Submission no. 11

## Section 1: Legislation

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

Yes

**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:**

## 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?**

Yes

**2 Was the information appropriately presented?**

Yes

**3 Are there any changes you would like to suggest?**

No

**4 Comments or suggestions**

**Comments or suggestions on section 2:**

## Section 3: Application for approval of a clinical trial

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

Yes

**2 Is the application process adequately described?**

Yes

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

Yes

**4 Comments or suggestions**

**Comments or suggestions on section 3:**

## Section 4: Notification of clinical trial sites

**1 A revised (simplified) process has been proposed for notifying clinical trial sites where subjects stay overnight as part of the investigation. Is the explanation of the requirements clear?**

Yes

**2 Is the revised process adequate to ensure that only trial sites with adequate access to emergency medicine facilities are used in clinical trials?**

Yes

**3 Are the instructions on the accompanying Clinical Trial Site Notification Form clear and easy to understand?**

Yes

**4 Is it clear that clinical trial applicants no longer have to notify trial sites where subjects stay overnight, and that this is the responsibility of the site manager?**

Yes

**5 Do you have changes to suggest that could be considered?**

No

**6 Comments or suggestions**

**Comments or suggestions on section 4:**

## Section 5: Good clinical practice requirements

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

Yes

**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:**
The following new requirements are problematic, and should be changed or removed, or they will have a chilling effect on research in NZ:
“The principal investigator must maintain a product specification file. A copy of relevant sections of the current version must be held by any contract manufacturing sites. The product specification file must be consistent with the approved clinical trial documents (for example specifications in the Investigators Brochure, etc.). “
This is not reasonable, as a clinical PI will usually have no involvement in product manufacturing, which usually takes place overseas. The PI maintains a current copy of the IB, but is not likely to be in a position to maintain a full product specification file, which is the role of the manufacturer. I think this paragraph should be removed entirely.
Similarly:
“The principal investigator should receive a Certificate of Analysis for investigational products, and should verify that the product meets the approved specifications and is suitable for release.“
Trial PIs, as clinicians, are not likely to be familiar with manufacturing processes for medicines, nor for critically reviewing Certificates of Analysis, or with matching the contents of these with product specifications. It is simply not reasonable to request these documents. This should be removed entirely, or at a minimum should be re-worded to, e.g. ‘The Principal Investigator should seek confirmation from the manufacturer that the product meets approved specifications and is suitable for release’.

## Section 6: Records and reporting

**1 Are the responsibilities of the sponsor regarding record keeping and reporting clear?**

Yes

**2 Do you agree that submitting a synopsis of the final report of the clinical trial is sufficient, and that a full report does not need to be submitted unless this is asked for by Medsafe?**

Yes

**3 Do you have suggestions or recommendations to make that could be included in this section?**

Yes

**4 Comments or suggestions**

**Comments or suggestions on section 6:**
I think to avoid having to update the document on regular bases with changes of legislation, we should have more broad statement such as instead of The applicant/sponsor must ensure compliance with New Zealand privacy legislation (Privacy Act 1993) and the Health (Retention of Health Information) Regulations 1996", it could be replaced by "The applicant/sponsor must ensure compliance with New Zealand
current privacy legislation and the Health Regulations "

## General: Layout and format of the guideline

**1 Do you agree with the proposed structure of the guideline?**

Yes

**2 Do you have suggestions, recommendations or other information that could be included in this guideline?**

No

**3 Comments or suggestions**

**Comments or suggestions on layout and format:**

## Clinical Trial Site Notification Form

**1 Does this form capture the appropriate essential information?**

Yes

**2 Is it obvious who should make the notification?**

Yes

**3 What information do you think would be useful to be published on Medsafe's list of clinical trial sites?**

**Comments or suggestions on what would be useful:**

## Re-notification of clinical trial site

**1 Since the self-certification process is changing to a notification procedure, would you be amenable to re-notifying your clinical trial site (if applicable) when this revised and updated guideline takes effect, so that the list of clinical trial sites is up-to-date?**

Yes

**2 Comments or suggestions**

**Comments or suggestions on re-notification:**

## Your details

**1 Your details**

**Name and designation:**
XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX

**Company/organisation name (if applicable):**
CCDHB and HVDHB

**Address:**
XXXXXXXXXXXXXXXXXXXXXXXXXXXX

**Phone number:**
XXXXXXXXXXXXX

**Email address:**
XXXXXXXXXXXXXXXXXXX

**2 This submission is:**

made on behalf of a group or organisation(s)

**3 I am, or I represent an organisation, based in:**

New Zealand

**If you selected other, please specify:**

**4 I am, or I represent, a:**

Institution (eg, university, hospital)

**If you selected health professional, please indicate your type of practice:**

**If you selected other, please specify:**

## Publishing submissions and privacy

### 1 Publishing submissions

You may publish this submission

### 2 Official Information Act responses

Remove my personal details from responses to Official Information Act requests

### 3 Commercially sensitive information

This submission does not contain commercially sensitive information

**If your submission contains commercially sensitive information, please let us know where.:**

## Help us improve our consultations

### 1 How easy did you find using this website to make a submission?

Adequate

### 2 If you have made submissions to Medsafe or the Ministry of Health before, was making today's submission:

About the same

### 3 If there was one change you could make to the submission process, what would it be?

**Top suggested change:**
it would be better to have continue button taking you to next lot of questions rather then Question index

### 4 Any other comments or suggestions?

**Other comments:**