Hi,

I reviewed Part 11, but I put my comments into a word document as I had done it prior to realising you were collecting the information via web survey. Sorry, but as today is the last day I think it best to just send it in as is, particularly as some of the information is recorded in comment boxes.

I have attached it for your information.
Feel free to contact me if you have questions.

Section 2.5
A clinical trial involving a new organism or genetically modified organism requires compliance with the Hazardous Substances and New Organisms Act 1996 is required. This is independent of the process for approval for a clinical trial under section 30 of the Medicines Act.
[repetition of required]

Section 2.6
It may not be in the public's best interests to remove the information relating to compensation. The HDEC guidelines are only guidelines and are apparently not legally binding. I have not found an Act that specifically dictates the requirement for Sponsored trials to provide ACC-equivalent compensation for patients.

The ethics committee's will check that compensation arrangements are in place, but as the Pharma companies also agree to abide by the Medicines NZ guidelines, which are not necessarily ACC equivalent, some patients would not be eligible for compensation. For example, patients may only be eligible if their injury is serious and enduring, not temporary discomfort or injury, which ACC may still pay.

Is there a way to include in this Act the requirement for the provision of injury compensation so that it is legally binding? Perhaps include a clause about: Trial participants who are not eligible for ACC compensation must be provided with ACC-equivalent compensation by the sponsor.

There is significant 'grey' area within the patient compensation arena caused largely by the conflicts within the Medicines NZ guideline, the ambiguity around what 'ACC-equivalent' compensation is and the lack of legally binding legislation.

This issue has been an ongoing problem within the industry for some time and attempts have been made to address it but to date it is unresolved. Potentially the best options would be to have all patients covered by ACC, which may require an ACC charge for trials. At this stage it is not looking as though a change of this kind is imminent, but it would be good to ensure any language would allow for this event as well as the possibility that private insurance is provided by Sponsors without compromising patient protection.

Section 4.3
I'm sorry, it may be that I'm just tired but I'm struggling with this clause.

Applicants for approval of a clinical trial where subjects are kept overnight for monitoring purposes as a result of receiving the study medications need to check that the proposed clinical trial site has been notified. This can be done by checking Medsafe's Notified Clinical

Trial Sites webpage. If the site has not been notified, the applicant should contact the manager of the site to submit a notification.

[Is this correct? Is there possibly a word missing? Should it be, 'Applicants requesting approval...'.Maybe it's just me but this is much harder to understand than the original language.]

Section 5.2.1
Is it worth mentioning approval is required by the HDEC as well? It wasn't previously mentioned so it would be an addition.

- 3rd bullet

- notifying and seeking approval for any changes in the clinical trial protocol to the Director-General of Health (through Medsafe)
[Maybe include a reference to section 6.6 which also covers Amendments.]

When the application is approved the applicant becomes the 'sponsor' and is responsible for ensuring that the trial is conducted in accordance with both New Zealand law and Good Research Practice standards.
[Is there a reference for which Good Research Practice Standards are required? Perhaps it is not required but if you have one it may be useful.

Section 6.1
- 5th bullet

The timeframes for retention of records will depend on the nature and duration of the trial. Records must be kept for a minimum of 10 years from date the study ends.
[It may be better to add a bit more onto this. '.. or as specified for paediatric participants' or something to that effect.]

Below is the reference link and actual text relating to paediatric patients, which may require further consideration.

https://ethics.health.govt.nz/guides-templates-forms-0/potentially-vulnerable-study-participants-%E2%80%93-guidance/children-and-young

Study data on child participants should be kept by the researcher for 10 years after that participant has reached 16 years of age.

Section 6.6
It's easier having the sections split, but I think more information needs to be included regarding the HDEC requirements and approvals for each of the sections, particularly for the Amendments section (as also mentioned in 5.2.1 above).