STANDARD OPERATING PROCEDURE (SOP)

Title: Submitting and updating a Clinical Trial Notification (CTN) to the TGA

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CONTENTS

1. PURPOSE

For MCRI sponsored trials, MCRI has delegated the Sponsor responsibility for managing CTN submissions and completions to nominated staff within the Melbourne Children's Trials Centre (MCTC).

This SOP describes the procedure for the MCRI/RCH Sponsor-Investigator/delegate liaising with MCTC staff to enable MCRI, as the institutional Sponsor, to meet its responsibilities in accordance with legislative, regulatory and Good Clinical Practice (GCP) requirements when conducting clinical trials in Australia using 'unapproved' therapeutic goods.

2. BACKGROUND

The trial Sponsor and reviewing Human Research Ethics Committee (HREC) are responsible for determining the appropriate regulatory pathway for the use of 'unapproved' therapeutic goods in a clinical trial. In Australia, there are two pathways –the Clinical Trial Notification (CTN) scheme and the Clinical Trial Application (CTA) scheme.

The CTA scheme is rarely applicable to investigator-initiated trials.

The CTN scheme is applicable for any clinical trial that uses 'unapproved' therapeutic goods. That is, any therapeutic good that is being used in a manner not consistent with the registration of that therapeutic good on the Australian Register of Therapeutic Goods (Australian Register of Therapeutic Goods (ARTG)).

Common examples include:

a) Not listed in the ARTG at all, including goods with a new formulation, strength, dosing regime, size, manufacturer, etc.
b) Not ARTG listed for use within the trial's intended population
c) Not ARTG listed for the trial's intended indication
d) Not ARTG listed for the trial's intended application e.g. oral, intramuscular, etc.

A therapeutic good includes:

- Medication
- Medical Device
- Biologicals

Refer to Appendix 1 for more detailed information.

A trial-specific CTN must be in place, that is acknowledged by the TGA, before the unapproved therapeutic goods are supplied/administered to trial participants.

Any changes to information listed on the current Acknowledged CTN must be submitted to the TGA, and the CTN Variation acknowledged by the TGA. Refer below for types of changes that must be notified and the timing of the notification.

Change to Trial Details	**Notification Timing**
Addition of new sites	Before recruitment commences
Addition of unapproved therapeutic goods	Before recruitment commences
Change of Site Principal Investigator	As soon as possible but within 4 weeks of change
Change of expected completion date	Before the current expected completion date has passed

3. SCOPE

This SOP applies to all MCRI/RCH Sponsor-Investigator/delegates involved in conducting trials using therapeutic goods that are 'unapproved' in Australia and are using the TGA's CTN scheme to supply the 'unapproved' therapeutic good(s) for use in trial participants recruited at Australian sites.

It also applies to MCRI/RCH lead Investigators requiring exemption from the TGA to use unapproved skin prick test allergens in MCRI/RCH led trials and observational research studies.

It does not apply to staff involved in trials that are externally sponsored or do not use 'unapproved' therapeutic goods.

A separate SOP provides the procedure for MCTC staff responsibilities in the management of CTNs, MCTC041 SOP Submitting and managing Clinical Trial Notifications at the Melbourne Children's when MCRI is the trial sponsor.

4. RESPONSIBILITY

For investigator-initiated trials, both the institutional Sponsor and the Sponsor-Investigator have responsibilities for managing the process for CTN submission (initial and any variations) and CTN completion to the Therapeutic Goods Administration (TGA) in accordance with the requirements outlined in the TGA's Australian clinical trial handbook: Guidance on conducting clinical trials in Australia using 'unapproved' therapeutic goods.

As per section 5.10 of ICH GCP (E6 (R2)), the **sponsor** is responsible for submitting a CTN (or CTA) to the TGA.

According to the TGA, the sponsor:

> *"must be a resident of Australia or be an incorporated body in Australia and conducting business in Australia where the representative of the company is residing in Australia".*

For this reason, trials with an international sponsor may require MCRI to act as the local Australian Sponsor, and therefore take on the responsibility to submit a CTN or CTA.

