Position Title: Clinical Trial Coordinator

Campus: Ballarat

Directorate: Chief Medical Office

Department: **Clinical Trials Unit**

Reporting to:

- **Direct:** Manager Clinical Trials
- **Indirect:** Senior Clinical Trial Coordinator

Appointment Terms/Conditions:

- **Classification and Code:** QRED1/ Health Information Manager Grade 2 Year 1: JA7
- **Enterprise Agreement:** Nurses and Midwives (VPS) (Single Interest Employers) Enterprise Agreement/ Allied Health Professionals (Victorian Public Sector) (Single Interest Employers) Enterprise Agreement

ORGANISATIONAL INFORMATION

Grampians Health was established on 1 November 2021, bringing together Edenhope and District Memorial Hospital, Stawell Regional Health, Wimmera Health Care Group and Ballarat Health Services as one united health service. More information can be found at www.grampianshealth.org.au

Our purpose is to provide high quality and accessible health care services in each of the communities we serve. We currently service the healthcare needs of more than 250,000 Victorians and we employ more than 6,300 people across 21 campuses and sites with an annual operating revenue of over $700m.

Collaboration *We are stronger together.*	***Compassion*** *We show that we care.*	***Accountability*** *We do what we say and say what we do.*	***Respect*** *We appreciate and value all people.*	***Innovation*** *We adapt and innovate to achieve best outcomes.*
Recognising and utilising strengths to share knowledge, solve problems, build relationships and deliver the best outcomes possible.	All people deserve to be treated with compassion, kindness and empathy.	Openness, honesty and transparency support us to be courageous, take responsibility for our actions and follow through on our commitments	Our actions and words reflect our commitment to a safe and fair health service for all.	Every day, we apply expertise and integrity to make responsible choices, always striving for continuous improvement.

POSITION PURPOSE

This role is responsible for the coordination of clinical trials growth inclusive of oncology and non-oncology trials. As a member of the research team, the Study Coordinator will have responsibility for, the delivery of direct and indirect care, associated data collection for concurrent research studies undertaken in the Clinical Trials Unit.

These trials are run in accordance with the: Therapeutic Goods Administration (TGA), Note for guidance on Good Clinical Practice (CPMP/I CH/135/95) and the National Health and Medical Research Council (NHMRC) National statement on ethical conduct in research involving humans and other relevant guidelines and legislation.

The Study coordinator will ensure the highest standard of care is delivered to research participants and, where relevant, their families, in partnership with all members of the multidisciplinary and research team.

KEY ACCOUNTABILITIES

Patient screening and registration

• Ensures that for all potentially eligible patients who are identified for clinical trials, informed consent is obtained where appropriate and according to GCP.

• Ensures that all consenting patients are screened for eligibility as per the protocol and are registered /randomised as required.

• In an effort to meet planned target accruals:
    o Liaises with clinicians and other health professionals to assist in the identification of eligible patients.
    o Ensure that the relevant departments/staff are aware of upcoming/current trials by the appropriate dissemination of information.

Clinical Trial Coordination

• Ensures that the clinical trial is coordinated as per protocol and as per the ICH guidelines for good clinical practice.

• Protects patient safety by ensuring that all trial related investigations, procedures and treatments are performed by the appropriately trained and experienced staff and as per the trial protocol.

• Ensures the protocol/project requirements are met and maintains the interest and support of participants and other colleagues.

Data Collection and Entry – Case Record Forms

• Ensures all relevant data is collected and case record forms are completed according to individual protocol/project requirements and GCP guidelines, thus enabling the objectives of the individual projects to be achieved.

• Ensures that all protocol data collection requirements are met, case record forms are completed accurately and filed or dispatched securely.
• Obtains data and completes data collection forms by liaising with clinicians and other health professionals, reviewing patient medical records, using other patient information systems and interviewing patients where appropriate.

• Ensures that all Data collected can be verified to source as per GCP.

• Attends outpatient clinics to obtain patient data.

• Develops competence in accessing data through the hospital computer information systems.

• Maintains up-to-date data by developing systems for following up relevant patients in a timely manner.

• Maintains integrity of information in the case record forms by identifying missing data, taking steps to collect the data, checking the consistency and accuracy of data and making appropriate corrections.

• Sends case record forms to sponsors/coordinating bodies in a timely fashion.

