Health and Disability Ethics Committees

Minutes

Committee:	Central Health and Disability Ethics Committee
Meeting date:	26 February 2013
Meeting venue:	Deloitte House

Time	**Item of business**
12pm	Welcome
	Confirmation of minutes of meeting of 29 January 2013
	New applications (see over for details) i 13/CEN/20 ii 13/CEN/24 iii 13/CEN/25 iv 13/CEN/26 v 13/CEN/27 vi 13/CEN/28 vii 13/CEN/30 viii 13/CEN/31
	Substantial amendments (see over for details)
	Review of approved studies (see over for details)
	General business: Noting section of agenda
3.45pm	Meeting ends

Member Name	Member Category	Appointed	Term Expires	Apologies?	
Mrs Helen Walker	Lay (consumer/community perspectives)	01/07/2012	01/07/2015	Present	
Dr Angela Ballantyne	Lay (ethical/moral reasoning)	01/07/2012	01/07/2015	Present	
Mr Paul Barnett	Lay (the law)	01/07/2012	01/07/2014	Present	
Mrs Gael Donoghue	Non-lay (health/disability service provision)	01/07/2012	01/07/2014	Present	
Mrs Sandy Gill	Lay (consumer/community perspectives)	01/07/2012	01/07/2014	Present	
Dr Patries Herst	Non-lay (intervention studies)	01/07/2012	01/07/2015	Present	
Dr Dean Quinn	Non-lay (intervention studies)	01/07/2012	01/07/2015	Present	
Dr Lynne Russell	Non-lay (observational studies)	01/07/2012	01/07/2014	Present	

Welcome

The Chair opened the meeting at 12pm and welcomed Committee members.

The Chairperson welcomed Associate Professor Martin Tolich who will be observing the committee's proceedings today as part of a Marsden grant to study New Zealand ethics committees and Maori consultation.

The Committee also welcomed Lynne Andrews who also attended the meeting as an observer. Ms Andrews is currently studying towards a Diploma in Clinical Research at Victoria University of Wellington.

The Chair noted that the meeting was quorate.

The Committee noted and agreed the agenda for the meeting.

Confirmation of previous minutes

The minutes of the meeting of 29 January 2013 were confirmed.

New applications

1	**Ethics ref:**	**13/CEN/20**
	Title:	CLDK378A2203
	Principal Investigator:	Associate Professor Mark McKeage
	Sponsor:	Novartis Pharmaceuticals Pty Ltd
	Clock Start Date:	14 February 2013

Associate Professor Mark McKeage was not present in person or by teleconference for discussion of this application.

Potential conflicts of interest

The Chair asked members to declare any potential conflicts of interest related to this application.

No potential conflicts of interest related to this application were declared by any member.

Summary of ethical issues

The main ethical issues considered by the Committee were as follows.

- The committee noted at the onset of the review that the participants in this study are likely to have a poor prognosis, and that they fall within the definition of 'vulnerable' as set out in Section 5.28 (page 14) of the guidelines - *People with serious illness which the study treatment offers potential benefits that substantially exceed those of any available treatment.* The Committee noted the researcher incorrectly ticked "patients are not vulnerable". http://neac.health.govt.nz/streamlined-ethical-guidelines-health-and-disability-research
- Page 24, P4.1 [Consultation with Maori consultation]. The Committee noted that while the PIS and other documentation clearly states samples will be returned to whanau/hapu on request, and that there is a Maori liaison contact person, this information has not been added to the application form. For future applications, the Committee requests that all detail on Maori consultation, and awareness of Tikanga Maori, is included in the ethics application form. However, the Committee commended the researcher for ensuring there is a Maori contact person for Maori participants.
- Page 24, P3.3 [Reimbursements]. For future reference, the committee requested the researcher is specific about what reimbursement is being offered to participants.
- Page 22, p3.2, p3.3. The committee requested the researcher adds a specific timeframe for consent to participate in the study.
- Page 3, A1.4. Please amend the commencement date of the study.

Participant Information Form (PIS)

- The Committee congratulated the researcher on the PIS, noting it is only 11 pages. The Committee suggested the PIS could be shortened by removing the following paragraphs:

  1) biomarker paragraph on the bottom of page two "To see what effect the drug is having on your cancer 'biomarker' studies will also be included in this trial….In addition, multiple genes and proteins in your tumour samples may be treated to try to learn more about the tumour and to understand how the LDK378 may be working in cancer".
- 2) Page 4, Sentence 3 [CTS scan]. Please amend sentence to read …." You should not expect **any** significant increase in risk from the imaging being done in this study.'

