Government of Western Australia
North Metropolitan Health Service

North Metropolitan Health Service
Job Description Form

HSS Registered January 2019

Clinical Trials Manager

Health Salaried Officers Agreement: Level G-8

Position Number: 008228

Medical Oncology Clinical Trials Unit / Medical Specialties Division

Sir Charles Gairdner Hospital

Reporting Relationships

Medical Co-Director, Medical Specialties Division
Position Number: 007331

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Head of Department, Medical Oncology
Position Number: 002104

⬅ Also reporting to this supervisor:

- Consultant medical Oncologists -5.0 FTE
- Registrars – 7.0 FTE
- RMOs – 3.0 FTE

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This Position

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Directly reporting to this position:

Title	Classification	FTE
Clinical Research Coordinator	HSO G7	1.0
Research Data Manager	HSO G5	7.0

Other positions under control

- Contracted clinical research staff
- Contracted clinical trials business officer

Prime Function / Key Responsibilities

Manages the physical, financial and human resources of the Medical Oncology Clinical Trials Unit. Responsible for the delivery and management of direct and indirect patient care and associated data collection for clinical research studies undertaken in the Unit, in accordance with the Therapeutic Goods Administration (TGA) Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95) and the National Health and Medical Research Council (NHMRC) National Statement on Ethical Conduct in Research Involving Humans. Ensures GCP-compliant operation of the Unit, trial selection, data collection and protocol submissions. Ensures the highest standard of care is delivered to clinical trial participants.

Develops and maintains effective working relationships with internal and external stakeholders including clinical trial sponsors, contract research organisations, clinicians, Human Research Ethics Committees (HRECs), the NHMRC Clinical Trials Centre and National/International Clinical Trial Groups. Responsible for contract negotiations, protocol budgets and Clinical Trials Unit cost centres.

Brief Summary of Duties

1. Leadership and Management

1.1 Responsible for the operational management of all staff within the Clinical Trials Unit.

1.2 Develops and implements budgeting processes and reporting systems for the Clinical Trials Unit. Prepares financial reports including monthly management reports, periodic budget and performance reports and Annual Financial Statements. Manages the invoicing system for the Unit.

1.3 Leads the development and execution of clinical trials contracts; manages the negotiation and consultative processes with Sponsors and internal and off-site service suppliers.

1.4 Oversees and ensures the appropriate training and development of all members of trials staff, including the Principal Investigator, Sub-Investigator, Research staff and other clinical and non-clinical support departments.

1.5 Undertakes recruitment and selection processes for staff of the Clinical Trials Unit.

2. Research Management

2.1 Conducts and manages clinical research in accordance with TGA, International Conference on Harmonisation (ICH) GCP, the NHMRC National Statement on Ethical Conduct in Research Involving Humans, HRECs and any other statutory and regulatory requirements and local institutional/hospital policies and procedures.

2.2 With the Head of Department, develops and executes a strategy for clinical research within the Medical Oncology department.

2.3 Leads the development, initiation, implementation and monitoring of new clinical research protocols.

3. Communication and Stakeholder Management

3.1 Develops and maintains effective relationships with internal and external stakeholders, including multidisciplinary clinical teams, clinical trial sponsors, contract research organisations, the NHMRC Clinical Trials Centre, and National and International Academic clinical trial groups.

3.2 Raises the profile of the clinical research program among health professionals, patients and the public.

3.3 Ensures sound internal and external networks and negotiates, consults and manages relationships with sponsors and other key stakeholders.

3.4 Promotes the Unit's reputation with industry partners to ensure the long-term viability and success of the Unit.

3.5 Responds and deals with queries from relevant regulatory bodies to work towards successful and timely initiation of clinical trials.

3.6 Represents the Sir Charles Gairdner Hospital at interstate and international investigator meetings.

3.7 Communicates and liaises with research participants and their relatives regarding specific studies and the inclusion and exclusion criteria.

4. Clinical Research Management

4.1 Works within and monitors standards of care for participants in research studies. Develops policies and procedures to ensure adherence to and delivery of a high quality, safe and timely service.

4.2 Proposes and develops working practices/innovative processes within clinical research areas and oversees their implementation.

4.3 Manages and coordinates the development of all clinical trial documentation prior to submission to the relevant Regulatory bodies; HRECs, Research Governance Office (RGO) Clinical Drug Trials Committee (CDTC) and Scientific Review Sub-Committee (SRS).

4.4 Liaises, negotiates and organises with internal and external stakeholders clinical trial service requirements to ensure compliance to the clinical trial protocol.

4.5 Coordinates and participates in internal and external clinical trial monitoring/auditing activities.

4.6 Actively supports and contributes to accreditation and Quality Improvement activities for the Clinical Trials Unit.

5. NMHS Governance, Safety and Quality Requirements

5.1 Ensures, as far as practicable, the provision of a safe work environment in consultation with staff under their supervision.

5.2 Participates in an annual performance development review and undertakes performance development review of staff under their supervision.

5.3 Supports the delivery of safe patient care and the consumers' experience including identifying, facilitating and participating in continuous safety and quality improvement activities, and ensuring services and practices align with the requirements of the National Safety and Quality Health Service Standards and other recognised health standards.

5.4 Completes mandatory training (including safety and quality training) as relevant to role.

5.5 Performs duties in accordance with Government, WA Health, North Metropolitan Health Service and Departmental / Program specific policies and procedures.

5.6 Abides by the WA Health Code of Conduct, Occupational Safety and Health legislation, the Disability Services Act and the Equal Opportunity Act.

6. Undertakes other duties as directed.

Work Related Requirements

Essential Selection Criteria

1. Bachelor's degree in a Health Science or related field.
2. Evidence of further education including postgraduate study and/or continuous professional development in clinical research.
3. Extensive relevant experience in clinical research at a senior level demonstrating the appropriate competencies and skills for the job and clinical setting.
4. Demonstrated knowledge of local Human Research Ethics Committee and Research Governance Office requirements for clinical research and other statutory and regulatory requirements including comprehensive understanding of International Conference of Harmonisation - Good Clinical Practice guidelines and other relevant National/International codes of conduct for clinical research.
5. Demonstrated practical experience in initiation and execution of sponsored, collaborative and investigator initiated clinical research studies including management of clinical trial budgets and finances.
6. Demonstrated ability to lead and work as a part of complex multidisciplinary team structures and effectively communicate, consult, negotiate, influence, develop and maintain effective working relationships with key internal and external stakeholders.
7. Well-developed analytical and problem solving skills.
8. Proficient in the use of Microsoft Office software applications including Outlook, Word, Excel, and PowerPoint.
9. Current knowledge of legislative obligations for Equal Opportunity, Disability Services and Occupational Safety and Health, and how these impact on employment and service delivery.

Desirable Selection Criteria

1. Experience with development and submission of clinical trial protocols for competitive funding.
2. Participation in National Oncology Clinical Research Groups.

Appointment Prerequisites

Appointment is subject to:

- Completion of 100 Point Identification Check.
- Successful Criminal Record Screening Clearance.
- Successful Pre-Employment Integrity Check.
- Successful Pre-Employment Health Assessment.

Certification

The details contained in this document are an accurate statement of the duties, responsibilities and other requirements of the position.

Manager/Supervisor	Dept./Division Head	Position Occupant
Name:	Name:	Name:
Signature/HE:	Signature:	Signature:
Date:	Date:	Date: