



# NORTHEAST HEALTH WANGARATTA

## Clinical Trial Research Support Service

In 2019, through the support of Department of Health & Human Services (DHHS), the Clinical Trial Research Support Service (CTRSS) was established at Northeast Health Wangaratta (NHW). The CTRSS is located in the Margaret Boyd Education Centre at NHW.

2022 saw the extension of the CTRSS program with Department of Jobs, Precincts & Regions (DJPR) and the establishment of the CTRSS Australian Teletrial Program (CTRSS-ATP). With support from the Medical Research Future Fund (MRFF) via Queensland Health, our aim is to improve and increase the delivery of clinical trials and teletrials to rural, regional and remote areas of Victoria.

### **NHW CTRSS Profile**

02 March 2023

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# NHW CTRSS BACKGROUND

## NHW CTRSS PROVIDES

Highly respected Investigators with expertise and experience in:

- The conduct of clinical trials
- Cohort studies, registries, quality improvement research, and translational research
- Contributors to biomarker development research
- Collaborations with National & International Investigators
- Novel clinical trial design including teletrials

Multi-disciplinary research teams:

- Based on therapeutic area
- Consisting of Research Nurses, Clinical Trial Coordinators, Clinical Trial Assistants, Clinical Trial Interns, Principal & Sub Investigators, Pharmacists, Allied Health and Nurse Practitioners
- Led by experienced senior staff members
- The team has over 25 years collective experience

SiteDocs Portal:

- Real time remote monitoring of unit core documents and study specific electronic investigator site file

## NHW CTRSS SERVICES

Centrally located within the Northeast region of Victoria, the following services can be provided:

- Pathology
- Pharmacy
- Imaging
- Intensive Care Unit
- Specialty clinics and outpatient services
- Central clinical trial management across multiple therapeutic areas

# NHW CONTACTS

**NHW DETAILS** Northeast Health Wangaratta  
Education & Research Unit  
Margaret Boyd Education Centre  
35-47 Green Street  
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**MANAGEMENT Executive Director**  
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**Operational Director**  
Jacqui Verdon  
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**Research Development & Governance Officer**  
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**CTRSS STAFF CTRSS-ATP Clinical Medical Officer**  
Dr Kay Xu  
[Kay.Xu@nhw.org.au](mailto:Kay.Xu@nhw.org.au)

**CTRSS-ATP Clinical Trial Coordinator**  
Nicole Humphreys  
03 5722 5521  
[clinical.trial@nhw.org.au](mailto:clinical.trial@nhw.org.au)

# NHW CONTACTS

**CTRSS STAFF**    **CTRSS-ATP Regional Study Start Up Specialist  
(NHW, Goulburn Valley Health, & La Trobe Regional Hospital)**

Jelena Dragovic  
03 5722 5756  
clinical.trial@nhw.org.au

**CTRSS Clinical Trial Assistant with Enhanced Duties**

Jacqueline Lake  
03 5277 5005  
clinical.trial@nhw.org.au

**DEPARTMENT**    **Allied Health**  
**LEADS**            Courtney Ward-Jackson

**Anaesthetics**  
Dr Jade Radnor  
Dr Anthony Baird

**Emergency Medicine**  
Dr Johann De Witt Oosthuizen

**General Surgery**  
Mr Peter Thomas

**Gerontology/Dementia Care**  
Dr Lakshmi Dhakal

**Infectious Diseases & Hospital in the Home**  
Dr David Turner

# NHW CONTACTS

**DEPARTMENT LEADS** Intensive Care Unit  
Prof David Tuxen

**Medical Oncology**  
Dr Kay Xu

**Orthopaedics**  
Mr Richard Kjar

**Paediatrics**  
Dr Terry Stubberfield

**Physician Training & Nephrology**  
Dr Annabel Martin

**PHARMACY** NHW Director Pharmacy  
David Ford  
03 5722 5160  
David.Ford@nhw.org.au

# EXPERIENCE & CAPABILITIES

## Therapeutic Areas

Anaesthesia, Gerontology & Dementia Care, Oncology, Stroke Management

## Trial Phase Capabilities

Phase I - IV, teletrials, registries & translational research

## Research Experience

Sponsored, Collaborative & Investigator Initiated

## Patient Population

Adult, Adolescent, Young & Paediatric

## Open & Recruiting Studies

2

## Active & Follow-Up Studies

4

## Audit History

No regulatory or sponsor initiated audits

## Potential Therapeutic Areas

- Allied Health
- Cardiology
- Emergency Medicine
- Gastroenterology
- Infectious Disease
- Intensive Care
- Nephrology
- Obstetrics & Gynaecology
- Orthopaedics
- Paediatric Medicine
- Palliative Care
- Surgery

