



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 Notifications (CTN) forms. The system is accessed through the TGA's Business Services.

The online system 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 SMHS is the sponsor.

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.

Research Support & Development Unit

Telephone: (08) 6152 8224

Email: SMHS.RGO@health.wa.gov.au

www.southmetropolitan.health.wa.gov.au

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 Research Support and Development Unit via the email SMHS.RGO@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 system roles](#).

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

Task / Access	Drafter	Submitter	Financial	Administrator
Dashboard	Yes ¹	Yes ¹	Yes ¹	Yes ¹
News	Yes	Yes	Yes	Yes
Interaction History	Yes	Yes	Yes	Yes
Update my contact details	Yes	Yes	Yes	Yes
Reset my password	Yes	Yes	Yes	Yes
View drafts and submissions	Yes ²	Yes ²	No ²	No ²
Create new;	No	No	No	Yes
• Contact				
• Organisation address				
Activate / deactivate organisation contact	No	No	No	Yes
Update organisation details	No	No	No	Yes
Assign / modify roles	No	No	No	Yes
View invoices and make payments	No	No	Yes	No

¹Customised for each role

²Multiple 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 a researcher initiated project where SMHS is the sponsor.

Obtaining a user ID

1. Contact your RGC to obtain a user ID.
2. RGC adds the PI as a contact.
3. The TGA emails the PI with a unique user code.
4. PI has **24 hours** to log into the TGA Business Services website (<https://business.tga.gov.au/>) and change their password.
5. Read the TGA's Business Services Terms and Conditions (see Appendix 3)

Drafting a CTN

1. Go to the secure online TGA Business Services site at <https://business.tga.gov.au/>
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).

Figure 1. [www.business.tga.gov.au](https://business.tga.gov.au/)

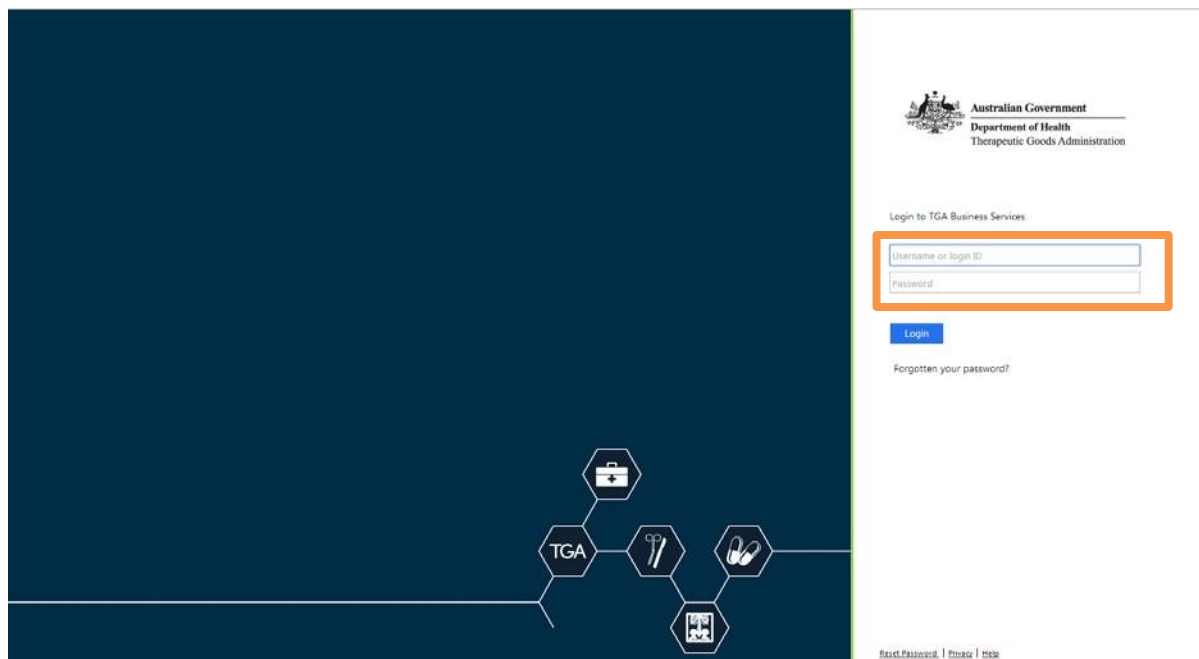
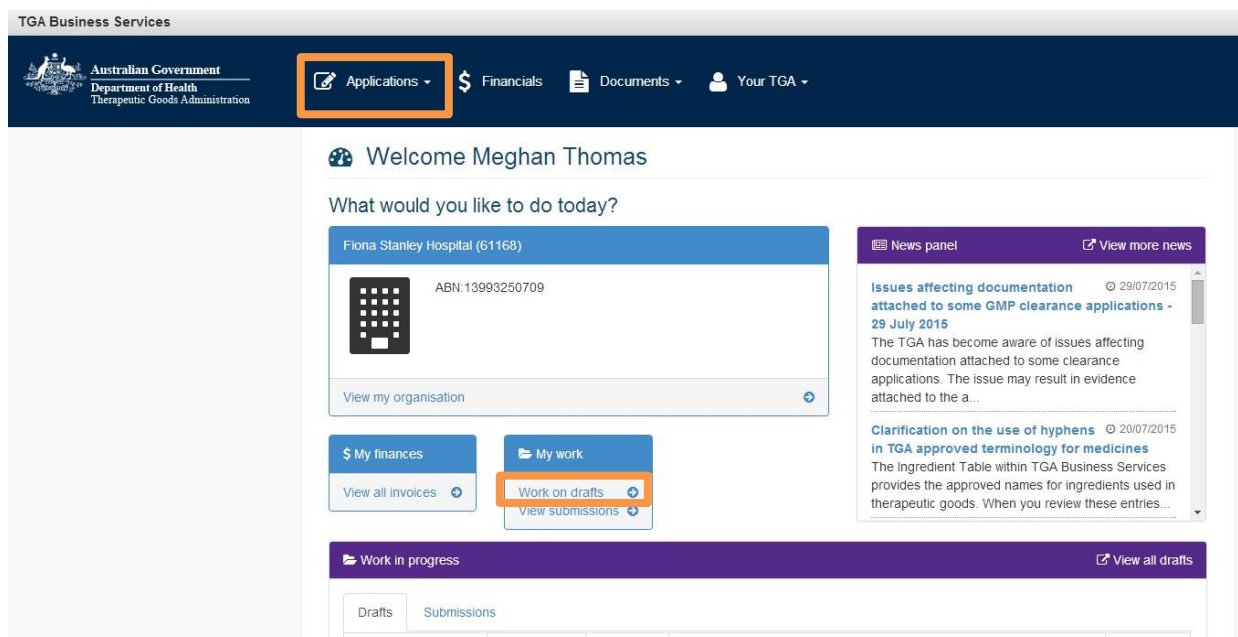


Figure 2. Personalised TGA homepage



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).

Figure 3. Applications – Clinical Trial Notification

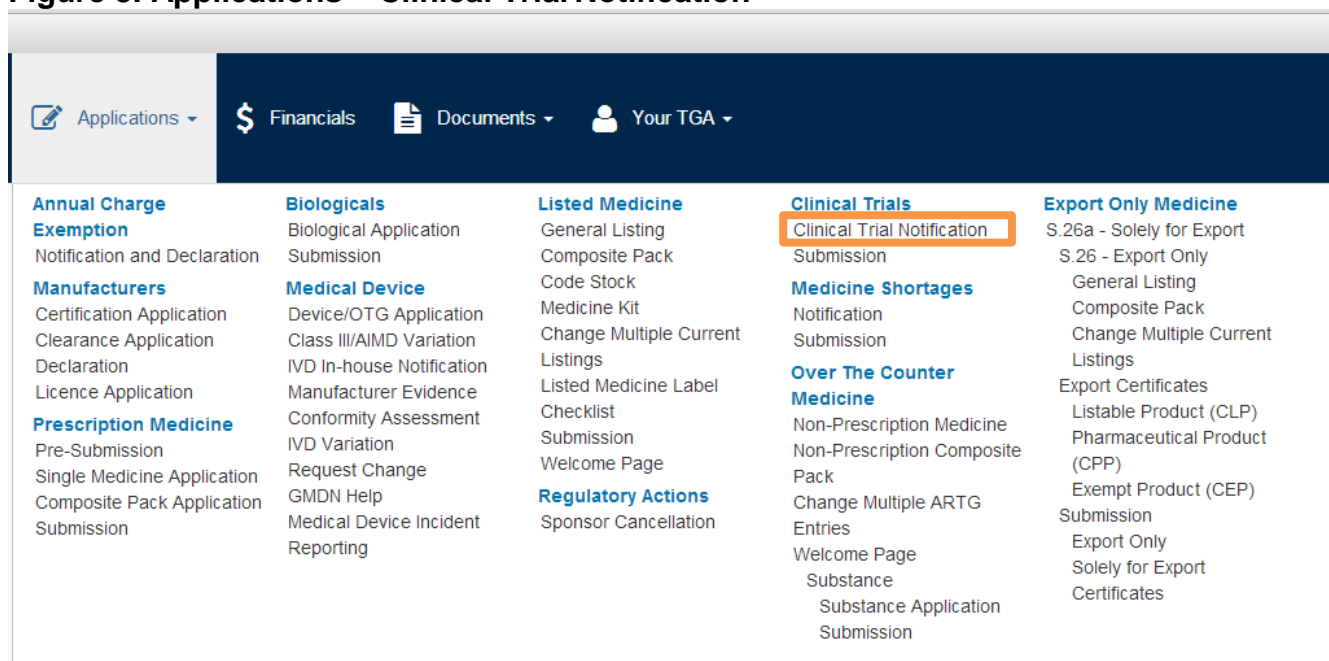


Figure 4. Application tab

The screenshot shows the 'Application' tab of the TGA eBusiness Services Clinical Trial Notification form. At the top left is the TGA logo and 'Clinical Trial Notification' text. To the right, it displays 'Application ID: CT-2015-CTN-01185-1 v.1', 'Status: Draft', and 'Loaded'. Below this are buttons for 'Close', 'Save', 'Validate', 'Print Preview', and 'Please Read'. A 'Client Reference' field contains the text 'Reference for Client use only'. The 'Application' tab is highlighted with an orange box. Below the tabs, there are three dropdown menus: 'Sponsor Name' (pre-filled with 'Fiona Stanley Hospital'), 'Sponsor Address' (with a placeholder 'Select a Sponsor then addresses will be selectable...'), and 'Notification Fee' (empty).

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>

Figure 5. Trial Details tab

The screenshot shows the 'Trial Details' tab of the TGA eBusiness Services Clinical Trial Notification form. The 'Application' tab is also visible. The 'Trial Details' section includes: 'Contact Name' (eg: Joan Johnson), 'Contact Phone Number' (eg: 0987654321), 'Contact Email' (email.address@domain.com.au), and 'Confirm Email' (email.address@domain.com.au). Below this is the 'Trial Details' section with fields for 'Protocol Number', 'Expected Trial Start Date' (22/04/1931), 'Expected Completion Date' (19/12/1990), and 'Potential use of restricted goods' (radio buttons for Yes/No). The 'Title of Study' field has a placeholder 'Enter the title of the study here ...'. The 'Trial Type' section has checkboxes for Phase 1, Phase 2, Phase 3, Phase 4, Bioavailability/Bioequivalence, and Device. A 'Description (if necessary)' field is also present. The 'This Trial' section has checkboxes for various characteristics: 'Involves Animal excipients', 'Involves the use of a Medicine', 'Involves the use of a Therapeutic Device', 'Is placebo controlled', 'Involves a Genetically Modified Organism', 'Is a multicentre trial', 'Is being conducted in other countries', 'Involves the use of a Biological', 'Involves the use of a Medical Device', 'Is comparator controlled', 'Involves gene therapy', and 'Has relevant preceding trials'. At the bottom, there are 'Total Number of Patients to be Enrolled in Trial' and 'Therapeutic Area' dropdown menus. The 'Trial Site Details' section has 'Add Site' and 'Remove Selected Site(s)' buttons. A table at the bottom has columns for 'Site', 'Site Address', 'State', and 'Principal Inves'.

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

The screenshot shows a web form titled "Site Details" with a close button (x) in the top right corner. The form is organized into four main sections, each with a title and a red asterisk indicating a required field:

