to advancing medical knowledge, we invite you to explore the possibilities of collaboration with Grampians Health Ballarat Clinical Trials Unit – where excellence in research meets compassionate care for our communities.

[Capability evaluation of a large regional clinical trials unit to assess growth over time. | Journal of Clinical Oncology \(ascopubs.org\).](#)

## Facilities and services

- Dedicated patient assessment and central processing facilities.
- On-site clinical trials pharmacy with secure, controlled access and storage of IP.
- On-site pathology with phlebotomy, processing, reporting services; archival, and fresh tissue preparation diagnostic services.
- Access to a robust clinical safety data management system for phase I trials.
- Established internal quality assurance procedure and effective evaluation processes (CAPA SOP).

**In addition to clinical trials, Grampians Health offers a comprehensive range of medical services, including:**

- On-site Dorevitch Pathology.
- Ballarat Austin Radiation Oncology Centre (BAROC).
- Advanced imaging services (X-ray, CT, MRI, nuclear medicine, and PET through agreement with Lake Imaging at select locations).
- Ophthalmology services.
- A 13-bed Intensive Care Unit (ICU), with capabilities in:
  - Indirect calorimetry and catabolism management
  - Optimisation of continuous renal replacement therapy (CRRT)
  - Delirium management and prevention
  - Point-of-care blood analysis systems
  - Novel thromboelastographic (TEG)
  - Various CRRT circuits to improve biocompatibility
  - Extracorporeal mechanical cardiac support
- Emergency Department.
- Local oncology service, reviewing approximately 1,500 new medical oncology/haematology patients annually.
- Tumour-stream-based Multidisciplinary Meetings and streamlined referral pathways.
- Comprehensive allied health services.

## Specialised units

### Rapid Access Lung Lesion Clinic (RALLC)

Dr Wasek Faisal

Grampians Health operates a Rapid Access Lung Lesion Clinic (RALLC) which provides a streamlined pathway for patients with suspected or diagnosed lung cancer. This clinic aims to improve timely access to diagnosis and treatment for patients in the Grampians region.

**Key features of the RALLC at Grampians Health include:**

- Single referral pathway: the clinic offers a centralised point of entry for patients with proven or suspected lung cancer.
- Timely assessment and monitoring: RALLC closely monitors potential lung cancer patients, enabling faster diagnosis and treatment initiation.

- Clinical trial participation: the clinic's involvement in clinical trials has led to Grampians Health recruiting the first Australian patient for a rare lung cancer study, demonstrating organisation commitment to advancing lung cancer research and treatment.

The RALLC at Grampians Health plays a crucial role in addressing the healthcare disparities faced by patients in remote and rural areas of Australia, particularly in relation to lung cancer diagnosis and treatment.

### Phase I trials

Grampians Health is at the forefront of oncology research, offering phase I clinical trials. Our phase I oncology clinical trials program is a key component of our commitment to innovative cancer care and research excellence.

### Cardiology

By actively engaging in clinical trials, Grampians Health is not only improving the current standard of care for cardiac patients and those with other conditions, but also contributing to the broader advancement of medical knowledge and treatment options.

Key statistics for cardiology patients in the Grampians region:

- Our region experiences higher rates of chronic diseases - particularly cardiovascular disease - leading to increased premature deaths and lower life expectancy for both men and women compared to the Victorian average, with the health inequity gap widening over the past decade.
- Risk factors: the region has higher rates of several risk factors associated with cardiovascular disease compared to the Victorian average, including:
  - higher rates of smoking
  - higher rates of obesity
  - higher rates of physical inactivity
  - higher rates of sugar-sweetened beverage consumption.
- Hospitalisation rates: the hospitalisation rate for cardiovascular diseases in the Grampians region was reported to be 587 per 100,000 population.

At Grampians Health, our cardiology services include:

- Coronary angiography, Percutaneous Coronary Intervention (PCI)
- Temporary and permanent pacemaker insertion
- Implantable Cardioverter-Defibrillator (ICD)
- Cardiac Resynchronisation therapy (CRT)
- Direct Current Cardioversion (DCR)
- Transthoracic echocardiogram
- Transoesophageal echocardiogram
- Stress echocardiogram
- Nuclear medicine scans
- Access to CMR

Our site conducts approximately 150 STEMI's per year.

## Site address and contacts

### **Clinical Trials Unit Grampians Health Ballarat**

Ballarat Base Hospital  
1 Drummond Street North  
Ballarat VIC 3350

### Staff contacts

#### **Management staff**

Ashleigh Clarke  
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#### **Senior staff**

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## Key investigators

### Anaesthetics

- Dr Greg Henderson  
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### Medical oncology

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- Dr Geoffrey Chong  
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### Neurology

- Dr Duncan Austin  
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- Dr Thomas Kraemer  
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### Obstetrics and gynaecology

- Dr Natasha Frawley  
[natasha.frawley@gh.org.au](mailto:natasha.frawley@gh.org.au)

### Paediatrics

- Dr Dave Tickell [david.tickell@gh.org.au](mailto:david.tickell@gh.org.au)

### Palliative Care

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## Experience

|                                     |                                                                                                                                                                                                        |
|-------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Therapeutic area</b>             | Allied health, anaesthetics, cardiology, gastroenterology, haematology, intensive care, infectious diseases, medical oncology, nephrology, neurology, obstetrics and gynaecology, paediatrics, surgery |
| <b>Trial phase capabilities</b>     | Ib, II, III, IV                                                                                                                                                                                        |
| <b>Research experience</b>          | Industry and investigator initiated                                                                                                                                                                    |
| <b>Patient population</b>           | Adults, paediatric (including neonates)                                                                                                                                                                |
| <b>Open and recruiting studies</b>  | Over 50                                                                                                                                                                                                |
| <b>Active and follow-up studies</b> | Over 75                                                                                                                                                                                                |
| <b>Audit history</b>                | Sponsor initiated audits and EMA inspections within the last two years with no critical findings. No reports will be provided due to confidentiality                                                   |

## Qualifications

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
|-----------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Type</b>           | Public hospital                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| <b>Staff training</b> | <p>All site staff actively coordinating and managing clinical trials are TransCelerate Good Clinical Practice (GCP) accredited (available on SiteDocs).</p> <p>Study Coordinators hold certificates for the Civil Aviation Academy Australia Safe Transport of Infectious Substances (available on SiteDocs).</p> <p>Study Coordinators are trained in the Clinical Trials Unit Standard Operating Procedures (SOPs) with records available on request.</p> <p>Clinical Trial site staff qualifications and training records maintained as per Grampians Health Standard Operating Procedures and templates found within Site Staff Qualifications, Training Records and Capability and available, with these records being available on SiteDocs upon request.</p> <p>Grampians Health training for clinical trial staff goes beyond GCP with regular clinical trial education, including mandatory competencies from the Australian Clinical Trials Education Centre (A-CTEC) ensuring research is delivered at the highest of standards.</p> <p>Grampians Health has adopted the National Standard Operating Procedures (SOPs) for clinical trials, including Teletrials. The Grampians Health Clinical Trial Standard</p> |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                                                     |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------|
| Operating procedures will standardise procedures for key operations for all clinical trial activity at Grampians Health. Consistent with the National Statement on Ethical Conduct in Human Research and aligned with the National Clinical Trials Governance Framework, the Grampians Health Clinical Trial Standard Operating Procedures are aimed at integrating high-quality clinical trials into routine hospital care for improved patient outcomes. All Grampians Health study personnel are expected to work within their scope of practice. |                                                     |
| <b>Policies</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | Available on <a href="#">SiteDocs</a> upon request. |
| <b>Medical licences</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | Available on <a href="#">SiteDocs</a> upon request. |

## Facilities

|              |                                                                                                                                                                                                    |
|--------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Type</b>  | Public hospital                                                                                                                                                                                    |
| <b>Hours</b> | 24/7 emergency department<br>24/7 inpatient care<br>24/7 cardiac catheterisation laboratory<br>Monday to Friday 0830 to 1630 outpatient care<br>Monday to Friday 0800 to 1730 clinical trials unit |

## Informed consent

|                      |                                                                                                                                                                                                                                      |
|----------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Unit policies</b> | Grampians Health Standard Operating Procedure: Participant Informed Consent Process and Documentation.                                                                                                                               |
| <b>Language</b>      | Non-English language consent forms can be submitted for approval and use. Facilitate the adoption of remote consent and Teletrial opportunities with our cutting-edge platform, REDCap to streamline clinical trial consent process. |