- 3) Page 5, paragraph beginning “If you agree to the optimal tumour biopsies…..” Please delete this paragraph.
- 4) Page 5, paragraph beginning “In rare instances where a nurse, doctor or a laboratory technician, sustains an exposure to you blood, tissue or body fluids by needle stick…..” Please delete this paragraph.
- The Committee requested the researcher also include a lay title to make clearer the purpose of the study to the participant.
- The Committee commended the researcher for designing a PIS for female partners of male participants.

Consent form

- Page 11. The Committee requested the researcher deletes the reference to biomarkers “ I consent to blood and tissue biomarker samples.....15 years) to reflect the above changes to the PIS.
- Page 11. The Committee requested the researcher deletes question 4 “ I do not want my samples to be sent back to my family/next of kin yes/no’ as the question immediately below duplicates this question.

Compensation for injury to participants

- Page 16, r.1.7. The Committee advised the researcher incorrectly responded ‘no’ to this question. The correct response is ‘yes’. This needs to be confirmed in writing to the Committee.

Decision

This application was *provisionally approved* by subject to the following information being received.

- Please amend the Participant Information Sheet to address the Committee’s concerns above [*Ethical Guidelines for Intervention Studies para 6.22*]

- Please amend the Consent form to address the Committee’s concerns above and add a specific timeframe for consent to participate in the study. [*Ethical Guidelines for Intervention Studies para 6.22*]

- Please confirm how participants will be compensated. [*Ethical Guidelines for Intervention Studies para Section 8*]

This following information will be reviewed, and a final decision made on the application, by Dr Dean Quinn.

2	**Ethics ref:**	**13/CEN/24**
	Title:	Maxigesic 325 OA Study
	Principal Investigator:	Dr Douglas White
	Sponsor:	AFT Pharmacetuicals Ltd
	Clock Start Date:	14 February 2013

Dr Douglas White was not present in person or by teleconference for discussion of this application.

Potential conflicts of interest

The Chair asked members to declare any potential conflicts of interest related to this application.

No potential conflicts of interest related to this application were declared by any member.

Summary of ethical issues

The main ethical issues considered by the Committee were as follows.

- Page 28, F3.2. The Committee held a robust discussion on the extent to which this study meets the equipoise standard. The key concern was whether there is sufficient scientific justification to allow 100 participants to experience pain prior to deciding to issue rescue pain medication. Some committee members noted that pain is subjective experience and for some patients, a placebo is perceived to be beneficial. The Committee concluded that on the basis that rescue remedy is available, that participation is voluntary and that participants are adequately informed about the use of placebo as a trial arm, and they can withdraw consent to participate in the study at any time, no additional conditions would be requested.
- Page 26, F4.1. The Committee noted the researcher intended to collect ethnicity data, but more analysis is needed on how the study will benefit Maori, including how tissue samples will be managed to reflect an understanding of Tikanga Maori. For future reference, the Committee requires more detail to answer this section.
- Page 26. While the Committee noted the researcher recognised the importance of whanau in Maori culture, there is no evidence of Maori consultation. The Committee requested feedback on what Maori consultation will be undertaken.
- Page 23, F2.1. The Committee requested that intolerance or allergy to Oxycodon or other similar opiates are included to the exclusion criteria in the protocol and PIS.

Participant Information Form (PIS)

- The Committee noted the PIS is reasonably well written.
- The exclusion criteria listed in the PIS should reflect the exclusion criteria in the protocol.
- Please add to the PIS the diagram on page 17 of 56 of the protocol.
- Please add to the PIS information on what is contained in the rescue pain relief.
- Please amend the title of the ethics committee to read 'Central Health and Disability Ethics Committee' and make any other necessary corrections throughout the documents submitted to the Committee.

Decision

This application was *provisionally approved* by consensus subject to the following information being received.

- Please amend the Participant Information Sheet to address the Committee's concerns above [*Ethical Guidelines for Intervention Studies para 6.22*]

- Please address the Committee's concern about appropriate consultation with Maori [*Ethical Guidelines for Intervention Studies para 6.22*]
- Page 23, F2.1. Please add opiates and intolerability for allergy to the exclusion criteria [*Ethical Guidelines for Intervention Studies section 5*]

This following information will be reviewed, and a final decision made on the application, by Dr Patries Herst.

3	**Ethics ref:**	**13/CEN/25**
	Title:	Tivantinib vs Placebo for the treatment of Inoperable Hepatocellular Carcinoma
	Principal Investigator:	Professor Edward Gane
	Sponsor:	Daiichi Sankyo Pharma Development
	Clock Start Date:	14 February 2013

Professor Edward Gane was not present in person or by teleconference for discussion of this application.

Potential conflicts of interest

The Chair asked members to declare any potential conflicts of interest related to this application.

No potential conflicts of interest related to this application were declared by any member.

Summary of ethical issues

The main ethical issues considered by the Committee were as follows.