Please refer to MCTC037b MCRI Sponsorship Application Process for IITs for more information on seeking MCRI Sponsorship.

Nominated MCTC staff will manage the submission of CTNs (initial, variations and completion advice) to the TGA on behalf of the Principal Investigator / Sponsor Investigator to ensure the quality and consistency of the data, and continuity of access.

The **trial Sponsor-Investigator/delegate** is responsible for:

1. Drafting the CTN and ensuring the information on the CTN (and subsequent variations) is accurate, complete and up-to-date before submission to the TGA and during the trial (up until the last participant's last visit).
2. *Paying the TGA fee upon receipt of invoice.*
3. *Informing MCTC when the CTN Completion form can be submitted to the TGA.*

For multi-centre trials, where the CTN lists multiple sites, the MCRI Principal Investigator is usually the Coordinating Principal Investigator (CPI) or Sponsor-Investigator. In this case, the CPI/Sponsor-Investigator/delegate is responsible for managing the CTN on behalf of all participating sites listed on the CTN and providing them with all versions of the CTN (submitted and acknowledged) required to comply with their local site-specific authorisation.

5. PROCEDURE

5.1. Workflow

Please refer to Appendix 2: Workflow - Submitting and updating a Clinical Trial Notification (CTN) to the TGA for an overview of the procedure to submit a new CTN or variation to the TGA, as detailed below.

5.2. Submit a request for a new CTN

5.2.1. Recommended timing for initial CTN request

The reviewing HREC will usually require a copy of the validated draft CTN included in the ethics application and some sites require evidence of CTN submission/acknowledgement prior to receiving site governance approval. The Sponsor-Investigator (or delegate) should therefore seek to submit a CTN request to MCTC approximately **2-3 weeks** prior to submitting the study for HREC approval to ensure time for adequate MCTC review.

5.2.2. Lodge a request to MCTC

In the majority of cases, the Sponsor-Investigator (or delegate) must lodge a request to MCTC to draft a new CTN using MCTC's online Clinical Trials Notification Request Form. This form includes fields for all data required by the TGA. If unsure of the data required, the Sponsor-Investigator (or delegate) may refer to the TGA's CTN User Guide for clarification on what is required for each data field.

Note 1: For some trial teams, it may be appropriate for a select number of nominated trial team members to be responsible for drafting CTNs directly in the TGA Business Portal, bypassing the MCTC Clinical Trials Notification Request Form. This is more likely for trial teams that submit a high volume of CTNs or list a large number of therapeutic goods (medicine/device/biological) on the CTN. This will be determined by MCTC on a case-by-case basis. When it is appropriate, MCTC will organise a TGA business account with 'drafter' status.

Note 2: The correct details for the approving HREC and Approving Authority for each site is important. Please refer to National Mutual Acceptance HRECs, RGOs and Organisations contact list for details. Note this document will get updated periodically so please always ensure you use the latest version.

5.3. Review accuracy and completeness of CTN prior to submission

Once the CTN details have been drafted by the Sponsor-Investigator/delegate, MCTC staff will review the details entered to ensure they are consistent with the trial protocol and meet the TGA requirements for information to be provided on the CTN.

The Sponsor-Investigator/delegate must liaise with MCTC until both parties are satisfied that the information provided on the CTN is accurate and complete for the purpose of the trial.

Note: This may need to be revisited if there is a delay between drafting the CTN and submitting to the TGA. In this case, the Sponsor-Investigator should pay particular attention to the following fields, which may change between the first review and submission to the TGA:

- Updated projected start and expected finish date(s)
- Change in open sites
- Change in site contact details
- New medicine/medical device/biological manufacturers

5.4. Essential documents to be provided to MCTC pre-CTN submission

As soon as it is available, the Sponsor-Investigator/delegate must provide MCTC with evidence of HREC approval for the trial.

MCTC will then submit the CTN to the TGA and provide a record of the submitted CTN to the Sponsor-Investigator/delegate to file in the Trial Master File and if required, include in participating site local governance application(s).

