

Section 1: Legislation

1 Are the additional guidance documents listed in this section appropriate?

No

2 Are there other guidance documents relevant to the conduct of clinical trials of medicines in New Zealand that should be considered for inclusion?

No

3 Comments or suggestions

Comments or suggestions for section 1:

Add section 32 Treatment Injury to the Accident Compensation Act 2001

Section 2: Overview of regulation of clinical trials in New Zealand

1 Does this section adequately describe the situations when approval is required for clinical trials, and the types of approvals that are required?

Not Answered

2 Was the information appropriately presented?

Not Answered

3 Are there any changes you would like to suggest?

Yes

4 Comments or suggestions

Comments or suggestions on section 2:

Section 2.5 Other legislative requirements:

Accident Compensation Act 2001 s 32:

Treatment injury suffered as a result of a clinical trial will only be covered by ACC if:

- the claimant did not agree in writing to the trial, or
- an ethics committee (approved by the Health Research Council of NZ or the DG of Health) approved the trial and was satisfied that the trial was not conducted principally for the benefit of the manufacturer or distributor of the medicine or item being trialled.

ACC is not responsible for injuries occurring within an approved sponsor initiated clinical trial – those injuries need to be managed by the sponsor in accordance with agreed guidelines.

Section 3: Application for approval of a clinical trial

1 Are the roles and responsibilities of the various parties involved clearly explained?

Not Answered

2 Is the application process adequately described?

Not Answered

3 Is the sole circumstance for an abbreviated process for clinical trial approval clearly explained?

Not Answered

4 Comments or suggestions

Comments or suggestions on section 3:

Section 5: Good clinical practice requirements

1 Does the text in this section adequately explain what is required?

Not Answered

2 Are there other good clinical practice-related safety issues or safety concerns that you consider should be included in this section?

Yes

3 Comments or suggestions

Comments or suggestions on section 5:

Section 5.2

ACC is not responsible for injuries occurring within an approved sponsor initiated clinical trial – those injuries need to be managed by the sponsor in accordance with agreed guidelines.

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