Clinical Trial Notification (CTN) Scheme Online Guide

Background

As of 1 July 2015 the Therapeutic Goods Administration (TGA) implemented an online system for lodging Clinical Trial Notification (CTN) forms. The system is accessed through the TGA’s Business Services (TBS).

The TBS requires sponsors to lodge the main details of the study once ethics and site governance approval has been given (as has always been the case) (Appendix 1). Although the hard copy signatures are no longer required to be sent to the TGA there is a requirement (under the Therapeutic Goods Act) that sponsors maintain evidence that the Human Research Ethics Committee (HREC) and site approvals have been obtained.

This document contains instructions on how to draft a CTN online form for research projects where the South Metropolitan Health Service (SMHS) is the sponsor. SMHS may act as the sponsor of a research project when the principal investigator is employed within SMHS (i.e. Fiona Stanley Hospital, Fremantle Hospital, Rockingham Peel Group).

Approving authority details are provided in Appendix 2 to enable sponsors to complete the CTN for SMHS sites once ethics and site governance approvals have been obtained.

Scope

According to the TGA, the CTN and the Clinical Trial Exemption (CTX) Schemes provide avenues by which unapproved therapeutic goods may be lawfully supplied.

An "unapproved good" is one which has not been evaluated by the TGA for quality, safety and effectiveness and therefore does not have marketing approval. Therefore either notification under the CTN Scheme or application under the CTX scheme is required for all clinical investigational use of a product (medicine or device) where the use involves:

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

A comparator (product) is defined in the ICH guidelines as “An investigational or marketed product
(i.e. active control), or placebo, used as a reference in a clinical trial.

If the good being used meets the definition of an ‘unapproved good’ and is being supplied within
the context of a clinical trial then it should be notified on the CTN form.

If the good is considered a medical device and is not on the ARTG, then a CTN exemption must be
in place before it can be supplied to the patient. This applies even if the good is not being
investigated in the trial, but being supplied for use on the patient.

The Therapeutic Goods Act 1989 defines a device as;

41BD What is a medical device

1. A medical device is:
   a) 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:
      i. diagnosis, prevention, monitoring, treatment or alleviation of disease;
      ii. diagnosis, monitoring, treatment, alleviation of or compensation for an injury or
          handicap;
      iii. investigation, replacement or modification of the anatomy or of a physiological
           process;
      iv. 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 that may be assisted in its function
      by such means; or

   b) an accessory to such an instrument, apparatus, appliance, material or other article.

The Therapeutic Goods Act 1989 defines a medicine as:

(a) therapeutic goods (other than biologicals) that are represented to achieve, or are likely to
    achieve, their principal intended action by pharmacological, chemical, immunological or
    metabolic means in or on the body of a human; and

(b) any other therapeutic goods declared by the Secretary, for the purpose of the definition of
    therapeutic device, not to be therapeutic devices.

Written advice from the TGA to SMHS stated that “…the decision as to whether or not the good is a
medical device or medicine lies with the sponsor in consultation with the responsible HREC…” (30
April 2015).

With the implementation of the online CTN Scheme SMHS will be focusing on ensuring that
unapproved goods (e.g. an experimental stent, drugs, or topical agents applied to a wound) that
are the primary intervention are correctly reported to the TGA via the CTN Scheme.
Roles and Responsibilities

For commercially sponsored or Collaborative Research Group (CRG) projects where the commercial company or CRG is the sponsor, the sponsor is responsible for drafting the CTN, submitting the CTN to the TGA and paying the fee.

For investigator-initiated and CRG projects where SMHS is the sponsor, the Principal Investigator (PI) is responsible for contacting the Research Governance Coordinator (RGC) to request a user ID, drafting the CTN and paying the fee. The SMHS RGC is responsible for requesting access for the PI, submitting the CTN to the TGA and forwarding the invoice to the PI for payment.

In all scenarios, at the time the CTN online form is submitted with the TGA an email confirmation should be provided to the SMHS REG unit via the email SMHS.REG@health.wa.gov.au

To complete the CTN online form, it is necessary to provide information for each site regarding the local PI, approving HREC and approving authority details. Please see Appendix 2 for information regarding SMHS HREC and Approving Authority details.

Types of Users

Within the TGA’s online system individuals are assigned system roles of Drafter, Submitter, Financial or Administrator. Individuals can have multiple system roles. The capabilities/access of these system roles varies. Table 1 summarises these capabilities and further information is available at: TGA Business services - how to use the site.

