# Clinical Trials Research Officer

## Position Details

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| Position Number: | CG002527 |
| Classification: | HSO Level G5 |
| Agreement: | Health Salaried Officers Agreement |
| Directorate: | Cancer, Imaging and Clinical Services Division |
| Department: | Medical Oncology Research Unit |
| Location: | Sir Charles Gairdner Hospital, North Metropolitan Health Service |

## Reporting Relationships

This position reports to:

| | | |
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| 008228 | Clinical Trials Manager | HSO Level G-8 |

Positions under direct supervision:

NIL

**Primary Purpose of the Role**

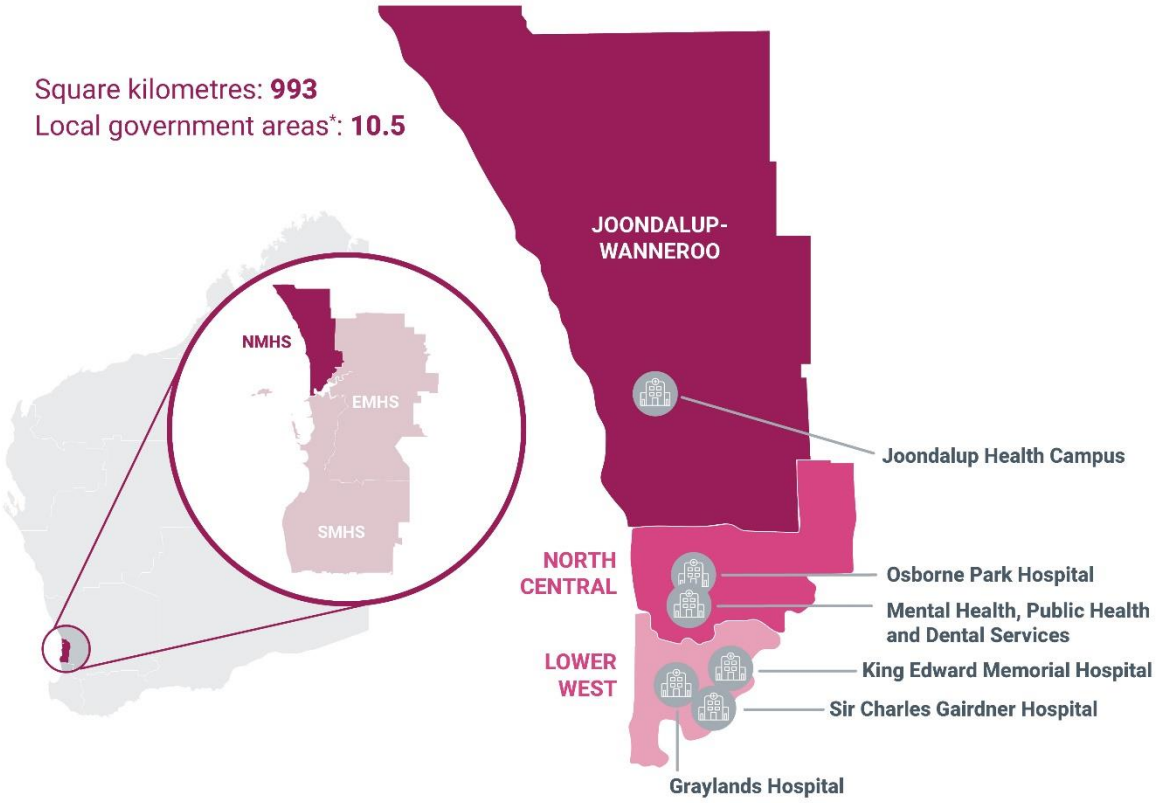
*The incumbent of this position will be responsible for the collation, analysis, reporting and quality of data from clinical trials and research activities, undertaken within the area of specialty in accordance with ICH-GCP (International Conference on Harmonisation – Good Clinical Practice) Guidelines. The incumbent will contribute to the promotion and evaluation of clinical trials and research programs, and undertake the collection, analysis and the generation of reports which contribute to submissions for consideration and review by internal and external stakeholders and committees.*

## Vision

A trusted partner, delivering excellent health care for our people and our communities.

## Mission

To promote and improve the health of our people and our communities.




## North Metropolitan Health Service

Since our establishment in 2016, NMHS has embraced best practice to deliver improved clinical outcomes in the face of rising challenges for all healthcare providers. With a budget of $2.16 billion and 8,917 full-time equivalent (FTE) staff, we serve a population of 736,907 people (about 28% of Western Australia's total population) within a catchment area of almost 1,000 square kilometres. The population we serve is projected to increase by 17% between 2021 and 2031, and the number aged 65 years and older will increase by 41% over the same period. NMHS provides a comprehensive range of adult specialist medical, surgical, mental health and obstetric services in WA, delivered across three tertiary hospitals and two secondary hospitals, all fully accredited. NMHS oversees the provision of contracted public health care from Joondalup Health Campus operated under a public–private partnership. A range of statewide, highly specialised multidisciplinary services is offered from several NMHS hospital and clinic sites.

## Our values

### Care
We show empathy, kindness and compassion to all.

### Respect
We are inclusive of others and treat everyone with courtesy and dignity.

### Innovation
We strive for excellence and are courageous when exploring possibilities for our future.

### Teamwork
We work together as one team in a spirit of trust and cooperation.

### Integrity
We are honest and accountable and deliver as promised.

Please refer to NMHS Values – Organisational/Individual Behaviours for information on individual behaviours that reflect the organisation's values.