## Monitoring

|                           |                                                                                                                                                                                                                                                                                                                                                                 |
|---------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Unit policies</b>      | <p>Audit Readiness and Source Data Verification will follow Grampians Health Clinical Trial Standard Operating Procedures and Institutional Policies on access to Healthcare Records.</p> <p>The following clinical trial unit manuals also relate to site monitoring: Working Manual Remote Monitoring (available on request in <a href="#">SiteDocs</a>).</p> |
| <b>Onsite monitoring</b>  | <p>A single self-contained office with fully functional site workstation.</p>                                                                                                                                                                                                                                                                                   |
| <b>Onsite facilities</b>  | <p>Access to <a href="#">SiteDocs</a>, OPAL (electronic Medical Records; eMR), computer, photocopier/printer, and phone.</p>                                                                                                                                                                                                                                    |
| <b>Bookings</b>           | <p>Onsite visits are to be booked four weeks in advance.</p>                                                                                                                                                                                                                                                                                                    |
| <b>Offsite monitoring</b> | <p>Participant eMR (OPAL) and the electronic Investigator Site File (eISF, <a href="#">SiteDocs</a>) can be accessed remotely on request.</p>                                                                                                                                                                                                                   |

## Documentation

|                                      |                                                                                                                                                                                                          |
|--------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Unit policies</b>                 | <p>Adherence to Grampians Health Clinical Trial Standard Operating Procedures for essential document management access to Clinical Trial Unit Work Manuals in <a href="#">SiteDocs</a> upon request.</p> |
| <b>Investigator site file</b>        | <p>Records are stored on <a href="#">SiteDocs</a>. Wet Ink backups are stored within the Clinical Trials Unit Office.</p>                                                                                |
| <b>Patient source data</b>           | <p>Source data stored on OPAL (eMR)</p>                                                                                                                                                                  |
| <b>Electronic data capture (eDC)</b> | <p>Site staff are experienced in the use of several different eDC platforms, including but not limited to; Inform, iMedidata Rave, Oracle, RedCap, and Veeva Vault.</p>                                  |

|                                   |                                                                                                                                                                                                                                                                                                                                                                                                                                               |
|-----------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Safety reporting procedure</b> | Grampians Health follows the Grampians Health Clinical Trials Standard Operating Procedures for Safety Data Monitoring and Reporting and aligns with the NHMRC's safety monitoring and reporting guidelines for clinical trials with therapeutic goods (2016). Grampians Health has also updated institutional reporting for clinical trial safety events to comply with National Clinical Trial Governance Framework (available on request). |
| <b>Archival procedure</b>         | Available on <a href="#">SiteDocs</a> upon request.                                                                                                                                                                                                                                                                                                                                                                                           |
| <b>Archival facilities</b>        | Advanced Record Management<br>140 Broderick Road<br>Corio, VIC, 3214                                                                                                                                                                                                                                                                                                                                                                          |

## Investigational product (IP)

|                                 |                                                                                                                                                         |
|---------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Documentation</b>            | Grampians Health Clinical Trial Standard Operating Procedures on Management of Investigational Product. Contact Slade Health for their documentation.   |
|                                 | Grampians Health Ballarat has two pharmacies on site: general and oncology. The site also has two dedicated and experienced clinical trial pharmacists. |
|                                 | Oncology: the site has dedicated and experienced clinical trial pharmacists.                                                                            |
| <b>Comments</b>                 | Clinical trial pharmacists are to be contacted directly to arrange meetings for site selections, site initiation, monitoring, and close out visits.     |
|                                 | IP, chemotherapy, and immunotherapy are manufactured off site at Slade Health and shipped to site on the day of administration.                         |
| <b>Contacts</b>                 | James Yeung (Slade Health)<br><a href="mailto:james.yeung@sladehealth.com.au">james.yeung@sladehealth.com.au</a><br>03 9565 4473                        |
|                                 | Kimberly Soriano (Slade Health)<br><a href="mailto:Kimberly.soriano@sladehealth.com.au">Kimberly.soriano@sladehealth.com.au</a><br>03 9565 4462         |
| <b>IV infusion capabilities</b> | Yes                                                                                                                                                     |