# QUALIFICATIONS

## Unit Policies

Clinical trial and teletrial standard operating procedures (SOPs) are available on SiteDocs and NHW Website

## Staff Training

- TransCelerate accredited Good Clinical Practice (GCP) certification
- Civil Aviation Academy Australia Safe Transport of Infectious Substances certification
- Good Clinical Laboratory Practice training
- NHW CTRSS SOP and teletrial SOP training
- Certificates for relevant eCRF/trial platforms
- Participation in the Victorian Comprehensive Cancer Centre (VCCC) SKILLED Internship Program in 2021, 2022 & 2023. 2021 and 2022 Interns transitioned to NHW workforce post internship
- All certificates available on SiteDocs

## Specialist Clinical Trial Education & Training Program

- Role specific competency frameworks
- NHW Learning Management System
- Victorian Clinical Trial Education Centre (V-CTEC) online interactive training modules for specific roles including Principal Investigators
- Mentorship and supervision for VCCC SKILLED Interns
- Ongoing education opportunities including:
  - Clinical trial topics
  - Regulations and processes
  - Clinical, disease and drug specific topics
- Records available on request

## Curriculum Vitae (CV)

Staff CVs updated every 2 years and available on SiteDocs

## Practicing Certificates

Available on Australian Health Practitioner Regulation Authority (AHPRA) and SiteDocs

## Staffing

Study coordination facilitated centrally to resource all active departments across the organisation



# FACILITIES

## Type

- Regional Public Health Care Organisation
- Referral Health Service of approximately 90,000 people
- Annual admission rate of approximately 20,000 and 35,000 outpatient attendances
- 241 Acute Care beds
- 72 Residential Aged Care beds
- Multidisciplinary Outpatient Services
- Multiple Regional Health Service partnerships across the Northeast Region with teletrial capacity

## Hours

- 24/7 Emergency Department
- 24/7 Inpatient Care

## Affiliated Organisations

### University Partners

- University of Melbourne (on site)
- Rural Health Academic Network (RHAN)

### CTRSS-ATP Network

- Department Jobs, Precincts & Regions (DJPR)
- Barwon Health
- Bendigo Health
- Goulburn Valley Health
- Grampians Health
- La Trobe Regional Hospital
- Southwest Health

# INFORMED CONSENT

## Unit Policies

Refer to NHW CTRS-SOP-02 Informed Consent Process, and NHW TELERIAL-SOP-09 Participant Informed Consent Process and Documentation. Available on SiteDocs

## Language

- Refer to NHW CTRS-SOP-02 and NHW TELETRIAL-SOP-09 available on SiteDocs
- Participant Information and Consent Forms will be provided in English
- Interpreter service available using Victorian Telephone Interpreter Services as per NHW Policy

# MONITORING

## **Unit Policies**

Refer to NHW CTRS-SOP-14 Remote Monitoring. Available on SiteDocs

## **Onsite Monitoring**

Dedicated monitoring room

## **Onsite Facilities**

Access to SiteDocs, Medical Records, Printer and Photocopier

## **Bookings**

Onsite visits 4 weeks in advance

## **Remote Monitoring**

Provisions as per NHW CTRS-SOP-14

## **Co-monitoring & Multiple Days**

With approval from NHW CTRSS Staff

# DOCUMENTATION

## Unit Policies

- Refer to NHW CTRS-SOP-11 Essential Documentation Management, and NHW TELETRIAL-SOP-07 The Study Master File available on SiteDocs
- Source Data and Essential Document Location Form

## Unit Templates

- Investigator Site File (ISF) Table of Contents
- Study Master File Table of Contents
- Delegation Log
- Training Log
- CV templates
- Adverse Events Log
- Concomitant Medications Log

## ISF

- From September 2022 all records stored centrally in study specific electronic ISF (eISF) on SiteDocs
- Any original hardcopy documents will be stored in the Clinical Trial office until offsite archiving

## Clinical Trial Patient Records

Secured in Clinical Trial office with controlled access

## Patient Source Data Location

- Paper based Medical Records. Available for monitoring via Health Information Services
- Diagnostics (pathology, etc.) available electronically

## EDC Capabilities

Experience with Inform, Medidata Rave, Medrio, Marvin and REDCap. Certificates available on SiteDocs

## Archival Procedure

Refer to NHW CTRS-SOP-12 Archiving, and NHW TELETRIAL-SOP-13 Site Close-Out and Archiving available on SiteDocs

## Archival Facilities

Doc-U-Store  
10-16 Osboldstone Road  
Wanagaratta, VIC, 3677

# INVESTIGATIONAL PRODUCT (IP)

## IP Comments

- NHW can utilise the NHW Pharmacy for clinical trial IP management
- The NHW CTRSS can be contacted to arrange meetings with the NHW Pharmacy Department at site selection, site initiation, monitoring, and close out visits as required

