**Advice for completing CTN forms**

If you are unsure of how to compete the details for the CTN forms, please go to the TGA websites listed below. I have also copied the most current definition of a biological from the TGA website and some definitions from the TGA publication ***“Access to Unapproved Therapeutic Goods – Clinical Trials in Australia, October 2004”*** which may assist you when completing the CTN form. Please note that since 1st July 2015, the TGA uses an online process and not the paper forms mentioned in this 2004 document.
If you need any other advice please contact me at the Research Governance Office on 9340 1667

Dr Helen Atkinson

Research Governance officer

O Block, KEMH

Women and Newborn Health Service

**TGA websites**

<https://www.tga.gov.au/form/ctn-scheme-forms>

<https://www.tga.gov.au/completing-online-ctn-form>

**Definition of biologicals from TGA website** <https://www.tga.gov.au/products-regulated-biologicals>

Products regulated as biologicals (8 January 2013)

Biologicals are defined in Part 3-2A of the Therapeutic Goods Act 1989 (the Act) as a thing made from, or that contains, human cells or human tissues, and that is used to:

•treat or prevent disease, ailment, defect or injury

•diagnose a condition of a person

•alter the physiological processes of a person

•test the susceptibility of a person to disease

•replace or modify a person’s body parts.



Below are some definitions copied from the TGA publication ***“Access to Unapproved Therapeutic Goods – Clinical Trials in Australia, October 2004”***

**Abbreviations and Acronyms**

|  |  |
| --- | --- |
| ARTG | Australian Register of Therapeutic Goods |
| CTN | Clinical Trial Notification (Scheme) |
| CTX | Clinical Trial Exemption (Scheme) |
| GMDN | Global Medical Device Nomenclature |
| HREC | Human Research Ethics Committee |
| ICH | International Conference on Harmonisation (of Technical Requirements for Registration of Pharmaceuticals for Human Use) |
| NHMRC | National Health and Medical Research Council |
| OTGs | ‘other therapeutic goods’ |
| the Act | Therapeutic Goods Act 1989 |
| the medical devices Regulations | Therapeutic Goods (Medical Devices) Regulations 2002 |
| the National Statement | National Statement on Ethical Conduct in Research Involving Humans, NHMRC 2007 the Regulations Therapeutic Goods Regulations 1990 |
| TGA | Therapeutic Goods Administration |

**Approving Authority**

The body, organisation or institution that approves the conduct of a clinical trial at a particular trial site.

**Australian Register of Therapeutic Goods (ARTG)**

The ARTG is a computer database established under the Therapeutic Goods Act 1989 in which most therapeutic goods are required to be entered prior to their supply in, or export from, Australia. Note: Some goods are exempted from the requirement to be included in the ARTG, such as products approved for use in clinical trials and the Special Access Scheme.

**Bioavailability**

The rate and extent of absorption of an active ingredient from a dosage form as determined by its concentration/time curve in the systemic circulation or by its excretion in urine.

**Bioequivalence**

Two medicinal products are bioequivalent if they are pharmaceutically equivalent and their bioavailabilities after administration are similar to such a degree that their effects, with respect to both efficacy and safety will be essentially the same.

**Biological products**

Products in which the active ingredient is a biological substance including antisera, antivenins, monoclonal antibodies and products of recombinant technology.

**Clinical Trial (study)**

A planned study in humans designed to investigate and report upon the effectiveness and/or safety of a therapeutic good. In the context of these guidelines, this means a systematic study of a medicine or a medical device, conducted in humans in order to discover or verify the effects of and/or identify the adverse reactions to those products and/or study their absorption, distribution, metabolism and excretion in order to ascertain the efficacy and safety of the products. Each trial is supported by a single protocol, but that protocol may allow the trial to be carried out at a single site or multiple sites.

**Formulation**

A list of the ingredients used in the manufacture of a dosage form and a statement of the quantity of each ingredient in a defined weight, volume, unit or batch.

**Impurities**

Unintended components of the medicine substance or finished product. They may arise from decomposition of the medicine, they may be by-products of the synthesis, solvent or reagent residues, or they may be contamination from other sources.

**Investigator**

A person responsible for the conduct of the clinical trial at a trial site. If a trial is conducted by a team of individuals at a trial site, the investigator is the responsible leader of the team and may be called the principal investigator. An investigator assigned the responsibility for the coordination of investigators at different centres participating in a multicentre trial may be referred to as the coordinating investigator.