- Site Details:**
 - Site * (text input)
 - Site Address * (text input with placeholder: "Enter Site address (physical location)")
 - Location * (dropdown menu with placeholder: "Select a State/Territory from drop down list")
 - Expected Site Start Date * (text input with value: "22/04/1931")
- Principal Investigator Details:**
 - Name * (text input with placeholder: "Please specify a Principal Investigator Name")
 - Contact Phone Number * (text input with placeholder: "eg: 0987654321")
 - Contact Email * (text input with placeholder: "email.address@domain.com.au")
- Human Research Ethics Committee (HREC) Details:**
 - HREC Name * (text input with placeholder: "Please specify an HREC Name")
 - HREC Code * (text input with placeholder: "Please enter a HREC")
 - HREC Contact Officer * (text input with placeholder: "Please specify an HREC Contact Officer")
 - Position * (text input with placeholder: "Please specify a position")
 - Contact Phone * (text input with placeholder: "eg: 0987654321")
 - Contact Email * (text input with placeholder: "email.address@domain.com.au")
- Approving Authority Details:**
 - Name of Approving Authority * (text input with placeholder: "Please enter the Approving Authority Name")
 - Approving Authority Contact Officer * (text input with placeholder: "Please specify a contact name")
 - Position * (text input with placeholder: "Please specify a position")
 - Contact Phone * (text input with placeholder: "eg: 0987654321")
 - Contact Email * (text input with placeholder: "email.address@domain.com.au")

At the bottom left of the form, there are two buttons: "Add Site" (highlighted with an orange border) and "Close".

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>

Figure 7. Adding CTN items

TGA eBusiness Services Clinical Trial Notification

Close Save Validate Print Preview Please Read

Application Trial Details Change to Trial Details Completion Validation

Contact Name * eg: Joan Johnson
Contact Phone Number * eg: 0987654321
Contact Email * email.address@domain.com.au
Confirm Email * email.address@domain.com.au

Trial Details

Protocol Number *
Expected Trial Start Date * 22/04/1931
Expected Completion Date * 19/12/1990
Potential use of restricted goods Yes No
Title of Study * Enter the title of the study here ...
Trial Type * Phase 1 Phase 2 Phase 3 Phase 4 Bioavailability/Bioequivalence Device
Description (if necessary)
This Trial *
 Involves Animal excipients Is being conducted in other countries
 Involves the use of a Medicine Involves the use of a Biological
 Involves the use of a Therapeutic Device Involves the use of a Medical Device
 Is placebo controlled Is comparator controlled
 Involves a Genetically Modified Organism Involves gene therapy
 Is a multicentre trial Has relevant preceding trials
Total Number of Patients to be Enrolled in Trial
Therapeutic Area *

Biologicals / Devices / Medicine Details

Device Details * Add Device Remove Selected Device(s)

Product Name	Manufacturer	Description
Devices Details		

Trial Site Details * Add Site Remove Selected Site(s)

Figure 8. Device Details

The screenshot shows a 'Device Details' window with the following fields and options:

- Product Name ***: Text input field with placeholder text 'Enter Product name (trade name if applicable)' and a red warning icon.
- Is this a: ***: Radio button options: Single Device, System, Procedure Pack, Software.
- Manufacturer ***: Text input field with placeholder text 'Enter the Name of the Manufacturer for this Device'.
- GMDN ***: Dropdown menu.
- Description ***: Text input field.
- Intended Purpose ***: Radio button options: Comparator, Investigational Product, Standard Care Therapy, Other.
- If 'Other' please provide a ***: Text input field with placeholder text 'description'.

At the bottom, there are two buttons: 'Add Device' (highlighted with an orange box) and 'Close'.

Figure 9. GMDN selection

The screenshot shows the 'Device Details' window with the GMDN dropdown menu open. The menu lists various medical device categories with their corresponding GMDN codes:

- Abacus (30056)
- Abdominal aorta endovascular stent-graft deployment aid (56295)
- Abdominal aortic aneurysm stent (46777)
- Abdominal binder (32234)
- Abdominal binder. reusable (47217)
- Abdominal binder. single-use (10003)
- Abdominal decompression chamber pump (35283)
- Abdominal fluid shunt system (47551)
- Abdominal hernia surgical mesh. collagen. antimicrobial (61107)
- Abdominal hernia surgical mesh. composite-polymer (44756)
- Abdominal hernia surgical mesh. synthetic polymer (60300)
- Abdominal hernia surgical mesh. synthetic polymer. antimicrobial (46200)
- Abdominal hernia truss. reusable (47218)
- Abdominal hernia truss. single-use (30883)
- Abdominal paracentesis needle. reprocessed (46011)
- Abdominal public health screening x-ray system (37675)
- Abdominal radial retractor (47431)
- Abdominal radial retractor seal cap (47432)
- Abdominal retractor. self-retaining. non-fixed (46481)
- Abdominal trocar (46899)
- Abdominal/thoracic port/catheter (61492)
- Abortion suction system. electric (55839)
- Abortion suction system. vacuum (55840)

The 'Add Device' and 'Close' buttons are visible at the bottom left of the form.