## Infusion Capabilities

Yes

## IP Storage

Secure, controlled access IP storage

## IP Shipment

ATTN: David Ford  
NHW Pharmacy Department  
35-47 Green Street  
Wangaratta, VIC, 3677  
**P:** 03 5722 5160  
**F:** 03 5722 5107  
**E:** David.Ford@nhw.org.au

## Temperature Monitoring

- Room, refrigerator and freezer temperature monitored
- Records available on SiteDocs

## Temperature Excursions

Centralised, alarmed, continuous temperature monitoring and recording system

## Power Outage

Backup electrical supply for power outages according to system failure plan

## Blinded IP Procedure

Adequately experienced and staffed to perform blinded and unblinded IP monitoring

## IP Destruction

- Onsite destruction capacity
- Refer to NHW CTRS-SOP-13 Receipt, Storage, Dispensing, Destruction or Return of Investigational Product, and NHW TELETRIAL-SOP-11 Management of Investigational Product available on SiteDocs

# IP ADMINISTRATION

## Main Treatment Area

- Trial dependent
- Oncology Day Unit (9 chairs)
  - Day Stay Ward

## Complex & Early Phase

No dedicated treatment area (dependent on therapeutic area), however, there is capacity within organisation to accommodate

## Overnight Admissions

No dedicated overnight beds, however, there is capacity within the organisation to accommodate

## Emergency Equipment

All treatment areas have full emergency equipment available (including crash cart)

## ICU/CCU

If an event requires CCU admission, patients will be transferred to the CCU Department at NHW or transferred to a Metropolitan Hospital as per standard procedures and criteria

## CONTROLLED SUBSTANCES

<b>Facilities</b>	Can be managed at NHW
<b>Unit Policies</b>	Refer to NHW CTRS-SOP-13 Receipt, Storage, Dispensing, Destruction or Return of Investigational Product, and NHW TELETRIAL-SOP-11 Management of Investigational Product available on SiteDocs
<b>Radio Labelled IP</b>	No

## GENETICALLY MODIFIED ORGANISMS (GMOs)

<b>Facilities</b>	Not currently available at NHW
<b>Unit Policies</b>	N/A
<b>Requirements</b>	N/A

# DIAGNOSTIC SERVICES

## Services

NHW utilises multiple regional services for diagnostic capability to include

- Imaging: CT, MRI, X-RAY, Mammography
- Nuclear Medicine
- Ultrasound
- Angiography
- Image guided biopsy
- Cardiac: ECG, ECHO, Holter monitoring (available via Wangaratta Cardiology)
- PET Scan (available via I-Med Radiology Network, Albury NSW)

NHW can facilitate central review

## Contacts & Capabilities

### **NHW Manager Medical Imaging**

Hayden Sharp

03 5722 5001

Hayden.Sharp@nhw.org.au

### **Wangaratta Cardiology & Respiratory Centre**

03 5722 1162

admin@wrc.com.au

### **I-Med Radiology Network Albury**

02 6022 5200



# LOCAL PATHOLOGY

## Local Pathology Comments

- NHW provides a pathology service with an onsite Dorevitch Pathology Laboratory. Dorevitch also service the Northeast region with multiple collection centres
- Samples may be transported to Dorevitch's main laboratories in Melbourne for processing

## Address

Dorevitch Pathology  
Northeast Health Wangaratta  
35-47 Green Street  
Wangaratta, VIC, 3677  
dorevitch.com.au

## Accreditation

NATA and Medicare

## Reference Ranges

Available on SiteDocs

# CENTRAL PATHOLOGY

## Location

- Dedicated space in the Education & Research Unit
- Utilisation of equipment available through Dorevitch Pathology

## Hours

- Monday to Friday, 8am to 5pm
- Same day collection available
- Out of hours samples subject to prior arrangement and availability

## Kit Storage

Secured laboratory kit storage available in the Clinical Trial office with controlled access

## Staff

- NHW CTRSS Staff, per NHW CTRS-SOP-09 Handling and Shipping of Infectious Substances, and NHW TELETRIAL-SOP-10 Handling and Shipping Biological Substances (Cat B) and Dangerous Goods available on SiteDocs
- Staff certified in Handling and Shipping of Infectious Substances

## Equipment

- Refrigerator
- -30 and -80 freezers
- Ambient and refrigerated centrifuges
- Dry ice for shipping