|                               |                                                                                                                                                                                                                                                                                                                                                                                                              |
|-------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>IP storage</b>             | Secured with controlled access on Level 2 BRICC.                                                                                                                                                                                                                                                                                                                                                             |
| <b>IP shipment</b>            | BRICC Pharmacy<br>1 Drummond Street North<br>Ballarat, VIC, 3350<br><br>Slade Health<br>14 Palmer Court<br>Mount Waverley, VIC, 3149                                                                                                                                                                                                                                                                         |
| <b>Temperature monitoring</b> | Room, refrigerator and freezer temperatures are monitored with records available on <a href="#">SiteDocs</a> (BRICC Pharmacy and Slade).                                                                                                                                                                                                                                                                     |
| <b>Temperature excursions</b> | All systems are alarmed in event of a temperature excursion. Management of excursions can be found in BRICC Pharmacy and Slade Health SOPs on <a href="#">SiteDocs</a> .                                                                                                                                                                                                                                     |
| <b>Power outage</b>           | Site has a generator backup in the event of a power outage. There is also an on-call pharmacist to assist in emergency situations.                                                                                                                                                                                                                                                                           |
| <b>Blinded IP procedure</b>   | Pharmacists and Clinical Trials Unit staff are adequately trained to perform blinded and un-blinded IP monitoring. BRICC Pharmacy has SOPs on <a href="#">SiteDocs</a> regarding blinding procedures performed on site.<br><br>The Clinical Trial Work Manual provides additional details on the circumstances and procedures for emergency and non-emergency unblinding (available on request in SiteDocs). |
| <b>IP destruction</b>         | Outlined in BRICC Pharmacy and Slade Health SOPs located on <a href="#">SiteDocs</a> .                                                                                                                                                                                                                                                                                                                       |

## Investigational product administration

|                             |                                                                                                                                                                                                    |
|-----------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Main treatment area</b>  | Chemotherapy Day Unit (CDU), Level 1 BRICC<br><br>16 chairs, 1:4 or greater staffing ratio, 1:1 ratio if clinically warranted.<br>Associate Nurse Unit Manager<br>Symptom and Urgent Review Clinic |
| <b>Overnight admissions</b> | Pre-booked in advanced if needed, but treatment not commenced until bed is guaranteed.                                                                                                             |

### Emergency equipment

CDU has full emergency equipment available (including crash cart), and the site has a Medical Emergency Team (MET) available to handle emergency situations.

### Intensive Care Unit (ICU)

If an event requires ICU admission (as deemed appropriate by ICU physician), patients are transferred within the site by a hospital orderly.

## Diagnostic services

### Services

Grampians Health Ballarat can provide the following diagnostic services onsite:

- imaging: CT, MRI, X-Ray
- nuclear medicine MUFA, bone scan
- ultrasound
- cardiac: ECG, ECHO, Holter monitoring, angiogram
- respiratory function testing
- ophthalmology
- fresh tumour and bone marrow biopsy

PET/CT is conducted locally but off site through Lake Imaging – St John of God Hospital Ballarat.

Grampians Health Ballarat can facilitate central review.

### Contacts

Grampians Health Ballarat Radiology  
1 Drummond Street North  
Ballarat, VIC, 3350  
03 5320 4270 or 03 5320 4271

Grampians Health Ballarat Diagnostic Services  
1 Drummond Street North  
Ballarat, VIC, 3350  
03 5320 4201

Lake Imaging – St John of God Hospital Ballarat  
101 Drummond Street North  
Lake Wendouree, VIC, 3350  
03 5304 9000

## Local pathology

|                         |                                                                                                                                                                                                                                                                                                    |
|-------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Location</b>         | Although Grampians Health Ballarat can utilise several local pathology services, the site contract is with Dorevitch Pathology. Dorevitch draws (Level 1 BRICC) and analyses most serology samples on site, with some samples being sent to the Melbourne central laboratory for further analysis. |
| <b>Address</b>          | Dorevitch Pathology – Drummond Street<br>104 Drummond Street North<br>Ballarat, VIC, 3350<br>03 5359 1778                                                                                                                                                                                          |
| <b>Accreditation</b>    | NATA and Medicare                                                                                                                                                                                                                                                                                  |
| <b>Reference ranges</b> | Available on <a href="#">SiteDocs</a> .                                                                                                                                                                                                                                                            |

