Therapeutic Goods (Clinical Trial Notification Form) Approval 2024

I, Claire Larter, as a delegate of the Secretary of the Department of Health and Aged Care, make the following approval.

Dated 20 August 2024

Claire Larter
Acting Assistant Secretary
Pharmacovigilance Branch
Health Products Regulation Group
Department of Health and Aged Care

Contents

1 Name

This instrument is the *Therapeutic Goods (Clinical Trial Notification Form) Approval 2024*.

2 Commencement

(1) Each provision of this instrument specified in column 1 of the table commences, or is taken to have commenced, in accordance with column 2 of the table. Any other statement in column 2 has effect according to its terms.

Commencement information		
Column 1	**Column 2**	**Column 3**
Provisions	**Commencement**	**Date/Details**
1. The whole of this instrument	The day after this instrument is made.	

Note: This table relates only to the provisions of this instrument as originally made. It will not be amended to deal with any later amendments of this instrument.

(2) Any information in column 3 of the table is not part of this instrument. Information may be inserted in this column, or information in it may be edited, in any published version of this instrument.

3 Authority

This instrument is made under the following provisions:

(a) paragraphs (a) and (ha) in column 3 of item 3 in Schedule 5A to the *Therapeutic Goods Regulations 1990*;

(b) paragraphs (a) and (h) in column 3 of item 2.3 in Part 2 of Schedule 4 to the *Therapeutic Goods (Medical Devices) Regulations 2002*.

4 Definitions

Note: A number of expressions used in this instrument are defined in subsection 3(1) of the Act, including the following:

(a) medical device;

(b) therapeutic goods.

In this instrument:

Act means the *Therapeutic Goods Act 1989.*

MD Regulations means the *Therapeutic Goods (Medical Devices) Regulations 2002*.

Regulations means the *Therapeutic Goods Regulations 1990*.

TGA Business Services means the TGA Business Services portal, accessed via the Therapeutic Goods Administration website.

Note: The Therapeutic Goods Administration website can be accessed at www.tga.gov.au.

Therapeutic Goods Administration, or ***TGA***, means the part of the Department known as the Therapeutic Goods Administration.

5 Approved form–clinical trial

For the purposes of:

(a) paragraph (a) in column 3 of item 3 in Schedule 5A to the Regulations; and

(b) paragraph (a) in column 3 of item 2.3 in Part 2 of Schedule 4 to the MD Regulations;

the approved form for notifying the Secretary of a clinical trial, and the therapeutic goods covered by the trial, is the online form titled *Clinical Trial Notification*, accessed via the *Clinical Trial Notification* item, under the *Clinical Trials* heading, within the *Create Applications & Submissions* section of the sponsor portal of TGA Business Services.

6 Approved form–additional trial site

For the purposes of:

(a) paragraph (ha) in column 3 of item 3 in Schedule 5A to the Regulations; and

(b) paragraph (h) in column 3 of item 2.3 in Part 2 of Schedule 4 to the MD Regulations;

the approved form for notifying the Secretary of an additional trial site is the *Change to Trial Details* section of the online form titled *Clinical Trial Notification*, accessed by selecting 'Vary' in relation to the relevant clinical trial in the *Clinical Trials Repository* link, under the *Your TGA Information* heading, within the sponsor portal of TGA Business Services.