PROCEDURE

Research Conducted Under the Clinical Trial Notification (CTN) Scheme

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TARGET AUDIENCE and SETTING

Researchers submitting clinical trials that involve an unapproved therapeutic good.

PURPOSE

A guide for researchers and/or sponsors regarding Clinical Trial Notification (CTN) requirements, sponsor responsibilities and regulatory obligations for research involving unapproved therapeutic goods.

DEFINITIONS and BACKGROUND

The Clinical Trial Notification (CTN) scheme is a process where the Australian clinical trial sponsor notifies the Therapeutic Goods Administration (TGA) that their research involves an 'unapproved' therapeutic good.

The CTN is a legal requirement under the *Therapeutic Goods Act 1989* (Cth).
The sponsor retains responsibility for the conduct, oversight and regulatory compliance of the clinical trial under the CTN scheme.

Lodgment of the CTN should occur after Human Research Ethics Committee (HREC) approval and Site-Specific Assessment (SSA) authorisation have been granted.

Research conducted under the CTN scheme cannot commence until the CTN has been lodged, and the TGA invoice has been paid.

For more information, visit the Clinical Trial Notification (CTN) scheme.

PROCEDURE

Commercially sponsored research conducted at a Monash Health site

For commercially sponsored trials, the responsibility of completing the CTN lies with the commercial sponsor. The commercial sponsor must be an Australian entity and be named on the Certificate of Insurance, Standard form of Indemnity and Research Agreement.

A pdf copy of the TGA acknowledgement must be forwarded to Research Support Services via email to research@monashhealth.org and to Clinical Trials Pharmacy.

Any subsequent CTN updates, amendments or notifications submitted to the TGA that affect the Monash Health site must also be provided to Research Support Services..

Collaborative group research conducted at a Monash Health site

The Collaborative Research Group or Cooperative Research Group (CRG) is considered the sponsor of the trial and is responsible for completing the CTN.

The sponsor is responsible for ongoing regulatory oversight, safety reporting and compliance with applicable requirements throughout the duration of the trial.

A pdf copy of the TGA acknowledgement must be forwarded to Research Support Services via email to research@monashhealth.org and to Clinical Trials Pharmacy.

Any subsequent CTN updates, amendments or notifications submitted to the TGA that affect the Monash Health site must also be provided to Research Support Services.

Investigator initiated research conducted at a Monash Health site

The sponsor is the institution considered to own the protocol. Researchers must be clear about the identity of the sponsor prior to submission of the HREC and SSA applications. If an external institution owns the protocol, the external institution is responsible for completing the CTN.

If Monash Health owns the protocol, the Research Support Services team will facilitate completion of the CTN.

The Principal Investigator remains responsible for ensuring that all sponsor obligations, regulatory reporting requirements and study oversight activities are fulfilled in accordance with applicable requirements, including, ICH GCP E6(R3) Guideline for Good Clinical Practice and the NHMRC Safety monitoring and reporting in clinical trials involving therapeutic goods(2016).

The process is as follows:

1. The Principal Investigator provides the required information for the CTN via email to research@monashhealth.org.
2. The Research Support Services team prepares the CTN form and provides a copy of the draft CTN to the Principal Investigator for review.
3. The Principal Investigator reviews the draft CTN to check if all details are correct.
4. Following review by the Principal Investigator, the Research Support Services team lodges the CTN on the TGA Business Services portal.Please note that the Research Support Services team will not be able to lodge the CTN until both HREC approval and Site Authorisation have been granted.
5. The Research Support Services team forwards a copy of the TGA invoice to the Principal Investigator. For the financial year beginning 01 July 2026, the cost of lodging a CTN is $464, and fees are typically increased each financial year.
6. Payment of the TGA invoice is the responsibility of the Principal Investigator. Upon payment, the Principal Investigator notifies the Research Support Services team that payment has been made.
7. Once payment has been made, the trial may commence.
8. The Research Support Services team checks the TGA portal for acknowledgement of the CTN, which usually takes around 1 week from the time payment is made. The Research Support Services team forwards a copy of the TGA acknowledgement to the Principal Investigator, for filing in the Investigator Site File.

