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

made under subsection 61(5AB) of the

Therapeutic Goods Act 1989

Compilation No. 1

Compilation date: 19 September 2024

Includes amendments: F2024L01177

Prepared by the Department of Health and Aged Care, Canberra

About this compilation

This compilation

This is a compilation of the *Therapeutic Goods (Clinical Trial Inspections) Specification (No. 2) 2020* that shows the text of the law as amended and in force on 19/09/2024 (the ***compilation date***).

The notes at the end of this compilation (the ***endnotes***) include information about amending laws and the amendment history of provisions of the compiled law.

Uncommenced amendments

The effect of uncommenced amendments is not shown in the text of the compiled law. Any uncommenced amendments affecting the law are accessible on the Register (www.legislation.gov.au). The details of amendments made up to, but not commenced at, the compilation date are underlined in the endnotes. For more information on any uncommenced amendments, see the Register for the compiled law.

Application, saving and transitional provisions for provisions and amendments

If the operation of a provision or amendment of the compiled law is affected by an application, saving or transitional provision that is not included in this compilation, details are included in the endnotes.

Modifications

If the compiled law is modified by another law, the compiled law operates as modified but the modification does not amend the text of the law. Accordingly, this compilation does not show the text of the compiled law as modified. For more information on any modifications, see the Register for the compiled law.

Self-repealing provisions

If a provision of the compiled law has been repealed in accordance with a provision of the law, details are included in the endnotes.

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1 Name

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

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.

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

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:

(a) the authorised officer who has exercised powers in accordance with regulation 12AC of the Regulations in relation to the clinical trial; or

(b) the authorised person who has exercised powers in accordance with regulation 7.4 of the MD 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.

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 (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

Endnotes

Endnote 1—About the endnotes

The endnotes provide information about this compilation and the compiled law.

The following endnotes are included in every compilation:

Endnote 1—About the endnotes
Endnote 2—Abbreviation key
Endnote 3—Legislation history
Endnote 4—Amendment history

Abbreviation key—Endnote 2
The abbreviation key sets out abbreviations that may be used in the endnotes.

Legislation history and amendment history—Endnotes 3 and 4
Amending laws are annotated in the legislation history and amendment history.

The legislation history in endnote 3 provides information about each law that has amended (or will amend) the compiled law. The information includes commencement details for amending laws and details of any application, saving or transitional provisions that are not included in this compilation.

The amendment history in endnote 4 provides information about amendments at the provision (generally section or equivalent) level. It also includes information about any provision of the compiled law that has been repealed in accordance with a provision of the law.

Misdescribed amendments
A misdescribed amendment is an amendment that does not accurately describe how an amendment is to be made. If, despite the misdescription, the amendment can be given effect as intended, then the misdescribed amendment can be incorporated through an editorial change made under section 15V of the *Legislation Act 2003*.

If a misdescribed amendment cannot be given effect as intended, the amendment is not incorporated and "(md not incorp)" is added to the amendment history.

Endnote 2—Abbreviation key

ad = added or inserted

am = amended

amdt = amendment

c = clause(s)

C[x] = Compilation No. x

Ch = Chapter(s)

def = definition(s)

Dict = Dictionary

disallowed = disallowed by Parliament

Div = Division(s)

exp = expires/expired or ceases/ceased to have effect

F = Federal Register of Legislation

gaz = gazette

LA = *Legislation Act 2003*

LIA = *Legislative Instruments Act 2003*

(md not incorp) = misdescribed amendment cannot be given effect

mod = modified/modification

No. = Number(s)

o = order(s)

Ord = Ordinance

orig = original

par = paragraph(s)/subparagraph(s) /sub-subparagraph(s)

pres = present

prev = previous

(prev…) = previously

Pt = Part(s)

r = regulation(s)/rule(s)

reloc = relocated

renum = renumbered

rep = repealed

rs = repealed and substituted

s = section(s)/subsection(s)

Sch = Schedule(s)

Sdiv = Subdivision(s)

SLI = Select Legislative Instrument

SR = Statutory Rules

Sub-Ch = Sub-Chapter(s)

SubPt = Subpart(s)

underlining = whole or part not commenced or to be commenced

Endnote 3—Legislation history

Name	Registration	Commencement	Application, saving and transitional provisions
Therapeutic Goods (Clinical Trial Inspections) Specification (No. 2) 2020	13 August 2020 (F2020L01017)	14 August 2020	—
Therapeutic Goods (Clinical Trial Inspections) Amendment Specification 2024	18 September 2024 (F2024L01177)	19 September 2024	—

Endnote 4—Amendment history

Provision affected	How affected
s 2……..	rep LA s 48D
s 4……..	am F2024L01177
s 6……..	rep LA s 48C
Schedule 1…….	am F2024L01177
Schedule 2…….	rep LA s 48C