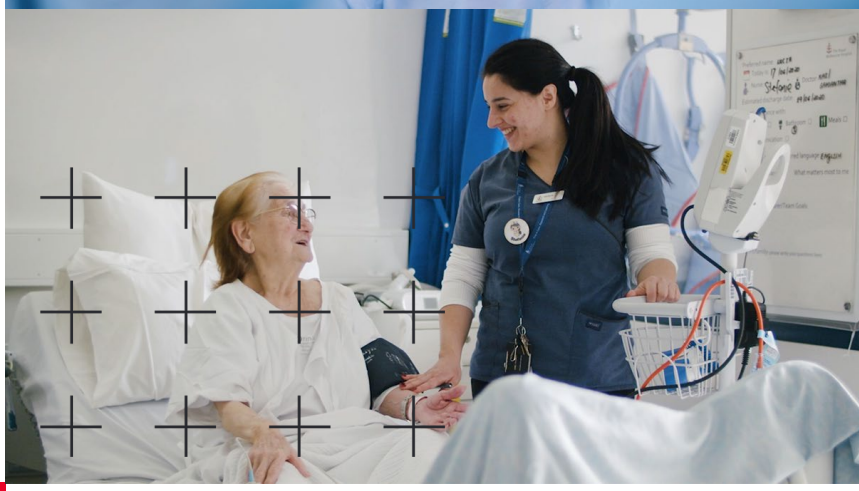
The Royal Melbourne Hospital



Advancing health for everyone, everyday.

Could this be you?

Join The Royal Melbourne Hospital Team

Position Description

Clinical Research Associate I/II

The Royal Melbourne Hospital

THE ROYAL MELBOURNE HOSPITAL

The Royal Melbourne Hospital (RMH) began in 1848 as Victoria's first public hospital. And while we only had 10 beds to our name, we had the community of Melbourne behind us, and we were ready to provide the best possible care for those in need.

Since those early years, we've moved forward with purpose. Always at the forefront, leading the way on improving the quality of life for all.

Today the RMH is one of the largest health providers in the state, providing a comprehensive range of specialist medical, surgical, and mental health services; as well as rehabilitation, aged care, outpatient and community programs.

Our reputation for caring for all Melburnians is as essential to who we are as any scientific breakthrough we make. We're here when it matters most, and we'll continue to be the first to speak out for our diverse community's wellbeing.

OUR VISION

Advancing health for everyone, every day.

THE MELBOURNE WAY

At The RMH we're inspired by our vision of Advancing health for everyone, every day. While we're each going about our different roles, we're united by a shared understanding of the way we do things around here. We call it The Melbourne Way. We put people first — leading with kindness and working together, we excel as one Royal Melbourne Hospital.

People First

People are at the heart of everything we do. We take the time to understand how we can make the most positive difference for them.

Lead with Kindness

Our care and compassion sets us apart. We lead the way with a respectful, inclusive spirit — embracing the things that make us all unique.

Excellence Together

True excellence is only possible when we work as one Royal Melbourne Hospital community. Through collaboration, we set the highest of standards and achieve our goals.

OUR PRIORITIES

The RMH Strategic Plan: Towards 2025. Advancing health for everyone, every day is our plan for the future — one which we are committed to achieving together. This position contributes to the achievement of the five Strategic Goals, articulated in the plan:

- Be a great place to work and a great place to receive care
- Grow our Home First approach
- Realise the potential of the Melbourne Biomedical Precinct
- Become a digital health service
- Strive for sustainability

The Royal Melbourne Hospital

Position Description

Position Title:	Clinical Research Associate I/II
Service:	Research
Location:	The RMH Parkville
Reports To:	Manager, Sponsor Office
Enterprise Agreement:	Victorian Public Health Sector (Health and Allied Services, Managers and Administrative Workers) Single Interest Enterprise Agreement 2025-2027
Classification:	HS4 + margin
Employment Status:	Ongoing Part Time
Immunisation Risk Category:	Category C
Date of Review:	July 2026

POSITION SUMMARY

The Clinical Research Associate Level I/II (CRA I/II) is a critical compliance and sponsor monitoring role. The CRA I/II will work under the oversight of the RMH Sponsor Office Manager (SOM) to conduct all forms of sponsor monitoring as required by ICH GCP Revision 3. This includes assisting with site feasibility and selection, start-up, initiation, interim and close out monitoring visits as well as assisting the SOM in all aspects of risk-based sponsor oversight as required by Melbourne Health as Sponsor. The CRA I/II will also be a source of knowledge and experienced advice to assist study teams at RMH with GCP compliance and sponsor obligations.

