Townsville Hospital and Health Service (THHS)
Townsville Institute of Health Research and Innovation (TIHRI)
Terms of Reference

1. PURPOSE/OBJECTIVE

These Terms of Reference describe the processes for the operation of the Townsville Institute of Health Research and Innovation to ensure research conducted at the Townsville Institute of Health Research and Innovation is of a high standard and compliant with all relevant guidelines and legislation.

2. BACKGROUND

THHS works in partnership with researchers to deliver the highest quality research, including clinical trials.

The THHS Research Development Committee sets the research agenda for THHS, through the THHS Research Strategy and Research Operational plans.

The Research Development Committee advises and makes recommendations to the THHS Executive Corporate and Strategic Governance Committee regarding:

- The benefits in patient care and safety arising from involvement in research studies
- The strategic direction, oversight and governance for the development, management and sustainability of research across the Townsville HHS
- The conduct and outcomes of research with a focus on systems, structures and processes to improve the quality and quantity of research in the Townsville HHS, and alignment with Townsville HHS strategic priorities

All research must comply with the:

- NHMRC National Statement on Ethical Conduct in Human Research and
- NHMRC Australian Code for the Responsible Conduct of Research (the Code) and
- TGA Guideline for Good Clinical Practice – annotated with TGA comments and
- HREC approval and
- THHS authorisation.

In addition, all researchers wishing to conduct research projects involving Townsville HHS staff, facilities, patients and or resources being conducted at THHS will follow these Terms of Reference and all associated research policies, procedures and standard operating procedures, including but not limited to:

- Queensland Health Research Management Policy QH-POL-013:2015
- Queensland Health GCP Standard Operating Procedures
- THHS Human research ethics committee review pathways procedure THHSCOR140725v4

- THHS Research complaints and misconduct management procedure THHSCOR161031v2
- THHS Research governance review pathway procedure THHSCOR160992v3
- THHS Research monitoring at THHS procedure THHSCOR181236v1
- THHS Research requirements post-authorisation procedure THHSCOR161008v2
- Townsville Institute of Health Research and Innovation (TIHRI) Clinical Trial Unit allocation of space and bookings standard operating procedure
- TIHRI space allocation standard operating procedure
- TIHRI Clinical Trial Unit laboratory management standard operating procedure
- TIHRI alarm management standard operating procedure
- TIHRI training and induction standard operating procedure
- TIHRI Clinical Trial Unit clean utility room - medications standard operating procedure
- Townsville Institute of Health Research and Innovation Clinical Trial Unit participant supervision standard operating procedure
- TIHRI Clinical Trial Unit food management standard operating procedure
- TIHRI Clinical Trial Unit standard equipment maintenance standard operating procedure

3. TOWNSVILLE INSTITUTE OF HEALTH RESEARCH AND INNOVATION STEERING GROUP

3.1 Membership

The Townsville Institute of Health Research and Innovation Steering Group shall be comprised of:

- THHS Manager Townsville Research Education, Support and Administration Unit
- THHS Director of Clinical Research
- THHS Executive Director of Clinical Governance
- *THHS experienced Clinical Research Coordinator x 2
- *THHS researcher representatives of clinical units that perform clinical trials x 2
- *James Cook University representative x 1

* To be filled through an Expression of Interest process. Selection to ensure a balanced skill set on the Steering Group, representation of both early career researchers and experienced researchers.

3.2 Role of Steering Group

- To consider the functioning of the Townsville Institute of Health Research and Innovation, including resource sharing, access to facilities including sample storage space, as well as storage space for clinical trials materials.
- To provide advice to the THHS Research Development Committee on strategic research planning regarding the Townsville Institute of Health Research and Innovation

3.3 Steering Group Meetings

- The Steering Group will meet at least annually face to face
- All other correspondence will be via email

3.4 Steering Group Meeting Secretariat

- Secretariat services will be provided by the Townsville Research Education, Support and Administration (TRESA) Unit
- The Secretariat will endeavour to distribute Steering Group meeting papers to the Steering Group (SG) members at least five (5) business days before the scheduled SG meeting date.

- The Chair of the Steering Group may allow the distribution of additional meeting papers closer to the meeting or to be tabled at the meeting.

