Therapeutic Goods Administration - CTN

Clinical Trial Notification

If you are conducting a clinical trial involving an investigational agent or device, you will require a Clinical Trial Notificatiom (CTN). The sponsor is responsible for managing the submission and payment of the CTN which must be finalised prior to starting the project. The CTN is completed on the TGA website:

Sign In (tga.gov.au)

If CAHS is the sponsor, please contact the governance office for drafting rights and liaise with our office for submission and payment of the CTN.

The TGA administers two pathways for clinical trials, the **Clinical Trials Notification (CTN)** and **Clinical Trials Approval (CTA)** schemes. These provide an avenue through which 'unapproved' therapeutic goods may be lawfully supplied for use solely for experimental purposes in humans.

The choice of which route to use (CTN or CTA) lies firstly with the Australian clinical trial sponsor and then with the Human Research Ethics Committee (HREC) that approves the protocol. The majority of clinical trial research involving a drug or device conducted within WA Health will use the CTN scheme. The CTA route is generally designed for high-risk or novel treatments where there is no or limited knowledge of safety. For medical device trials, the CTA scheme may be more appropriate where the experimental device introduces new technology, new material or a new treatment concept which has not been evaluated previously in clinical trials in any country. The CTA scheme should also be considered for medical devices that pose a risk of serious patient harm.