

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 and/or have been imported from overseas and not sourced from the local distributor, are considered 'unapproved'. Access and use of unapproved medicines and devices, including the use of placebo, requires notification to the TGA, regardless of whether the study is a clinical trial or not.

Medical devices regulated by the TGA:

- are used for humans
- are intended to diagnose, prevent, monitor, treat or alleviate a disease or injury, or modify or monitor anatomy or physiological functions of the body
- generally achieve their purpose by a physical, mechanical or chemical action.

Devices also include in vitro diagnostics as well as software.

The TGA has advised that a CTN is also required for devices/assays/software used within a study even though the device/assay/software is not the subject of the trial.

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 CTN acknowledged by the TGA before supplying the 'unapproved' good.

For further information visit <https://www.tga.gov.au/products/unapproved-therapeutic-goods/access-pathways/clinical-trials>

The TGA's [Australian Clinical Trial Handbook](#) also includes information about CTNs.

Commercially sponsored research undertaken at a Bayside Health (Alfred Care Group) 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 [HREC & Approving Authority CTN details](#) document can be provided to the sponsor to assist their completion of the CTN.

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

Collaborative group research undertaken at a Bayside Health (Alfred Care Group) 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 [HREC & Approving Authority CTN details](#) document can be provided to the sponsor to assist their completion of the CTN.

A pdf of the CTN acknowledged by the TGA 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 Bayside Health owns the protocol, the researchers will need to complete the [CTN details form](#) and submit this to the Office.

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

Where the project will be run at numerous sites, Bayside 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 form](#). The [CTN additional site form](#) should be sent to sites for them to complete and return.

The TGA charges a fee for CTNs.

This is both for the initial submission and certain variations to the CTN, including adding a site, changing a PI at a site, adding a drug etc.

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 forwarded to the researcher for approval and payment. The invoice specifies payment options.

The TGA's invoice must be paid by the TGA-specified deadline (2 weeks after the invoice is issued).

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 researchers.

If the invoice is not paid by the deadline the study may be withdrawn by the TGA, with associated consequences for the study and Bayside Health.

With no CTN in place, unapproved therapeutic goods cannot be used in the study and there may be legal consequences for doing so.