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



The screenshot shows the 'TGA eBusiness Services Clinical Trial Notification' interface. At the top, there are five buttons: 'Close', 'Save', 'Validate', 'Print Preview', and 'Please Read'. The 'Save' button is highlighted with an orange border. Below the buttons is a tabbed interface with tabs for 'Application', 'Trial Details', 'Change to Trial Details', 'Completion', and 'Validation'. The 'Application' tab is active. The form contains three input fields: 'Sponsor Name *' with the value 'Fiona Stanley Hospital', 'Sponsor Address *' with the placeholder text 'Select a Sponsor then addresses will be selectable...', and 'Notification Fee' which is currently empty.

Figure 11. Validating an application



The screenshot shows the same 'TGA eBusiness Services Clinical Trial Notification' interface as Figure 10. In this view, the 'Validate' button is highlighted with an orange border. The rest of the form, including the tabs and input fields, remains the same as in Figure 10.

Figure 12. Validation errors

The screenshot shows the TGA eBusiness Services Clinical Trial Notification interface. At the top, there are buttons for 'Close', 'Save', 'Validate', 'Print Preview', and 'Please Read'. Below these are tabs for 'Application', 'Trial Details', 'Change to Trial Details', 'Completion', and 'Validation'. The 'Validation' tab is selected and highlighted with an orange box. Below the tabs, there is a text label: 'List of validation messages as of last submission for validation.' Below this is a table with a header 'Error Message' and several rows of error messages, all for trial ID 'CT-2015-CTN-01185-1'. The table is also highlighted with an orange border.

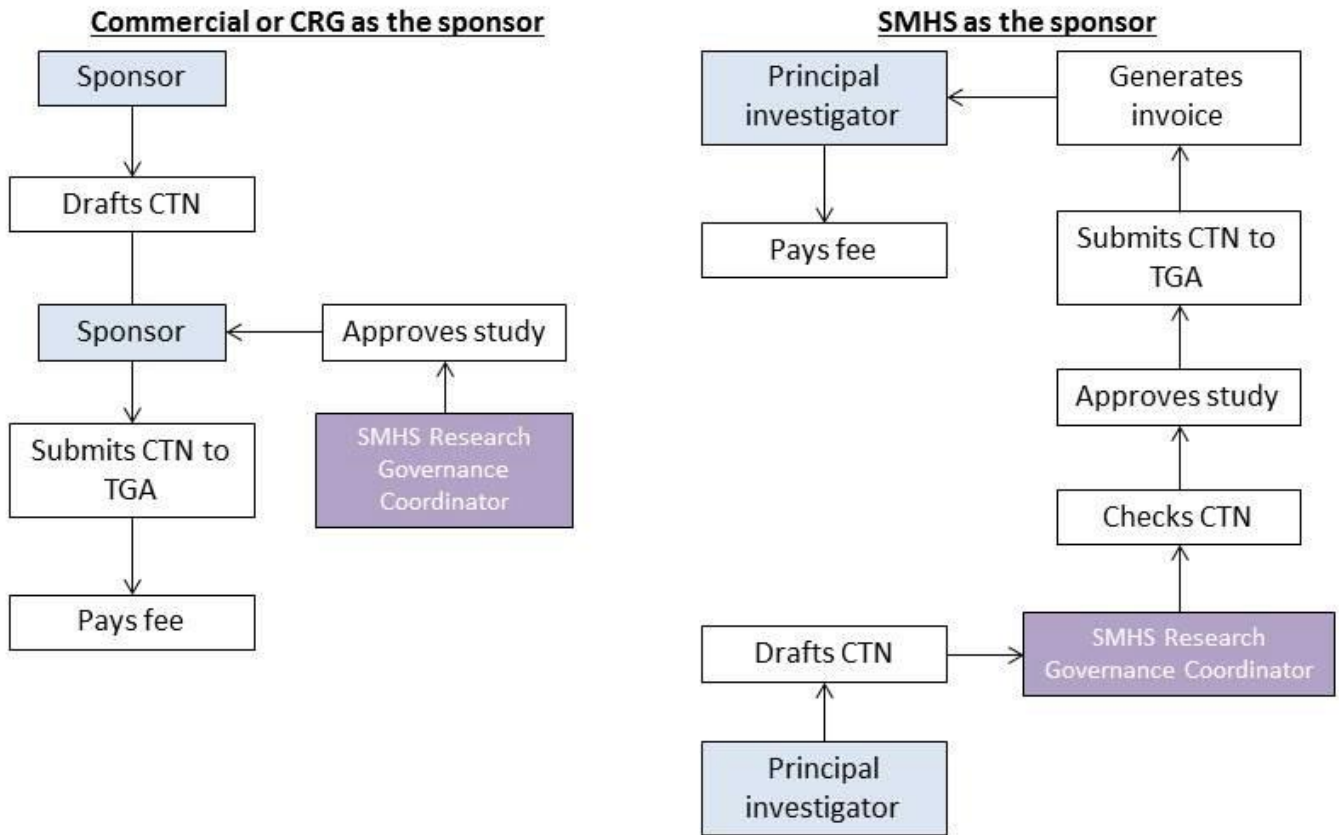
Error Message
(Expected Completion Date) is mandatory in Trial Details: CT-2015-CTN-01185-1
(Potential Use of Restricted Good) is mandatory in Trial Details: CT-2015-CTN-01185-1
(Contact Name) is mandatory in Trial Details: CT-2015-CTN-01185-1
(The contact phone number is invalid) in Trial Details: CT-2015-CTN-01185-1
(Please select a Total Patients) in Trial Details: CT-2015-CTN-01185-1
(Title of Study) is mandatory in Trial Details: CT-2015-CTN-01185-1
Site information is mandatory in Trial Details : CT-2015-CTN-01185-1
(Expected Trial Start Date) is mandatory in Trial Details: CT-2015-CTN-01185-1
(Trial Type) is mandatory in Trial Details: CT-2015-CTN-01185-1
(Please provide details of the Protocol Number.) in Trial Details: CT-2015-CTN-01185-1
(Contact Phone) is mandatory in Trial Details: CT-2015-CTN-01185-1
(The contact email is not a valid address) in Trial Details: CT-2015-CTN-01185-1
(Please select a Trial Therapeutic Area) in Trial Details: CT-2015-CTN-01185-1