The level of appointment (CRA I or CRA II) will be determined based on the candidate's qualifications, experience, demonstrated monitoring competency and ability to independently perform sponsor oversight activities. CRA II staff are expected to perform monitoring activities autonomously, provide mentorship and technical guidance to less experienced members of the research workforce.

The CRA I/II will work across a variety of protocols, sites, and therapeutic areas, ensuring the integrity and quality of clinical research data. Based in the RMH Office for Research Sponsor Office, the CRA I/II will assist the SOM to provide monitoring for Melbourne Health sponsored studies in accordance with the obligations of the Therapeutic Goods Administration (TGA) and the global regulatory framework governing the Australian clinical research sector. The CRA I/II may also provide services to Precinct Partners and small to medium commercial entities.

The CRA I/II is expected to travel (minimal) for the role with 60% of their time on-site at RMH or study sites and 40% of their time in a flexible arrangement.

KEY ACCOUNTABILITIES

- Sponsor monitoring including all aspects of monitoring (Site Initiation Visits, Interim Monitoring Visits, Close Out Visits, database lock and study closure (unblinded or blinded) whether on-site or remote.
- Ensure clinical research studies are conducted in accordance with the approved study essential documents, regulatory and legal frameworks and applicable site Standard Operating Procedures.
- Ensure the captured research data are accurate, complete, verifiable and attributable as source.
- Ensure the rights and wellbeing of research participants are protected.
- Provide clinical operations support and advice to investigators, study teams and RMH supporting departments.
- Assist with the establishment and maintenance of Trial Master File (including joint ISF/TMF) essential documentation.
- Assist study teams to comply with regulatory obligations where MH acts in the capacity of sponsor.
- Assist and provide advice to investigators and research teams on RMH and OfR processes to expedite start up.
- Assist and enable study feasibilities, site selection and qualification on behalf of RMH investigators as per current ICH-GCP.
- Build relationships with study Principal Investigators, study coordinators and site supporting departments.
- Support with site set up, including assistance in preparation of HREC and RGO and governance submission, preparation of regulatory doc packages, and essential document collection and management.
- Assisting with feasibility assessments, investigator identification and site selection activities.
- Monitoring study progress, recruitment, enrolment, data quality, query resolution and site performance.
- Managing the process of Serious Adverse Events (SAEs) and supporting safety reporting activities.
- Delivering protocol and study-specific training to site personnel and providing ongoing site support throughout the study lifecycle.
- Apply a risk lens to sponsor monitoring activities and be active in continuous improvement activities and risk identification, evaluation and mitigation.
- Assist and work with all other OfR functional areas as needed to support our strong team culture and allow the OfR to excel in all aspects of business operations.
- Site Management commensurate with experience of the individual.
- Collaborating with cross-functional project teams to support study execution, documentation and operational deliverables.
- Create a psychologically safe work environment where everyone feels safe to speak up. Monitor and achieve relevant KPIs and targets and operate within their allocated budget.
- Take reasonable care for your safety and wellbeing and that of others.
- Work collaboratively with colleagues across all RMH teams.
- Continue to learn through mandatory training and other learning activities.
- Seek feedback on your work including participation in annual performance discussion.
- Speak up for safety, our values and wellbeing.
- Prioritise wellbeing and ensure safe work practices are developed and adhered to in their area.
- Respect that the RMH is a smoke-free environment.

KEY RELATIONSHIPS

Internal

- Chief Research & Innovation Officer
- Director Office for Research
- Office for Research Functional Area Managers
- RMH Investigators, study teams and RMH Service Departments

External

- Parkville Local Health Service Network and Precinct Partners
- Universities and Medical Research Institutes
- Collaborator Sites
- Commercial Clients

KEY SELECTION CRITERIA

Formal Qualifications:

- Degree in a Health-Related, Life Sciences, Biomedicine, Pharmacy, Nursing or related technical discipline.