## Temperature Monitoring

Available on SiteDocs

## Temperature Excursions

Alarmed systems in the event of excursion

## Power Outage

Department power outage and system failure plan in place

## Accreditation

Dorevitch Pathology is accredited with NATA

## Calibration

Equipment is calibrated as per NHW policy. Certificates available on SiteDocs

# STUDY START UP

## Start Up Contacts

### **Nicole Humphreys**

Clinical Trial Coordinator  
03 5722 5521  
clinical.trial@nhw.org.au

### **Jelena Dragovic**

Regional Teletrial Start Up Specialist  
03 5722 5756  
clinical.trial@nhw.org.au

### **Jacqueline Lake**

Clinical Trial Assistant with Enhanced Duties  
03 5722 5005  
clinical.trial@nhw.org.au

## Ethics & Governance submission

NHW CTRSS staff undertake the site management of trials including administrative components of Ethics & Governance submissions, budget and contract negotiations, and financial operations on behalf of the Principal Investigator

## Timelines

- Average start up timeline is 30 days from HREC approval to site initiation visit
- Phase I clinical trials, average timeline is 50 days from HREC approval to site initiation visit
- Average timelines for multi-site trials are dependent on the lead site. The current average is 90 days
- Timelines are impacted by amendments, delays of Sponsor documents, budget negotiations, and communication between Contract Research Organisation (CRO) and Global Sponsor. To avoid unnecessary delays ensure all relevant documents (listed under Submission Documents below) are made available in allocated timeframes and ensure open, timely communication with site about upcoming or potential amendments

# STUDY START UP

## Research Development & Governance

### Research Development & Governance Officer

Dr Rowan O'Hagan

03 5722 5149

[research@nhw.org.au](mailto:research@nhw.org.au)

- Governance review can be performed in parallel with HREC
- A Site Specific Application (SSA) will be completed online using Ethics Research Manager (ERM)

# ETHICS

<b>Name</b>	Northeast Health Wangaratta Human Research Ethics Committee (HREC)
<b>Address</b>	Northeast Health Wangaratta 35-47 Green Street (PO Box 386) Wangaratta, VIC, 3677
<b>Website</b>	<a href="https://www.northeasthealth.org.au/clinical-research/">https://www.northeasthealth.org.au/clinical-research/</a>
<b>Registration Body</b>	National Health and Medical Research Council (NHMRC)
<b>Registration Number</b>	EC00256
<b>Type</b>	Local
<b>Relevant Registration Categories</b>	<ul style="list-style-type: none"><li>• Clinical trial phase I, II, III, IV</li><li>• Clinical trial drugs and devices</li><li>• Adults and children</li></ul>
<b>Meeting Frequency</b>	Bi-monthly
<b>Other Review Boards</b>	Northeast Health Research Committee <ul style="list-style-type: none"><li>◦ Oversees the development and implementation of the Research Strategy for NHW</li><li>◦ Provide guidance and feedback to the Research Development &amp; Governance Officer (RDGO) and researchers on proposed and active research projects, research training, and governance at NHW</li><li>◦ Contribute to the development of research capability and capacity at NHW</li><li>◦ Promote the translation of research evidence into practice</li></ul>

# ETHICS

## Payment

- On receipt of an application or amendment, NHW will generate either a HREC or Research Governance fee (but not both) in accordance with the fee schedule
- NHW HREC will accept a single ethics review process as per NHW HREC Guideline/Procedure 3.3.2, thus only RGO review is required for multi-site submissions

## Safety Reporting Policy

As per NHMRC guidelines

## Approving Authority Name

**Northeast Health Wangaratta HREC**  
research@nhw.org.au

**NHW HREC Secretariat**  
Paula Nottle

**NHW HREC Chairperson**  
Dr Leo Fogarty

## ETHICS DEADLINES

Submission Date 2023	Meeting Date 2023 (2nd Tuesday)
24 January	07 February
28 March	11 April
30 May	13 June
25 July	08 August
26 September	10 October
28 November	12 December

# SUBMISSION DOCUMENTS

## Documents Required for Multi & Single Site Submission

Documents to be provided 3 weeks prior to ethics submission

- Final protocol
- Investigator Brochure (IB)
- Draft Participant Informed Consent Forms (PICFs) in NHMRC template

Documents to be provided within 3 weeks

- Patient related materials (i.e. dosing diary, patient cards, etc.)
- Standard indemnity
- Certificate of Insurance
- HREA and HREC approval for multi-site NMA
- Draft budget and CTRA
- CTN
- Pharmacy Manual
- Laboratory Manual
- Other manuals as required

## Documents Required for Participating Site RGO Submission

Mandated documents

- Final protocol
- IB
- Draft budget and CTRA

Documents to be provided as soon as available

- Indemnity
- Certificate of Insurance
- CTN
- HREC approval letter(s)
- HREC approved documentation (including transfer from Sponsor of HREA, VSM, etc.)
- Pharmacy Manual
- Laboratory Manual
- Other manuals as required