## Our strategic priorities

We are focussing on six strategic priorities for the 2020-2025 period:

**Enabling healthy communities**
We build healthy and engaged communities

**People-centred care**
We will place our consumers' and their carers' best interests and experience at the core of all we do

**Integration and connection**
We will build strong connections and partnerships

**Innovation and adaptive models of care**
We will use research and technology to improve outcomes

**Trusted, engaged and capable people**
We will invest in our people and our culture

**Sustainable and reliable**
We will reduce harm, waste and unwarranted variation

## Key Accountabilities

### 1. Research data activities

1.1 Responsible for the collation, analysis, reporting and quality of data from clinical trials and research activities undertaken within the area of specialty in accordance with ICH-GCP (International Conference on Harmonisation – Good Clinical Practice) Guidelines.
1.2 Assists with the daily supervision and management of clinical trial and research clerical staff, including assessing workload, performance management, recruitment and ongoing development.
1.3 Liaises with, and provides advice and guidance to members of the multidisciplinary team, internal and external stakeholders in regards to data collection and analysis of information obtained and provided during clinical trials and research activities.
1.4 Undertakes analysis and submits reports in relation to budget for staff FTE under supervision of the Clinical Trials Manager in the area of speciality.
1.5 Assist medical staff in explaining to patients and their carers the nature of the study, the aims, and aspects of treatment involved, side effects and the requirements for follow up.
1.6 Ensure patient eligibility for clinical trials, ensure the patient's understanding of the protocol is adequate and ensure that the necessary registration forms have been completed.
1.7 Undertakes analysis and prepares reports regarding clinical trials and research finding data for use in the creation of abstracts, papers and journal articles for publication, seminars and conference presentations by members of the multidisciplinary team in the area of speciality as required.
1.8 Undertakes the analysis and prepares all necessary documentation for the more complex and new protocol submissions and amendments for the Ethics Committee, relevant sub-committees and Research Governance Office.
1.9 Designs and implements data collection forms/processes in consultation with other members of the multidisciplinary team.
1.10 Reports data management issues and problems identified in clinical trial and research activity data, protocol problems and violations without delay to the Clinical Trials Manager in the area of speciality.
1.11 Report serious adverse or unexpected adverse effects/toxicities without delay to relevant authorities
1.12 Ensures the confidentiality and security of patient information and data relative to clinical trials and research activities.
1.13 Ensures clinical trial/research staff is compliant with legislation, policies and protocols regarding records and information management within the area of speciality for clinical trials and research activities.
1.14 Assists in the preparation of staff rosters and managing clerical relief to ensure an effective and efficient clerical service is provided at all times.
1.15 Attend meetings both locally, nationally, and internationally when requested

### 2. Education and Development

2.1 Supports the delivery of training and education and development programs to ensure the multidisciplinary team has awareness and knowledge of the clinical trials undertaken, the overarching clinical trial protocols and processes, contemporary research methodologies and procedural changes in Human Research Ethics committees both locally and nationally.
2.2 Assists in the planning and delivery of training and development of all clerical staff in the area of speciality to enable the provision of high quality and effective clerical and information services.
2.3 Maintains a good working knowledge of the area of speciality, clinical trials and research activities conducted by the multidisciplinary team.

**3. Quality Performance and Innovation**

3.1 Participates in a continuous process to monitor, evaluate and develop service and performance.

3.2 Reviews and analyses clerical work practices including recommending and implementing new procedures and is responsible for quality assurance projects in the area of speciality.

**4. Departmental operation support**

4.1 Assist the Clinical Trials Manager to monitor and maintain budget and accounts. Support with preparation and payment of invoices and trial related payments between the department, Health Support Services (HSS) and clinical trial sponsors.

**5. Communication**

5.1 Maintains open and collaborative communication and support to the multidisciplinary team involved in clinical trials and research programs, patient care and service delivery in relation to an area of speciality.

5.2 Participates in research and multidisciplinary team meetings and represents the area of speciality at other meetings and committees as appropriate.

**6. NMHS Values: *Care, Respect, Innovation, Teamwork, Integrity***

6.1 Reflect the NMHS values in the way you work, behave and make decisions.

**7. NMHS Governance, Safety and Quality Requirements**

7.1 Participates in the maintenance of a safe work environment.

7.2 Participates in an annual performance development review.

7.3 Supports the delivery of safe patient care and the consumers' experience including participation in continuous quality improvement activities in accordance with the requirements of the National Safety and Quality Health Service Standards and other recognised health standards.

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

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

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

**8. Undertakes other duties as directed**.

## Work Related Requirements

The following criteria should be considered in the context of the NMHS Vision, Mission and Values.

**Essential Selection Criteria**

1. Demonstrated experience in the management of data, spreadsheet development and large relational databases to compile qualitative and quantitative information in a complex environment.
2. Demonstrated analytical and problem solving skills, with knowledge of hospital information systems relevant to clinical data collection, tracking and reporting.
3. Well-developed interpersonal and communication skills (written and verbal) including report writing skills.
4. Ability to work as a member of a research team.
5. Ability to supervise staff and prioritise workloads to meet deadlines.
6. Knowledge of quality improvement principles.
7. 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. Relevant degree, post graduate qualifications or progression towards relevant degree or diploma.
2. Demonstrated knowledge of research methodology and ethical considerations in the conduct of research.

**Appointment Prerequisites**

Appointment is subject to:

- Provision of the minimum identity proofing requirements.
- 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: Edwin Tan | Name: | Name: |
| Signature/HE: HE44375 | Signature: | Signature: |
| Date: 24 January 2022 | Date: | Date: |