5.5. Payment of TGA invoice

MCTC will forward a copy of the TGA invoice to the Sponsor-Investigator/delegate as soon as it is received.

The TGA's fee for review of a CTN is updated annually and can be found at TGA Schedule of fees and charges.

The Sponsor-Investigator/delegate must arrange payment. Options available include:

a) Forward the invoice to MCRI Accounts/Payable with MCRI cost centre details and email approval from the cost centre manager. MCRI Accounts will then upload the invoice to Unimarket and the cost centre manager will need to approve the invoice. This process typically sees TGA invoices paid in one week.
b) Pay the invoice via credit card, and forward both the initial invoice and record of payment to MCRI finance for reimbursement. This is recommended should the trial be seeking urgent TGA acknowledgement. Details how to pay by credit card

are available at: https://www.tga.gov.au/how-we-regulate/fees-and-payments/payment-options

The TGA's review will not commence until payment is received and generally takes **5-7 days**.

Failure to make prompt payment may result in the application being withdrawn.

5.6. CTN Acknowledgement – Notifying Sites and Record Keeping

MCTC will notify the Sponsor-Investigator when the CTN has been acknowledged by the TGA, and will send a copy of the acknowledged record to the Sponsor-Investigator/delegate.

The Sponsor-Investigator/delegate must ensure the TGA acknowledged CTN is filed in the Trial Master File (TMF) and Site Information Files (SIFs).

The Sponsor-Investigator/CPI must also forward a copy of the TGA acknowledgement to all listed sites to be filed in their Investigator Site File (ISF) and provided to their local Research Governance Office in accordance with their site-specific authorisation requirements.

Important: The Sponsor-Investigator/CPI is responsible for ensuring that each participating site is aware that receipt of the TGA acknowledged CTN is not the only approval required for the site to commence recruitment. Instead, they will need to have a fully executed Regulatory Green Light Form in place. The Regulatory Green Light process should be communicated to sites in advance of the Site Initiation Meeting. Refer to the following MCRI SOPs for details: MCTC033 SOP Regulatory Green Light Approval for Clinical Trial Site Activation and MCTC065 SOP Study Start Up for Clinical Trials

Please see Appendix 2: Workflow - Submitting and updating a Clinical Trial Notification (CTN) to the TGA for further clarification.

5.7. Keep MCTC informed regarding Site Specific Approval (SSA) and Site Activation

As each site receives SSA and becomes activated, the Sponsor-Investigator/delegate must inform MCTC by providing a copy of the following documents:

- Copy of local Research Governance Office Approval (SSA)
- Executed MCTC034 Regulatory Green Light Approval Form
- Signed and dated MCTC016 Site Activation Letter

5.8. CTN Variations

The TGA must be notified of any changes in the trial details listed on the current version of the TGA acknowledged CTN. The Sponsor-Investigator/delegate must advise MCTC staff of all such variations, who will then submit the update on their behalf. To notify MCTC of a variation, complete the eCTN Variation Submission Form. MCTC staff will then draft the variations and correspondence with trial team to confirm variation details are accurate and is ready to be submitted. Major variations incur a review fee, which is updated annually and can be found at https://www.tga.gov.au/how-we-regulate/fees-and-payments/payment-options. Common examples of a major variation include:

- New sites are opened or closed within Australia
- Trial expands from national to International
- New therapeutic goods (including additional or changed manufacturers)

There is no fee for minor amendments, such as:

- Change in Principal Investigator
- Change in HREC or site contact(s)
- Change in Expected Trial Completion Date

The variation must be submitted and managed as per the process detailed in Sections 5.2 – 5.7.

5.9. Submit a completion advice to the TGA

The Sponsor-Investigator/delegate must determine when the unapproved Therapeutic Good(s) is no longer in use for the clinical trial, and contact MCTC to organise a completion advice to be sent to the TGA. This will typically (but not necessarily) correspond with date of last participant's visit.

Where more than one site is listed on a CTN, the completion advice should be submitted only when all sites listed have ceased using the unapproved therapeutic good(s).