Essential:

- Minimum 2 years' experience as a CRA, Study Coordinator or equivalent for a CRO, pharmaceutical/Biotech/Medtech company or academic research organisation conducting sponsored trials.
- Monitoring skills ranging from Phase 1 to Phase 4 and Investigator-Initiated Trials.
- Experience in Clinical Operations, Start-Up, Study Coordination or Study Project Management.
- Practical working knowledge of the National Statement, ISO 14155, ICH-GCP both Revision 2 and 3, regulatory compliance in clinical research and safety/pharmacovigilance regulatory reporting. GCP certificate history preferred.
- Ability to interpret protocols and essential documents to assess risk for monitoring purposes.
- Excellent communication skills (written and verbal) with ability to present information clearly and effectively while being highly organised.
- Ability to work independently and as part of a cohesive team, self-manage, good time management and prioritisation skills with ability to escalate issue where warranted commensurate with expertise.
- Proactively identify, investigate and problem solve.
- Detail-oriented with a solid understanding of clinical trial procedures and regulatory guidelines.
- Applied regulatory and operational knowledge of Trial Master File and Investigator Site Files.
- Available to travel within Victoria and interstate.
- Ability to work and display expertise within a project team.
- Track record of working efficiently and effectively in a matrix environment.
- Ability to build good rapport, effective, positive and respectful relationships with personnel at all levels.
- Valid Driver's License for Victoria.
- Commitment to live the Melbourne Way - putting people first, leading with kindness and achieving excellence together.
- Mandatory Working with Children's Check and Police Check and Immunisation Assessment.

Desirable:

- Honours or further tertiary education preferred but not mandatory.
- Understand the role of clinical research in product development and clinical translation and be familiar with various study designs
- Good understanding of the NHMRC Statement on Ethical Conduct of Human Research including data governance and integrity
- Knowledge and understanding of audits and regulatory inspections and awareness of the sponsor requirements under the National Clinical Trials Governance Framework.
- General understanding of basic privacy principles as they apply to clinical research

KEY PERFORMANCE INDICATORS

Your performance will be measured through your successful:

- Scheduling and tracking of all allocated projects as per approved monitoring plans.
- Monitoring tasks including visit preparation and conduct, report writing, query resolution, SAE review and escalation conducted in accordance with approved procedures.
- Excellent rapport with Office for Research, study teams and Principal Investigators.
- Contemporaneous data entry into relative databases.
- Delivery of tasks within the expectations of the Sponsor Office Manager and Melbourne Health as Sponsor.
- Excellent working knowledge of GCP Revision 3 and provision of R3 advice to study teams.
- Participation in and satisfactory feedback through the annual performance review process and mandatory training requirements.
- Ability to maintain a safe working environment and ensure compliance with legislative requirements.

AT THE RMH WE:

- Aim to provide a working environment that is safe and without risk to the health, safety and wellbeing of all employees, patients and consumers, and visitors.
- Speak up for patient, consumer, colleague and visitor safety, escalating issues if required.
- Deliver Safe, Timely, Equitable, Person-centred Care (STEP) in line with our clinical governance framework.
- Work in accordance with relevant policies, procedures, standards and legislation including those related to clinical or competency requirements, risk management, discrimination, equal opportunity and health safety and wellbeing.

OUR COMMITMENT:

- **Equity, Inclusion, Belonging and Safety**
  - As a leader in healthcare, we recognise the need to foster a culture of equity, inclusion, and belonging — safe spaces where every individual is empowered to be their authentic self, contributing meaningfully to the collective well-being of our community.
- **First Nations Commitment**
  - We acknowledge and pay our respects to the Traditional Owners of the lands on which we work and stand in solidarity with Aboriginal and Torres Strait Islander peoples. We are committed to creating a culturally safe environment that honours First Nations voices, knowledge, and self-determination through inclusive governance, respectful policies, and a steadfast commitment to anti-racism. The Royal Melbourne aspires to lead by example in addressing the injustices of colonisation and its ongoing impacts.
- **Child Safe Standards**
  - RMH is a child safe organisation. We are dedicated to fostering an environment that respects and upholds the rights of children and young people, in line with the Child Safe Standards. We actively embed these standards in our culture, policies, and practices, ensuring that the safety and wellbeing of children and young people is a central priority.
- **Equal Opportunity and Accessibility**
  - We are proud to be an equal opportunity employer that champions diversity in all its forms. We value the strengths and perspectives that come from people of all backgrounds, identities, abilities, and lived experiences. We encourage applicants from all communities, and we will provide reasonable adjustments to support equitable participation.
- **Thriving Together**
  - Together, we are committed to fostering an environment where everyone feels respected, safe, and empowered to thrive.

ACCEPTANCE

I acknowledge and accept that this position description represents the duties, responsibilities and accountabilities that are expected of me in my employment in the position. I understand that The RMH reserves the right to modify position descriptions as required, however I will be consulted when this occurs.

Employee Signature

Employee Name (please print)

Date