## Central pathology

|                               |                                                                                                                                                                            |
|-------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Location</b>               | Grampians Health Ballarat has a dedicated laboratory for central laboratory sample processing and shipping on Level 2 of the Clinical Trials Unit                          |
| <b>Hours</b>                  | Monday to Friday 0800 – 1700<br>Same day collection is available (courier dependant)<br>Out of hours samples can be performed                                              |
| <b>Kit storage</b>            | Central lab kits have a dedicated storeroom on BRICC Level 2, within the Clinical Trials Unit office space. This office and the attached storeroom have controlled access. |
| <b>Staff</b>                  | All central laboratory samples are processed by the site study coordinators.                                                                                               |
| <b>Equipment</b>              | Refrigerator and -80°C freezers<br>Swing-bucket ambient/refrigerated centrifuge                                                                                            |
| <b>Temperature monitoring</b> | Available on <a href="#">SiteDocs</a> .                                                                                                                                    |
| <b>Temperature excursions</b> | Alarmed systems in the event of excursion.                                                                                                                                 |

|                     |                                                                              |
|---------------------|------------------------------------------------------------------------------|
| <b>Power outage</b> | Freezers have battery backup and the site has generator back up.             |
| <b>Calibration</b>  | Occurs annually with calibration documentation on <a href="#">SiteDocs</a> . |

## Study start-up

|                                          |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
|------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Start-up contact</b>                  | Rebecca Gurnett<br>Clinical Trials Manager<br><a href="mailto:rebecca.gurnett@gh.org.au">rebecca.gurnett@gh.org.au</a><br>03 5320 6478                                                                                                                                                                                                                                                                                                                                                                  |
| <b>Ethics and governance submissions</b> | Cancer Trials Australia (CTAus) coordinate the management of clinical trials at Grampians Health Ballarat, including administrative components of ethics and governance submissions, budget and contract negotiations, and financial invoicing of trial tasks.                                                                                                                                                                                                                                          |
| <b>Cancer Trials Australia contact</b>   | Katherine Wicking<br><a href="mailto:katherine.wicking@ct aust.org">katherine.wicking@ct aust.org</a><br>0459 142 898                                                                                                                                                                                                                                                                                                                                                                                   |
| <b>Project coordinator</b>               | Alexander Tynan<br><a href="mailto:alexander.tynan@ctaaust.org">alexander.tynan@ctaaust.org</a><br>0472 520 276                                                                                                                                                                                                                                                                                                                                                                                         |
| <b>Budgets</b>                           | Semiha Uyar<br><a href="mailto:semiha.uyar@ctaaust.org">semiha.uyar@ctaaust.org</a>                                                                                                                                                                                                                                                                                                                                                                                                                     |
| <b>Timelines</b>                         | <p>Time from lead ethics submission to approval depends on which NHMRC NMA certified HREC is chosen for submission.</p> <p>Post lead site approval governance submission to site-specific assessment authorisation is approximately six weeks.</p> <p>Amendments and delays of sponsor documents may impact the expected timelines. Ensure that all relevant documents are available and open communication with the site regarding potential amendments is maintained to avoid unnecessary delays.</p> |



### **Precinct implications**

Grampians Health Ballarat has a service agreement with Austin Health for the provision of radiotherapy services under the Ballarat Austin Radiation Oncology Centre partnership, and with Slade Health for the preparation and dispensing of investigational products administered by IV infusion. Where clinical trial activities occur across these institutions, they may need to be named on the CTN and schedule one of the clinical trial research agreements.

### **Ethics committee**

Grampians Health accepts submissions to any NHMRC accredited Ethics Committee, including Bellberry.

## **Submission documents**

### **Documents for lead site submission**

#### **Three weeks before ethics submission:**

- final protocol
- investigator brochures
- master PICFs in NHMRC template
- names of participating sites (for multi-site submissions).

#### **Within the three weeks to ethics submission:**

- patient related materials (e.g. participant cards, diaries, etc.)
- Medicines Australia/MTAA Standard form of Indemnity
- HREC Indemnity (multi-site submissions)
- certificate of insurance
- draft HREA
- draft Medicines Australia/MTAA CTRA
- draft CTN
- pharmacy and lab manual.

**Documents for participating  
site submission**

**Prior to RGO submission:**

- final protocol
- investigator brochures
- PI-signed Medicines Australia/MTAA CTRA
- Medicines Australia/MTAA standard form of indemnity
- certificate of insurance
- VSM
- HREC approval letter(s)
- HREC approved documents (including PICFs, HREA, participant materials, etc.).

**As soon as available:**

- lab manual
- pharmacy manual
- any other relevant documents.