5.10. Safety Reporting to the TGA

Refer to sections 5.5.4 – 5.5.7 of MCTC005 SOP | Safety Monitoring and Reporting Procedure for MCRI-sponsored investigator-Initiated Trials of Medicines/Medical Devices for detailed information and resources on Safety Reporting requirements at Melbourne Children's.

5.11. Note on Clinical Trial Approval (CTA) submissions to the TGA

The vast majority of trials conducted at Melbourne Children's fall under the CTN scheme; a CTA is required for high risk or novel treatments where there is limited information on the product's safety, such as gene therapy, Class 4 biologicals, or a new medical device which utilises new technology, material or a treatment concept.

Please see the Australian regulatory guidelines for biologicals (ARGB) for further guidance on class 4 biologicals.

The reviewing HREC may also determine that it does not have access to the appropriate scientific and technical expertise to review a therapeutic good and recommend the trial for review by the TGA under the CTA scheme.

Please contact MCTC prior to submitting a request for a new CTN if you believe your trial may require a CTA.

6. GLOSSARY

Australian Register of Therapeutic Goods (ARTG)
The register of all therapeutic goods which may be lawfully supplied within Australia.

Clinical Trial
The World Health Organization (WHO) definition for a clinical trial is: 'any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes'.

Clinical Trial Approval (CTA)
Formally known as Clinical Trial Exemption (CTX), one of two schemes used by the Therapeutic Goods Administration (TGA) to authorise the supply of unapproved therapeutic goods, including medicines, medical devices, and biologicals, to participants participating in clinical trials in Australia.

The CTA scheme is appropriate for trials where the reviewing ethics committee does not have access to the appropriate scientific and technical expertise to review the trial under the CTN scheme. It is generally used for high risk or novel treatments, such as gene therapy, where there is no or limited knowledge of safety.

Clinical Trial Notification (CTN)
One of two schemes used by the Therapeutic Goods Administration (TGA) to authorise the supply of unapproved therapeutic goods, including medicines, medical devices, and biologicals, to participants participating in clinical trials in Australia.

The CTN scheme is appropriate for trials where the reviewing ethics committee has enough scientific and technical expertise to review the proposed use of the unapproved therapeutic good(s). Most investigator-initiated trials would be in this category.

Clinical Trial Notification/Clinical Trial Application Completion Advice
Sponsors should notify the TGA of trial completion once the clinical trial-related activity afforded by a CTN exemption or CTA approval is no longer required. It is, however, the responsibility of the Sponsor to determine when the exemption or approval is no longer required. Notification of completion of a clinical trial should be made only after the trial has been completed at all sites. It is not necessary to notify completion dates for individual trial sites.

Essential Documents
Documents which individually and collectively permit evaluation of the conduct of a study and the quality of the data produced. These documents serve to demonstrate the compliance of the Investigator, Sponsor, and Monitor with the standards of Good Clinical Practice (GCP) and with all applicable regulatory requirements. Filing essential documents at the Sponsor site and participating trial sites also assists with the successful management of the trial.

Good Clinical Practice (GCP)
A standard for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of clinical trials that provides assurance that the data and reported results are credible and accurate, and that the rights, integrity, and confidentiality of trial participants are protected.

Human Research Ethics Committee (HREC)
A body which reviews research proposals involving human participants to ensure that they are ethically acceptable and in accordance with relevant standards and guidelines. The National Statement requires that all research proposals involving human participants be reviewed and approved by an HREC and sets out the requirements for the composition of an HREC.

International Conference on Harmonisation (ICH)
The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) is unique in bringing together the regulatory authorities and pharmaceutical industry to discuss scientific and technical aspects of drug registration.

Investigator
A person responsible for the conduct of the clinical trial at a trial site. There are three types of Investigator roles used to describe Investigators with different levels of responsibility for the conduct of clinical trials. These are described below.