The Research Support Services team is the account holder for Monash Health's TGA Business Services account. Monash Health researchers must not create their own TGA Business Services account as they are not authorised to complete the Approving Authority declaration.

Refer to the Monash Health Sponsor Responsibilities in Investigator Initiated Studies Procedure for more information.

Completing the CTN: Where Monash Health is a participating site

Lodgment of the CTN is a condition of SSA authorisation at Monash Health. During the SSA review process, a Research Support Services team member may ask the applicant to confirm if the CTN form has been prepared with the following details.
Researchers and sponsors should ensure that the details submitted through the CTN process remain accurate and current throughout the lifecycle of the study.

The TGA requires the CTN to list each physical location where use of the unapproved therapeutic good will occur. For trials conducted at more than one Monash Health campus, this means a Trial Site Details sub-form must be completed for each campus.
Refer to the Clinical Trial Notification (CTN) form User guide for more information.

Where applicable, sponsors should ensure appropriate oversight of service providers, electronic systems and trial-related activities associated with the conduct of the study.

Site details

Site Name	Monash Health
Site Physical Location *(insert one per sub-form – must list the full street address)*	Monash Medical Centre, 246 Clayton Road, Clayton VIC 3168
	Monash Children's Hospital, 246 Clayton Road, Clayton VIC 3168
	Moorabbin Hospital, 823-865 Centre Road, Moorabbin VIC 3165
	Dandenong Hospital, 135 David Street, Dandenong VIC 3175
	Casey Hospital, 62-70 Kangan Drive, Berwick VIC 3806
	Victorian Heart Hospital, 631 Blackburn Road, Clayton, VIC 3168
	Kingston Centre, 400 Warrigal Rd, Heatherton VIC 3202
State/Territory	Victoria
Expected Site Start Date *(must be after Expected Trial Start Date)*	[DD/MM/YYYY]

Principal Investigator details

Name	[Principal Investigator Name]
Contact Phone *(do not include spaces)*	[XXXXXXXXXX]
Contact Email	[Principal Investigator Email]

Approving Authority (Research Governance Office) details

Name of Approving Authority *(also known as RGO)*	Monash Health
Approving Authority Contact Officer	Ms Deborah Dell
Position	Head, Research Operations
Contact Phone *(do not include spaces)*	03 9594 4611
Contact Email	research@monashhealth.org

Completing the CTN: Where Monash Health is the reviewing HREC

Human Research Ethics Committee (HREC) Details

For trials reviewed by Monash Health HREC A:

HREC Name and Code	Monash Health Human Research Ethics Committee A [R] [C] (EC00382)
HREC Contact Officer	Mr Hayden Lee
Position	HREC Executive Officer
Contact Phone *(do not include spaces)*	03 9594 4611
Contact Email	research@monashhealth.org

For trials reviewed by Monash Health HREC B:

HREC Name and Code	Monash Health Human Research Ethics Committee B [R] [C] (EC00476)
HREC Contact Officer	Ms Toni Merritt
Position	HREC Executive Officer
Contact Phone *(do not include spaces)*	03 9594 4611
Contact Email	research@monashhealth.org

KEY STANDARDS, GUIDELINES OR LEGISLATION

1. Clinical Trial Notification (CTN) Form – User Guide
2. Australian Clinical Trials that use an unapproved therapeutic goods (2025)
3. Clinical Trial Notification (CTN) Scheme (2025)
4. ICH GCP E6(R3) Guideline for Good Clinical Practice
5. National Statement on Ethical Conduct in Human Research(2025)
6. NHMRC Safety monitoring and reporting in clinical trials involving therapeutic goods(2016)
7. Australian Code for the Responsible Conduct of Research 2018 | NHMRC

Document governance	
Policy or Framework supported by this Procedure	Human Research Policy
Executive Sponsor	Chief Medical Officer
Responsible Program, Service, Unit, Department or Committee	Research Support Services
Primary Contact	Head, Research Operations HREC Executive Officers