4. TOWNSVILLE INSTITUTE OF HEALTH RESEARCH AND INNOVATION OPERATIONAL PROCESSES

4.1 Access to facility

- All THHS will have 24/7 access to the facility. During office hours 8am – 5pm the doors to the open office area will be unlocked. Out of hours access will be via swipe card only.
- For the TIHRI clinical trial unit, for security reasons, access will be via swipe card only.
- Non THHS staff who require access to the facility will be required to complete a THHS ID application form and apply for access to the area. This process has been approved by Mr Jeremy Ries; THHS Manager Health Security.
- THHS staff may be required to sign a visitor's agreement, depending on their access.
- All access will comply with the Townsville Institute of Health Research and Innovation (TIHRI) Clinical Trial Unit allocation of space and bookings standard operating procedure and the TIHRI space allocation standard operating procedure

4.2 Facilitation of research

- The Director of Clinical Research, Professors of Nursing and Midwifery and Psychiatry, Principal Research Fellow Allied Health, and HREC and Research Governance staff should have an open-door policy. However, where their doors are closed, visitors must knock and there is no expectation that their business will be attended to immediately.
- Senior THHS staff, active in research, will support their colleagues in the development of research studies. Senior THHS research staff can be contacted directly through their QH email address or through the Townsville Research Education, Support and Administration (TRESA) Unit, who will maintain a list of available senior research staff.
- JCU and THHS have a service agreement for JCU to provide epidemiological support to THHS staff. All bookings for JCU epidemiological support are via email to the TRESA Unit.
- Research meetings will be held on a regular basis and advertised both within TIHRI and more broadly within the HHS. These meetings will be open to health service and James Cook University staff unless they are of a sensitive matter involving sensitive, patient or commercial in-confidence issues. These meetings should be of both TTH and JCU/AITHM based research groups.
- All research staff should make efforts to eat their meals in the tearoom, engaging freely with other individuals rather than reading electronic devices.

4.3 Utilisation of space within the facility

- The Institute office space has:
    - 1 office for the Human Research Ethics Committee (HREC) Coordinator and HREC Chair
    - 1 office for the Research Governance Administrator and Townsville Research Education, Support and Administration (TRESA) Unit Executive Support Officer
    - 1 office for the Manager Townsville Research Education, Support and Administration (TRESA) Unit
    - 1 office each for Director of Clinical Research, Professors of Nursing and Midwifery, Psychiatry and Allied Health.

    - 36 open area desk spaces
- The Institute clinical trial unit has:
    - 6 desk spaces
    - Two small multipurpose rooms suitable for interviews and focus groups
    - Two consult rooms equipped with computer, adjustable examination couches, suction and oxygen equipment
    - Procedure room equipped with a hospital bed, vital signs monitor, emergency trolley, suction and oxygen equipment, phlebotomy chair
    - Clean utility room equipped with a fridge for short term storage of study medication, dangerous drugs safe, pathology supplies
    - Dirty utility room equipped with a bedpan and bottle flusher and sanitizer
    - Specimen room equipped with PC2 hood for safe handling of human biospecimens, centrifuge, small fridge for the short-term storage of biospecimens and a -80 O freezer for long term storage of samples.

- **Main area utilisation**
    - Each desk in the main area has been allocated to a specific research group. In order to ensure maximum use of space all desks will also have a diary allocation.
    - Desks not in use for specific periods will be considered 'hot desks' and can be booked using the diary system.
    - All desk areas are considered to be 'quiet' spaces and conversation should be kept to a minimum.
    - The desk areas are not suitable for use by non- research staff.
    - Where possible, telephone calls should happen away from shared open plan desk areas.
    - Teleconferences must be conducted in a meeting room and not at an open desk area.
    - In the event of competing demands, prioritisation of access to the desk areas will be in consultation with the relevant research teams and the Manager Townsville Research Education, Support and Administration Unit.
    - Use of the Townsville Institute of Health Research and Innovation (TIHRI) Clinical Trial Unit will comply with the TIHRI allocation of space and bookings standard operating procedure and TIHRI space allocation standard operating procedure

- **Use of Clinical Trials Unit (CTU)**
    - Researchers utilising the clinical trials unit will provide their own specialist equipment.
    - Initially the Manager Townsville Research Education, Support and Administration (TRESA) Unit will liaise with researchers to ascertain commonly used equipment. These will initially be ordered by TRESA. It will be expected researchers utilising the clinical trials unit will be required to replace used items, costed to the relevant service group.
    - The CTU reception desk shall be manned by the research team occupying the CTU for the clinical trial/ study period.
    - The desks in the clinical trial unit will be used by the clinical trial staff utilising the clinical trials area.
    - To ensure safety of researchers, researchers will be required to sign in and out of the CTU.

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- **Use of meetings room located within the facility**
  - Within the facility area there are three meeting rooms: CS2.029 Mount Kosciuszko Meeting Room (6 people); CS2.034 Mount Bartle Frere Meeting Room (10 people) and CS2.045 Castle Hill Meeting Room (14 people).
  - All meeting rooms have video conferencing and electronic whiteboard facilities.
  - The meetings rooms will be able to be booked through the THHS Resource Management System (RMS). Priority will be given to research, clinical education and medical education & workforce services. Bookings for other work units will only be accepted inside one (1) month by phoning the confirmation officers.