Associate Investigator/Sub-Investigator

Any individual member of the clinical trial team designated and supervised by the Investigator at a trial site to perform critical trial-related procedures and/or to make important trial-related decisions (e.g., associates, residents, research fellows). May also be referred to as Sub-Investigator.

Principal Investigator

The PI is the person responsible, individually or as a leader of the clinical trial team at a site, for the conduct of a clinical trial at that site. As such, the PI supports a culture of responsible clinical trial conduct in their health service organisation in their field of practice and, is responsible for adequately supervising his or her clinical trial team.

The PI must conduct the clinical trial in accordance with the approved clinical trial protocol and ensure adequate clinical cover is provided for the trial and ensure compliance with the trial protocol.

Sponsor-Investigator / Coordinating Principal Investigator (CPI)

In investigator-initiated and collaborative research group trials the Principal Investigator taking overall responsibility for the study and for the coordination across all sites (if it is a multi-centre trial) is known as the Sponsor-Investigator or Coordinating Principal Investigator (CPI). In this case, the Sponsor will delegate many sponsor responsibilities to the Sponsor-Investigator/Sponsor-Investigator.

Investigator-Initiated Trials (IITs)

A clinical trial which is initiated and organised by an Investigator i.e. an individual rather than a collaborative group, company, or organisation. In these cases, the Investigator will take on the role of the trial sponsor and will then be responsible for the extensive GCP and regulatory requirements associated with both the management and conduct of the trial.

Investigational Medicinal Product (IMP)

A pharmaceutical form of an active ingredient or placebo being tested or used as a reference in a clinical trial, including a product with a marketing authorisation when used or assembled (formulated or packaged) in a way different from the approved form, or when used for an unapproved indication, or when used to gain further information about an approved use.

Investigational Medical Device (IMD)

A device that is the subject of a clinical study designed to evaluate the effectiveness and/or safety of the device.

Investigator Site File (ISF)

Filing repository controlled by the site Principal Investigator. It is held at the trial site and contains all the essential documents necessary for the site trial team to conduct the trial as well as the essential documents that individually and collectively permit evaluation of the conduct of the trial at the site and the quality of the data produced.

Melbourne Children's
The campus encompassing all staff from The Royal Children's Hospital, Murdoch Children's Research Institute and Department of Paediatrics University of Melbourne who initiate or carry out research under one or more of these institutional affiliations.

Melbourne Children's Trials Centre (MCTC)
Melbourne Children's Trials Centre (MCTC) is a collaboration between the Royal Children's Hospital, The Murdoch Children's Research Institute, The Royal Children's Hospital Foundation and The University of Melbourne. This Centre brings together expertise in research, clinical practice, and education and incorporates anyone who initiates or carries out research under one or more of these institutional affiliations.

Monitor
A person appointed by the Sponsor to undertake the role of monitoring for the trial. Monitors should be appropriately trained and should have the scientific and/or clinical knowledge needed to monitor the trial adequately.

Murdoch Children's Research Institute (MCRI)
An Australian paediatric medical research institute located in Melbourne, Victoria, affiliated with the Royal Children's Hospital and the University of Melbourne. The institute has six research themes: cellular biology, clinical sciences, genetics, infection and immunity, population health, and data science.

Recruitment
Recruitment of participants for a research project (known as a study) is the process where people are identified and contacted for further discussion, provide informed consent, are screened and (where eligible) enrolled in a study.

Research Ethics and Governance Office (REG)
REG supports the HREC and institutional research governance processes at MCRI.

Research Governance Office (RGO)
The Office or coordinated function at a recruiting site which is responsible for assessing the site-specific aspects of research applications, make a recommendation to the CEO / delegate as to whether a research project should be granted site-specific authorisation (SSA) at that site,

and overseeing that authorised research at the site meets appropriate standards (research governance).

Royal Children's Hospital (RCH)
A major children's hospital in Melbourne, which provides a full range of clinical services, tertiary care, as well as health promotion and prevention programs for children and young people.