Table 1. Individual capabilities of each user role in TGA Business Services

<table>
<thead>
<tr>
<th>Task / Access</th>
<th>Drafter</th>
<th>Submitter</th>
<th>Financial</th>
<th>Administrator</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dashboard</td>
<td>Yes¹</td>
<td>Yes¹</td>
<td>Yes¹</td>
<td>Yes¹</td>
</tr>
<tr>
<td>News</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Interaction History</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Update my contact details</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Reset my password</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>View drafts and submissions</td>
<td>Yes²</td>
<td>Yes²</td>
<td>No²</td>
<td>No²</td>
</tr>
<tr>
<td>Create new;</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>• Contact</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Organisation address</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Activate / deactivate organisation contact</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Update organisation details</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Assign / modify roles</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>View invoices and make payments</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
</tr>
</tbody>
</table>

¹ Customised for each role
² Multiple Drafters/Submitters for a single Client ID will be able to see drafts/submission of colleagues
Investigator initiated studies where SMHS is the sponsor

The instructions below are for researchers who need to submit a CTN as part of an investigator initiated project where SMHS is the sponsor.

**Obtaining a user ID**

1. Contact your RGO to obtain a user ID.
2. RGO adds the PI as a contact in TGA Business Services.
3. The **TGA emails the PI with a unique user code**.
5. Read the TGA’s Business Services Terms and Conditions (see Appendix 3)

**Drafting a CTN**

2. Enter your login details on the right hand side of the screen (Figure 1).
3. In the dashboard window there are three main menus: **Applications; Documents;** and **Your TGA**. If you also have Financial access, there would be an additional **Financials** menu displayed (Figure 2).

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**Figure 1.** [https://business.tga.gov.au/](https://business.tga.gov.au/)
4. To open an existing draft CTN form, select **Working on drafts** from the **My work** menu (Figure 2). A draft CTN form can be saved at any time (see step 15 below).

5. To begin completing a new CTN form, select the **Applications** menu from the top menu (Figure 2). This will open a list of various application types (Figure 3).

6. Select **Clinical Trial Notification** (Figure 3).

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**Figure 2. Personalised TGA homepage**

![Personalised TGA homepage](image)

**Figure 3. Applications – Clinical Trial Notification**

![Applications – Clinical Trial Notification](image)
7. A blank CTN form is then displayed, starting on the **Application** tab (Figure 4).

8. There are five tabs that make up the CTN form:
   - Application
   - Trial Details
   - Change to Trial Details
   - Completion
   - Validation

   These are located at the top left of the notification form, and you can navigate through the form by clicking on the individual tabs (Figure 4).

9. In the **Application** tab, select the Sponsor name (e.g. Fiona Stanley Hospital) and Sponsor address (e.g. PO Box 404 Bull Creek WA 6149) from the drop down menus.
   - These fields are pre-populated based on the user ID

10. In the **Trial Details** tab fill out the details of the trial (Figure 5).
    - For more information on how to complete each field and sub-section see https://www.tga.gov.au/completing-online-ctn-form
11. The Trial site details sub-form is always at the bottom of the CTN form.

12. Clicking the **Add Site** button will open a pop-up form (Figure 6). For information about the contact details of the SMHS ethics and authorising officers need to complete this section refer to Appendix 1.

   - If one CTN is being submitted for multiple sites it is necessary to have the ethics and authorising details of each individual site.

**Figure 6. Trial Site Details**

13. In the **This Trial** select any check boxes which are relevant to your trial (Figure 7).

   - When selected, most check boxes will open a new sub-section to the form (Figure 8). These will be added to the bottom of the Trial details page and need to be completed.

14. Selecting either **Involves the use of a Medical Device** or **Involves the use of a Therapeutic Device** will enable you to add the device (Figure 8).

15. As part of adding a device the Global Medical Device Nomenclature (GMDN) must be selected (Figure 9). For further information on the GMDN please refer to: [https://www.tga.gov.au/global-medical-device-nomenclature-gmdn](https://www.tga.gov.au/global-medical-device-nomenclature-gmdn)
Figure 7. Adding CTN items

Figure 8. Device Details
16. Save the CTN form by selecting the **Save** button (Figure 10). This will enable you to return to the application at any time.

17. Before an application can be submitted it must first be saved and then validated. The validation process identifies any errors in the draft application.

18. To validate an application select the **Validate** button (Figure 11).

19. Any validation errors will be shown in **Validation** tab (Figure 4)
   - Validation errors must be fixed by the PI before the RGC can further process the application.

20. If returning to a draft CTN more than 24 hours later, it may need to be re-validate before continuing with the submission.

21. Once the draft CTN has no validation errors inform the SMHS RGC that the application is ready for viewing.
Figure 10. Saving an application

Figure 11. Validating an application
Paying the TGA fee

1. Upon receipt of the TGA invoice the PI should organise payment through their Business Manager.
2. Payment methods include credit card, cheque and direct debit. Details on how to pay are available at: [https://www.tga.gov.au/payment-options](https://www.tga.gov.au/payment-options)
3. To ensure all payments are correctly allocated to each account, please include the TGA user ID and the full invoice number of the relevant invoice.
Appendix 1. Flow chart for submitting CTNs online

Commercial or CRG as the sponsor:

1. Sponsor
2. Drafts CTN
3. Sponsor
4. Approves study
5. Submits CTN to TGA
6. Pays fee

SMHS as the sponsor:

1. Smhs Research Governance Coordinator
2. Generates invoice
3. Submits CTN to TGA
4. Approves study
5. Checks CTN
6. Smhs Research Governance Coordinator
7. Drafts CTN
8. Principal investigator
9. Pays fee
Appendix 2. SMHS Details

This document lists the contact details of the South Metropolitan Health Service (SMHS) Human Research Ethics Committee and the research governance officers at SMHS sites as they should be entered into the CTN online form.