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>
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.
4. Current fee as of 1 July 2020 is \$380.00 for each notification of one or more additional sites.

1.

Appendix 1. Flow chart for submitting CTNs online



Appendix 2 – Contact details of SMHS ethics and governance officers for CTN Scheme Online Form

This document lists the contact details of South Metropolitan Health Service (SMHS) ethics and governance officers as they should be entered into the CTN online form for research conducted at SMHS sites, and/or under the approval of a SMHS HREC.

If you have any queries, please contact:

SMHS Research Support and Development Unit

(08) 6152 8224

SMHS.RGO@health.wa.gov.au

Human Research Ethics Committee

HREC Name: South Metropolitan Health Service HREC

HREC Code: EC00265

HREC Contact Officer:

Natalie Giles

Position: Ethics Coordinator

Contact Phone: (08) 6152 2064

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

Approving Authority Details for SMHS sites

Fiona Stanley Hospital

Name of Approving Authority: Fiona Stanley Hospital

Contact Officer: Catherine Gartner

Position: Research Governance Coordinator

Contact Phone: (08) 6152 8224

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

Fremantle Hospital & Health Service

Name of Approving Authority: Fremantle Hospital and Health Service

Contact Officer: Catherine Gartner

Position: Research Governance Coordinator

Contact Phone: (08) 6152 8224

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

Rockingham/Kwinana Health Service

Name of Approving Authority: Rockingham Peel Group

Contact Officer: Catherine Gartner

Position: Research Governance Coordinator

Contact Phone: (08) 6152 8224

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

Appendix 3 – TGA Business Services (TBS) Terms and Conditions

8/24/2015

TGA Business Services (TBS) Terms and Conditions | Therapeutic Goods Administration (TGA)



Australian Government
Department of Health
Therapeutic Goods Administration

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:
 - o not to tell any person your password or allow any person to observe as you enter the password;
 - o 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

Content last updated: Tuesday, 28 April 2015

URL: <https://www.tga.gov.au/node/537241> ([//www.tga.gov.au/tga-business-services-tbs-terms-and-conditions](https://www.tga.gov.au/tga-business-services-tbs-terms-and-conditions))

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