Sponsor
An individual, organisation or group taking on responsibility for securing the arrangements to initiate, manage and finance a study. For investigator-initiated trials, MCRI or RCH will act as the Sponsor but delegate many sponsor responsibilities to the Coordinating Principal Investigator. In this case the CPI has the role of both Sponsor and Investigator and hence the MCTC has adopted the term **Sponsor-Investigator** to reflect the dual role of the CPI in investigator-initiated trials.

Standard Operating Procedure (SOP)
Detailed, written instructions to achieve uniformity of the performance of a specific function.

Therapeutic Good
In relation to the evaluation, assessment and monitoring done by the TGA, therapeutic goods are broadly defined as products for use in humans in connection with:

- preventing, diagnosing, curing, or alleviating a disease, ailment, defect, or injury
- influencing inhibiting or modifying a physiological process
- testing the susceptibility of persons to a disease or ailment
- influencing, controlling, or preventing conception
- testing for pregnancy

This includes things that are:

- used as an ingredient or component in the manufacture of therapeutic goods
- used to replace or modify of parts of the anatomy.

Refer to Appendix 1 for examples of therapeutic goods.

Therapeutic Goods Administration (TGA)
The Therapeutic Goods Administration (TGA) is Australia's regulatory authority for therapeutic goods.

Trial Master File (TMF)
Filing repository controlled by the Sponsor/Sponsor-Investigator. It is the collection of essential documents that allows the Sponsor responsibilities for the conduct of the clinical trial, the

integrity of the trial data and the compliance of the trial with Good Clinical Practice (GCP) to be evaluated.

Unapproved Therapeutic Good

For the purposes of this handbook, the reference to 'unapproved' therapeutic goods is an abbreviated expression[1] which is intended to include:

- any medicine not included in the ARTG, such as any new formulation, strength or size, dosage form, name, indications, directions for use or type of container of a medicine already in the ARTG
- any medical device (including an in vitro diagnostic device (IVD)) not included in the ARTG, such as any new sponsor, manufacturer, device nomenclature system code, classification or unique product identifier (for certain classes of medical devices only) of a medical device already in the ARTG
- any in-house IVD medical device, used for the purpose of a clinical trial, where the laboratory providing the in-house IVD is unable to comply with the regulatory requirements for in-house IVDs (a laboratory developed test used for research purposes where results of such testing are not being used in patient diagnosis, treatment or management decisions would not be considered an in-house IVD)
- any biological not included in the ARTG such as:
    - any new applicable standards, intended clinical use or principal manufacturer of a Class 1 or 2 biological already in the ARTG
    - any new product name, dosage form, formulation or composition, therapeutic indication, type of container or principal manufacturer of a Class 3 or 4 biological already in the ARTG
- therapeutic goods already included in the ARTG to be used in a manner not covered by the existing entry in the ARTG

When a product is included in the ARTG, the entry applies to a particular sponsor (i.e. the individual or company intending to supply the goods). If a same or similar product is imported by another company or individual it is considered 'unapproved'.

7. REFERENCES

National Mutual Acceptance HRECs, RGOs and Organisations contact list

Therapeutic Goods Administration (2021) *Clinical Trial Handbook*

https://www.tga.gov.au/resource/australian-clinical-trial-handbook

Therapeutic Goods Administration (2018), *Integrated Addendum to ICH E6 (R1): Guideline for Good Clinical Practice ICH E6 (2) 2016*
https://www.tga.gov.au/publication/note-guidance-good-clinical-practice

8. COLLABORATORS

This SOP was reviewed by:

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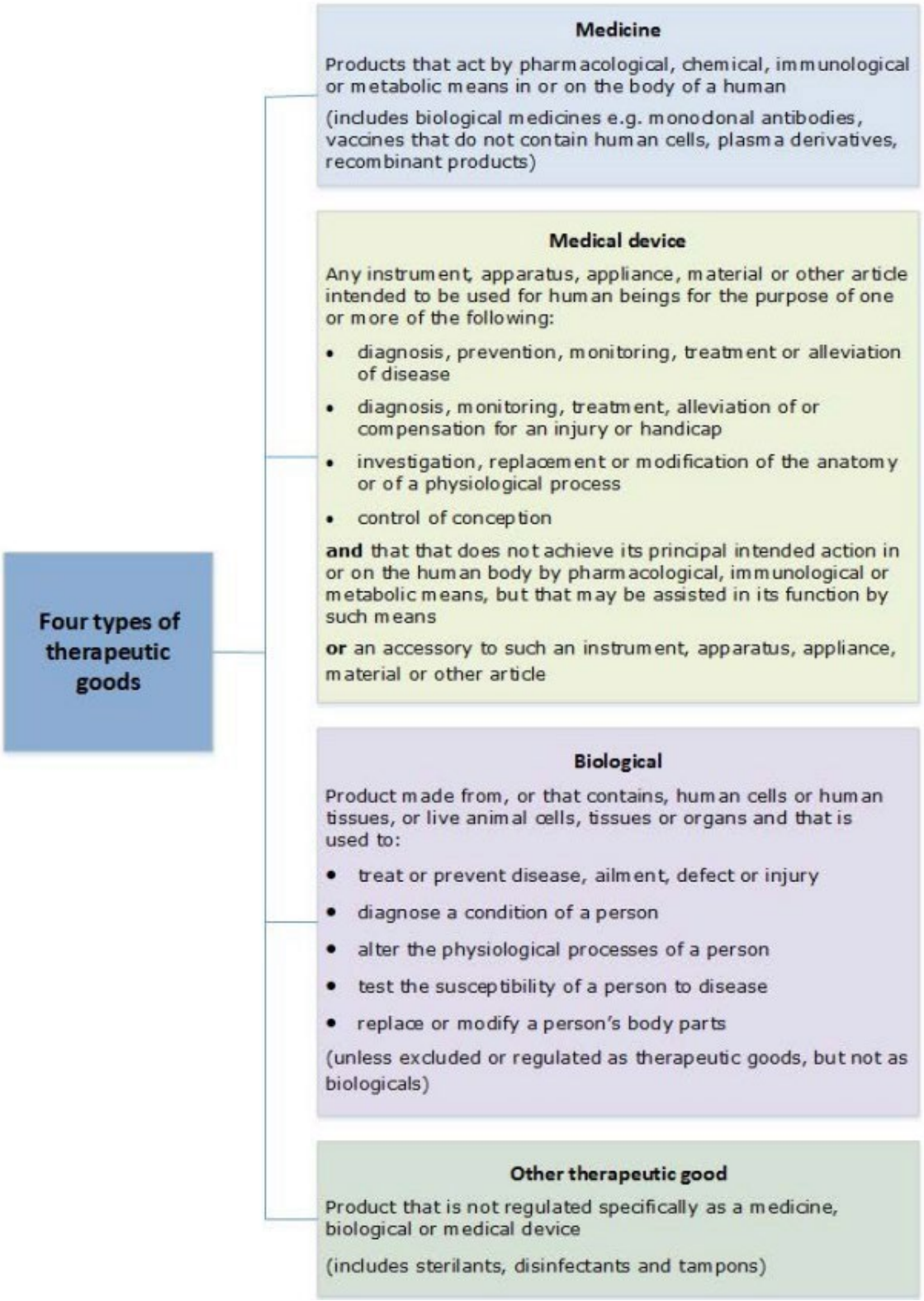
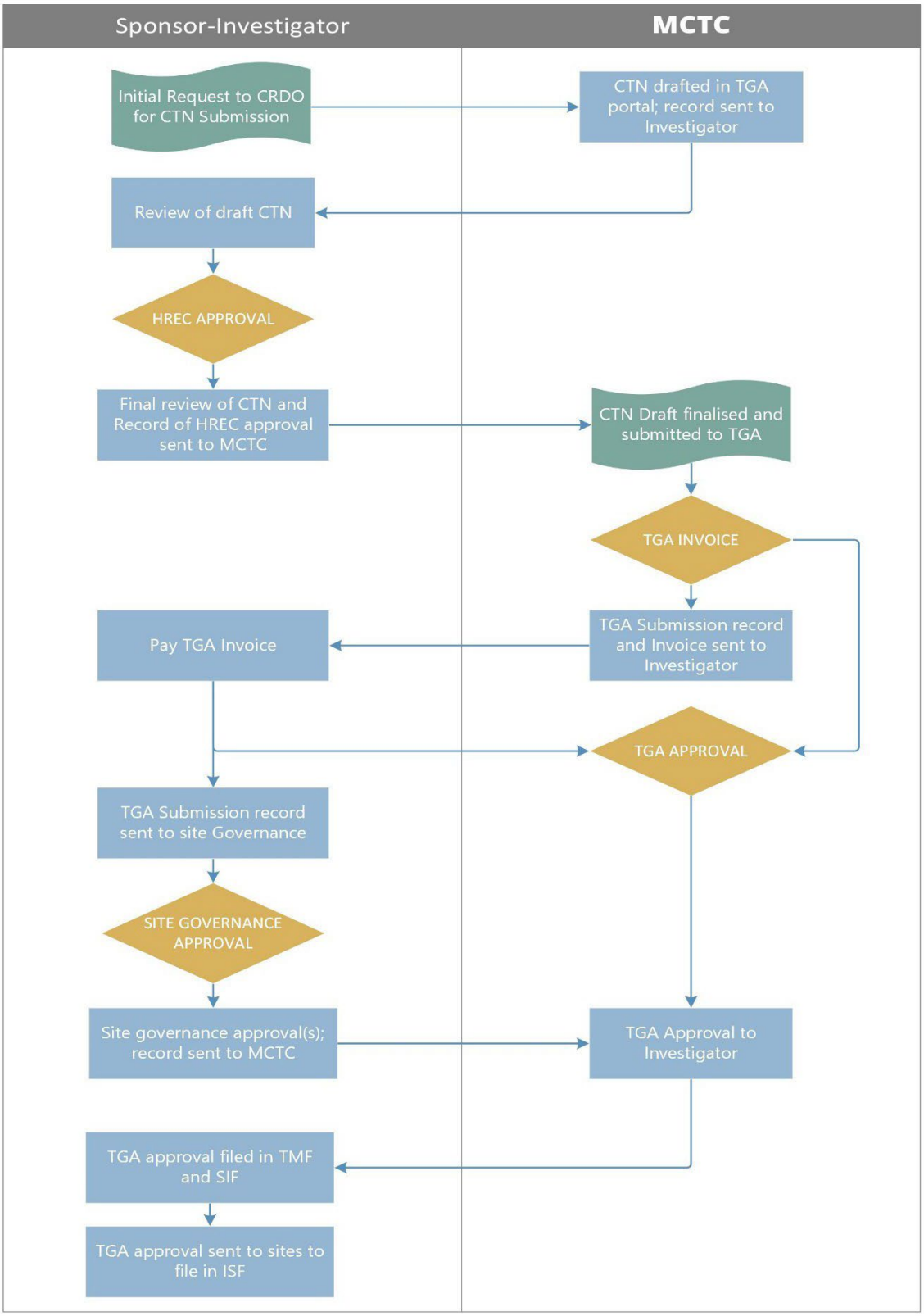
9. APPENDICES

9.1. Appendix 1: Types of Therapeutic Goods



Source: Australian Clinical Trials Handbook

9.2. Appendix 2: Workflow – Submitting and updating a Clinical Trial Notification (CTN) to the TGA



10. RELATED DOCUMENTS

MCTC005 SOP | Safety Monitoring and Reporting Procedure for MCRI-sponsored investigator-Initiated Trials of Medicines/Medical Devices

MCTC016 TEMPLATE | Site Activation Letter

MCTC033 SOP | Regulatory Green Light Approval for Clinical Trial Site Activation MCTC034 TEMPLATE | Regulatory Green Light Approval Form

MCTC037 SOP | Institutional Sponsorship Application and Approval

MCTC065 SOP| Study Start Up for Clinical Trials

DOCUMENT END