If you have any queries, please contact:

**Department of Human Research Ethics and Governance**
**South Metropolitan Health Service**
(08) 6151 1180
SMHS.REG@health.wa.gov.au

**Human Research Ethics Committee**
HREC Name: South Metropolitan Health Service HREC
HREC Code: EC00265
HREC Contact Officer: Wendy Khoo
Position: Ethics Coordinator
Contact Phone: (08) 6151 1180
Contact Email: SMHS.REG@health.wa.gov.au

**Approving Authority Details for SMHS sites**

Name of Approving Authority: Fiona Stanley Hospital
Contact Officer: Nola Mammatt
Position: Research Governance Coordinator
Contact Phone: (08) 6151 1180
Contact Email: SMHS.REG@health.wa.gov.au

Name of Approving Authority: Fremantle Hospital and Health Service
Contact Officer: Cathy Gartner
Position: Research Governance Coordinator
Contact Phone: (08) 6151 1180
Contact Email: SMHS.REG@health.wa.gov.au

Name of Approving Authority: Rockingham Peel Group

Contact Officer: Cathy Gartner

Position: Research Governance Coordinator

Contact Phone: (08) 6151 1180

Contact Email: SMHS.REG@health.wa.gov.au

Please note, for the purposes of Human Research Ethics and Governance, the Peel Health Campus is not included within the Rockingham Peel Group.
Appendix 3. TBS Terms and Conditions

TGA Business Services (TBS) Terms and Conditions

28 April 2015

Any use of the Service by you or any user is subject to these terms and conditions of use:

Acceptance of these terms and conditions

1. You will be taken to have accepted these Service terms and conditions, when you or any user first uses the Service.

Administrator

2. A single user will be established within the TBS by the TGA and assigned the role of Administrator. The user with the role of Administrator for a specific organisation will be able to establish other users within the TBS and assign them roles; Financial, Submitter, Drafter. The administrator will also facilitate access for those users.

3. The TBS Administrator is responsible for the establishment and management of all users for the specific organisation that the Administrator represents. The TBS Administrator must ensure that all TBS Users within the organisation are aware of, and comply with, the terms and conditions for use of their access to TBS. The organisation is responsible for any electronic transactions made by the TBS Administrator or by a TBS user created by the TBS Administrator.

Other terms and conditions

4. These terms and conditions are in addition to any terms and conditions agreed to as part of completing the Client Details form and to the extent of any inconsistency between the two, these terms and conditions will prevail.

Changes to the Service

5. TGA may change the functionality or content of the Service or withdraw or
deny access to the Service at any time without prior notice.

**Access to the Service**

6. You agree that TGA will give access to the Service to anyone who uses a valid identification and password.

**Security of passwords and information**

7. You agree to keep your passwords safe and secure. In particular you agree:
   - not to tell any person your password or allow any person to observe as you enter the password;
   - if you write down or store your password, you are responsible for keeping the record secure and protected. We advise you to keep any record of your User ID and password separate from each other.

8. You agree to change your password the first time you use the Service and at frequent intervals thereafter. We strongly recommend that you do not use an obvious password such as a dictionary word, name, date or vehicle details or any other combination that is directly associated with yourself.

9. You agree to immediately tell TGA if you suspect the security of a User ID or password has been compromised. TGA may cancel the use of your access for the Service at any time without notice if we believe the access is being used, or will be used, in a way that will cause losses to you or to TGA.

10. We will take such reasonable precautions as may be necessary to ensure that information concerning your organisation transmitted by us through the Service will remain confidential and protected from unauthorised access but we will not be liable for any unauthorised access by any means to that information.

**Contact details**

11. It is your responsibility to keep your contact details, including email addresses, up to date. You agree that TGA may send emails to you at the email addresses recorded by you in the Service.

**Liability**

12. You acknowledge that, subject to your rights implied at law which cannot be excluded, we will not be liable for any loss or damage in connection with any use of the Service unless the loss or damage is directly attributable to our fraudulent or negligent conduct.
Changes to these terms and conditions

13. TGA may change these terms and conditions at any time. We must notify you of any such changes.

Termination

14. TGA may terminate the Service at any time without notice to you.

Interpretation

15. We, us means TGA.

16. You, organisation means the person, persons or body in relation to which an ‘organisation’ record has been established in TGA Business Services and includes, where the context permits, the Administrator and any other user.

17. TGA Business Services, TBS or Service refers to the service, which you access via the Internet. This facility allows you to obtain information regarding your entries in the Australian Register of Therapeutic Goods, applications that you have made to the TGA, to carry out transactions on your own applications and to update your contact information.

18. User - any person You permit to access TBS, whether Administrator or other user.

Tags: tbs, terms
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