**Investigational product**

Any investigational medicine or device, reference product or device or placebo being tested or used as reference in a clinical study.

**Medicine**

A therapeutic good (substance or preparation) that is represented to achieve (or is likely to achieve) its principal intended action by pharmacological, chemical, immunological or metabolic means in or on the body. It may be intended for administration to humans in order to:

• prevent, diagnose, alleviate or cure a disease, ailment, defect or injury; or
• test the susceptibility of a person to a disease or ailment; or
• influence, inhibit or modify a physiological process; or
• influence, control or prevent conception.

**Medical Device**

Any instrument, apparatus, appliance, material or other article (whether used alone or in combination, and including the software necessary for its proper application) intended, by the person under whose name it is or is to be supplied, to be used for human beings for the purpose of one or more of the following:

• diagnosis, prevention, monitoring, treatment or alleviation of disease;
• diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap;
• investigation, replacement or modification of the anatomy or of a physiological process;
• control of conception;

and that does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but may be assisted in its function by such means; or an accessory to such an instrument, apparatus, appliance, material or other article.

**Multicentre study**

A study conducted simultaneously by several investigators at different centres, with identical methods (ie, following the same protocol).

**Protocol**

A document that provides the background, rationale and objectives of the study and describes its design, methodology, organisation and the conditions under which it is to be performed and managed.

**Sponsor of the trial**

The sponsor of the trial is the company, institution or organisation, body or individual (enterprise) that takes overall responsibility for the conduct of the trial and usually initiates, organises and supports a clinical study of an investigational product in human subjects. If the investigator initiates and organises the trial, he or she is to be defined as the sponsor of the trial and will be responsible for the sponsor’s functions. This includes where another party (usually a pharmaceutical company) provides the medicinal product used in the clinical trial but has no other involvement in the conduct of the trial. The sponsor of the trial should be an Australian company or individual.

**Trial site**

The location where trial-related activities are actually conducted.

**Regulation of Medicine and Medical Device Clinical Trials in Australia – An Introduction to the CTN and CTX Schemes**

Clinical trials of medicines and medical devices conducted in Australia are subject to Commonwealth Government regulation administered by the Therapeutic Goods Administration (TGA).

There are two schemes under which clinical trials involving therapeutic goods may be conducted, the Clinical Trial Exemption (CTX) Scheme and the Clinical Trial Notification (CTN) Scheme. Either notification under the CTN Scheme or application under the CTX Scheme is required for all clinical investigational use of a product, where that use involves:

* any product not entered on the Australian Register of Therapeutic Goods, including any new formulation of an existing product or any new route of administration, or in the case of an existing medical device, new technology, new material or a new treatment modality; or
* use of a product beyond the conditions of its marketing approval, including new indications extending the use of a medicine to a new population group and the extension of doses or duration of treatments outside the approved range.

Clinical trials in which registered or listed medicines or medical devices are used within the conditions of their marketing approval are not subject to CTN or CTX requirements but still need to be approved by a Human Research Ethics Committee (HREC) before the trial may commence.

**The CTN Scheme**

Under the CTN scheme, all material relating to the proposed trial, including the trial protocol is submitted directly to the HREC by the researcher at the request of the sponsor. The TGA does not review any data relating to the clinical trial. The HREC is responsible for assessing the scientific validity of the trial design, the safety and efficacy of the medicine or device and the ethical acceptability of the trial process, and for approval of the trial protocol. In some institutions a scientific review or drug subcommittee may review the proposal before consideration by the HREC. The institution or organisation at which the trial will be conducted, referred to as the 'Approving Authority', gives the final approval for the conduct of the trial at the site, having due regard to advice from the HREC.

The TGA 'Notification of Intent to Conduct a Clinical Trial' form (the CTN Form) is submitted by the investigator on behalf of the sponsor to the HREC and to the Approving Authority. Once the sponsor, the principal investigator, the Chairman of the HREC and the person responsible from the Approving Authority have signed the CTN Form, it is submitted by the sponsor of the trial to the TGA along with the appropriate notification fee. The Therapeutic Goods Regulations require that the Secretary of the Department of Health and Aged Care. Sponsors must use the current CTN form (located at Appendix 2). Use of old (out-of-date) CTN forms will invalidate the notification.