Therapeutic Goods (Clinical Trial Inspections) Specification (No. 2) 2020

I, Tracey Duffy, as delegate of the Minister for Health, make the following specification.

Dated 12 August 2020

Tracey Duffy
First Assistant Secretary
Medical Devices and Product Quality Division
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1 Name

This instrument is the *Therapeutic Goods (Clinical Trial Inspections) Specification (No. 2) 2020*.

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 registered.	

Note: This table relates only to the provisions of this instrument as originally made.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 subsection 61(5AB) of the *Therapeutic Goods Act 1989*.

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) Secretary; and
(c) therapeutic goods.

In this instrument:

Act means the *Therapeutic Goods Act 1989*.

approving authority, in relation to a clinical trial of therapeutic goods, means a person, body or organisation:

(a) at whose site the clinical trial, or part of the clinical trial, is being conducted; and

(b) who is responsible for the governance of the clinical trial, other than in relation to those matters within the remit of the responsible ethics committee, at that site.

authorised officer has the same meaning as in the Regulations.

National Statement means the *National Statement on Ethical Conduct in Human Research* published by the National Health and Medical Research Council, as in force or existing at the commencement of this instrument.

Note: The National Statement is published on the internet at www.nhmrc.gov.au.

Practice Guideline means the *Integrated Addendum to ICH E6(R1): Guideline for Good Clinical Practice E6(R2)* published by the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), as in force or existing at the commencement of this instrument.

Note: The Practice Guideline is published on the internet at www.ich.org and may be accessed through www.tga.gov.au.

procedural protocol, otherwise known as trial protocol, in relation to a clinical trial of therapeutic goods, means the protocol that describes the objectives, design, methodology, statistical considerations and organisation of the clinical trial.

Regulations means the *Therapeutic Goods Regulations 1990*.

relevant authorised officer, in relation to a clinical trial of therapeutic goods, means the authorised officer who has exercised powers in accordance with regulation 12AC of the Regulations in relation to the clinical trial.

responsible ethics committee, in relation to a clinical trial of therapeutic goods, means the ethics committee that is responsible for approving the procedural protocol and monitoring the conduct of the clinical trial at each trial site.

Therapeutic Goods Administration has the same meaning as in the Regulations.

therapeutic goods information has the meaning given by subsection 61(1) of the Act.

5 Release of therapeutic goods information

For subsection 61(5AA) of the Act, in relation to each item, the kinds of therapeutic goods information specified in column 2 of the table in Schedule 1, may be released to the kinds of persons or bodies specified in column 3, for the purpose specified in column 4 of that table.

Note: Under subsection 61(5AA) of the Act, the Secretary may release to a person or body that is specified under subsection 61(5AB), specified kinds of therapeutic goods information for a specified purpose.

6 Repeals

Each instrument that is specified in Schedule 2 is repealed as set out in the applicable items in that Schedule.

Schedule 1—Therapeutic goods information

Note: See section 5.

Therapeutic goods information that may be released			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Kinds of information**	**Kinds of persons or bodies**	**Purpose**
1	in relation to a clinical trial of therapeutic goods, other than medical devices (the ***relevant trial***), information about the conduct of the relevant trial that has been obtained by a relevant authorised officer, including information that relates to compliance of the relevant trial with: (a) the National Statement; (b) the procedural protocol; (c) the Practice Guideline	the following persons or bodies in relation to the relevant trial: (a) the approving authority; (b) the responsible ethics committee	to ensure that clinical trials are conducted in a safe and lawful manner, including in accordance with applicable ethics and good clinical practice considerations

Schedule 2—Repeals

Note: See section 6.

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1 The whole of the instrument

Repeal the instrument.