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

Medicines and devices that do not appear on the Australian Register of Therapeutic Goods (ARTG) or are being used outside of the marketing approval are considered 'unapproved'. Access and use of unapproved medicines and devices, including the use of placebo, requires notification to the TGA.

The sponsor of the study is responsible for the notification process which is completed online.

The notification process is complete and considered 'acknowledged' by the TGA once payment has been made. The sponsor must be in receipt of an ethics approval letter, site approval (authorisation letter/ERA alert) and TGA acknowledgement before supplying the 'unapproved' good.

For further information visit https://www.tga.gov.au/clinical-trials

Commercially sponsored research undertaken at an Alfred Health site

For commercially sponsored studies the responsibility of completing the online CTN lies with the commercial sponsor. The commercial sponsor must be an Australian entity and be named on the insurance, indemnity and Agreement.

If the Alfred Hospital Ethics Committee is conducting the ethics review, a pdf draft CTN should be provided as part of the ethics submission.

The *Alfred Health and Alfred Hospital Ethics Committee CTN details* can be provided to the sponsor to assist their online entry.

A pdf of the TGA acknowledgement must be forwarded to the Office of Ethics and Research Governance (Office) and Clinical Trials Pharmacy.

Collaborative group research undertaken at an Alfred Health site

The Collaborative Research Group or Cooperative Research Group (not to be confused with a collaboration of researchers) is considered the sponsor of the study. The CRG will be responsible for the CTN.

If the Alfred Hospital Ethics Committee is conducting the ethics review, a pdf draft CTN should be provided as part of the ethics submission.

The *Alfred Health and Alfred Hospital Ethics Committee CTN details* can be provided to the CRG to assist their online entry.

A pdf of the TGA acknowledgement must be forwarded to the Office and Clinical Trials Pharmacy.

Investigator initiated studies

The sponsor is the institution considered to own the protocol. Researchers must be clear about the sponsor identity up-front.

If an external institution owns the protocol, the external institution is responsible for the CTN.

If Alfred Health owns the protocol, the researchers will need to complete the *CTN Details Form* found on the Alfred Health website and submit this to the Office.

Alfred Health researchers **are not** to create their own client ID with the TGA.

Where the project will be run at numerous sites, Alfred Health is responsible for notification of each site to the TGA.

Details of other sites to be notified can be included in the *CTN Details Form* or on the *CTN Additional Site Details Form.* The *CTN Additional Site Details Form* can be sent to sites for the site to complete and return.

The TGA charges a fee for CTNs.
Once the CTN has been submitted by ethics office staff, the TGA's online system generates an invoice and sends this by email to the Office. The invoice will be provided to the researcher for payment. The invoice contains payment options. The CTN will not be acknowledged by the TGA until payment has been made.

The Office will retrieve the TGA acknowledgement and provide this to the researchers.

External sites may request confirmation of notification of their site.

Alfred Health's HREC providing HREC review only
Where the Alfred Hospital Ethics Committee is providing HREC review only, the sponsor or the institution acting as the sponsor will complete the online submission. It is requested that the CTN acknowledgement be forwarded to the Office.