• Ensures that data entry is completed in a timely and accurate fashion to enable project deadlines to be met.

Professional Development and Education

• Demonstrates a commitment to personal continuing professional development and participates in performance appraisal and review.

• Undertakes additional training to acquire the knowledge and skills needed to implement new study protocols from a variety of clinical specialties.

• In conjunction with Manager, identify areas that require additional knowledge and work towards meeting the learning objectives set.

• Maintains mandatory training requirements as defined by hospital policy. To function as an integral member of the Clinical Trials team.

• Develops and participates in appropriate quality activities

• Participates in team and unit meetings

• Takes responsibility for ensuring trial participants are seen and that protocol requirements are carried out according to protocol and without incident.

KEY SELECTION CRITERIA

ESSENTIAL

- Relevant tertiary qualification in Science, Health Information Management, Clinical Trial Management or a related paramedical field
- Understanding of medical terminology.
- Demonstrated excellent written and oral communication and interpersonal skills.
- Personal confidence and initiative required to deal with people from diverse backgrounds and experiences.
- Excellent organisational and time-management skills.
- Attention to detail.

- High motivation, willingness to learn and contribute to the team
- Consults widely and considers the opinions and perspectives of others before making a decision.
- Commitment to excellence in patient management, organisation and communication.
- Sound knowledge and demonstrated experience using Microsoft Office software including Word, Access, Excel and Outlook.
- Demonstrated awareness and understanding of the principles of Good Clinical Practice (GCP) guidelines and ethics guidelines

DESIRABLE

- Understanding of the key concepts relating to Clinical Trials
- Minimum of 3 months clinical trial experience and/or completion of the SKILLED study coordinator or clinical trial assistant internship program

ORGANISATIONAL REQUIREMENTS

- Grampians Health is committed to a consumer centred approach in the provision of health care and services, consistent with our values, purpose and vision. It is expected that team members demonstrate the core values of consumer centred care in every interaction.
- All team members of Grampians Health are responsible for supporting the safety, participation, wellbeing and empowerment of children.
- Quality care is a strategic and operational priority at Grampians Health, achieved through our Governance Framework.
- Participation in the Grampians Health integrated quality improvement and risk management systems by being aware of responsibilities to identify, minimise and manage risks and identifying opportunities for continuous improvement in your workplace through communication and consultation with managers and colleague.
- You must ensure that the affairs of Grampians Health, its patients, clients and staff remain strictly confidential and are not divulged to any third party except where required for clinical reasons or by law. Such confidentiality shall extend to the commercial and financial interests and activities of Grampians Health.
- All team members must adhere to infection control policies and procedures, together with any State and/or Commonwealth Government Covid19 rules, protocols and orders.
- In accordance with current legislation and organisational policy, employees must be willing to undertake and maintain a police check, working with children check and where necessary an NDIS Worker screening check. Ongoing employment will be dependent on the provision of satisfactory checks.

OTHER RELEVANT INFORMATION

- At Grampians Health we recognise and respect diversity. Each person has a right to high-quality health care and opportunities regardless of diversity factors which might include aspects such as cultural, ethnic, linguistic, religious background, gender, sexual orientation, age, and

socioeconomic status. Inclusiveness improves our service to our community and promotes engagement amongst Grampians Health employees.

- All Grampians Health employees are required to take reasonable care of their own health and safety in the workplace as well as take reasonable care for the health and safety of others who may be affected their acts or omissions. Persons with delegated management functions have an additional duty to provide and maintain a working environment that is safe and free of risks to health, so far as is reasonably practicable in areas where they have management or control. All employees have a duty to report issues they cannot rectify, follow all existing Grampians Health policies and protocols relating to health, safety, wellbeing and injury management and cooperate with any action taken by Grampians Health to comply with the OHS Act or Regulations.
- Statements included in this Position Description are intended to reflect in general the duties and responsibilities of this position and are not to be interpreted as being all inclusive.
- Management may alter this Position Description if and when the need arises. Any such changes will be made in consultation with the affected employee(s).
- An annual performance review will occur with your Manager. Your performance review is intended to be a positive discussion, outlining the key roles and responsibilities outlined in this Position Description. The performance review discussion provides an opportunity to clarify your role, revise key performance activities and identify any objectives or goals for the year ahead.