- The Committee held a robust discussion on the ethics around the researcher not making a commitment to continue to provide the drug to those on the placebo arm once the study is completed. The ethical concern was around removing a drug from a patient who might be responding well. The Committee conceded that the numbers were likely to be small, and that the study had a short 3 years span. Following this discussion, the Committee requested the researcher make it explicit in the PIS that those in the control arm (placebo) and those in the intervention arm that respond to the drug will not be entitled to continue access to the drug at the conclusion of the study.
- Page 22, r.5.4.1. The Committee commented the researcher's response to this question is inadequate. For future reference, the doctor/physician is in a dual role of both physician and researcher and this is where the conflict arises. Please address in future how this conflict will be managed eg having a research nurse doing the recruitment.
- Page 11, The Committee noted the information provided does not address the question and reminds the researcher to avoid 'cut and pasting' from other documents.
- Maori Consultation
- Page 26, P4.1. The Committee commented this section has not been sufficiently answered as it does not answer the question about how the study will benefit Maori. The committee requested written feedback on this section.
- Page 26, P4.2. The Committee further commented the researcher had also failed to identify Maori cultural issues associated with geonomic data banking overseas, and the taking and retention of samples. The Committee sought written comment to satisfy the Committee these cultural considerations have been taken on board by the researcher.
- Page 26, 4.3.1. The Committee discussed whether the description of Maori consultation is sufficient. For help with this section, the committee suggests the researcher approaches Naiad Glavish.
- Page 25, P3.2. The Committee noted the researcher incorrectly ticked "patients are not vulnerable' and commented participants would fall within the definition of 'vulnerable' as set out in Section 5.28 (page 14) of the NEAC guidelines [July 2012]"*People with serious illness which the study treatment offers potential benefits that substantially exceed those of any available treatment* for further information about vulnerable people. http://neac.health.govt.nz/streamlined-ethical-guidelines-health-and-disability-research.
- P2.1 (page 24) Timeframe for consent. The Committee requested the researcher place a specific timeframe for receiving informed consent to participate in the study.

Participant Information Form (PIS) main document

- Page 2. Please amend the name of ethics committee to Central Health and Disability Ethics Committee and add the study reference number.
- "Optional Banking of Pharmacogenomic Sample" Page 4 of 6, under "*Rights of research Subjects*". Please refer to the last sentence. If you wish please discuss whether you would like to take part or not with family and friends as well'. Please expand to advise Maori that that may wish to discuss Phar-macogenomic banking with their whanau and hapu given some Maori view Maori material as tapu.

Decision

This application was *provisionally approved* by consensus subject to the following information being received.

- Please amend the Participant Information Sheet to address the Committee's concerns above and add a specific timeframe for receiving informed consent to participate in the study [*Ethical Guidelines for Intervention Studies para 6.22*]
- Please address the Committee's concern about appropriate consultation with Maori [*Ethical Guidelines for Intervention Studies Section 4*]
- Please provide written feedback on the Maori cultural issues associated with geonomic data banking overseas, and the taking and retention of samples.

This following information will be reviewed, and a final decision made on the application, by Dr Angela Ballantyne.

4	**Ethics ref:**	**13/CEN/26**
	Title:	ICEOBAR-STEMI Clinical Study
	Principal Investigator:	Dr Mark Webster
	Sponsor:	Prospex Medical III, Inc
	Clock Start Date:	14 February 2013

Donna Katae, Trial Coordinator, was present for discussion via teleconference of this application.

Potential conflicts of interest

Summary of ethical issues

The main ethical issues considered by the Committee were as follows.

- Page 21, P3.3. The Committee discussed its concern that the researcher incorrectly identified the population group as 'not vulnerable' when they do fall within the definition of vulnerability as set out in the Ethical Guidelines for Intervention Studies (July 2012), vulnerable' Section 5.28 (page 14) "People with serious illness which the study treatment offers potential benefits that substantially exceed those of any available treatment". The researcher accepted the Committee's view. http://neac.health.govt.nz/streamlined-ethical-guidelines-health-and-disability-research
- Please forward a copy of Dr Simon Dixon's peer review of the study protocol.

Participant Information Sheet (PIS)

- The Committee requested that the PIS specifies what treatments or assessments that are not standard care for patients.
- The exclusions listed on page 13-15 in the protocol need to be added to the PIS. These should include all major exclusion identified
- Page 19. The researcher needs to provide a more specific time for the consent process ie remove 'adequate' and add a timeframe".
- Please correct the name of the ethics committee.

Reduce Inequalities

- Page 23, f1.1. The Committee expressed concern that the researcher tick no to this question and sought information on the researcher thoughts on where the inequalities were derived. The Trial Coordinator clarified this is a question more appropriately answered by Dr Webster. One suggestion was the timing of seeking medical assistance. The Committee clarified for future reference that in cases where there is a clear disproportionate impact on one group, the researcher needs to consider why this is the case and how the intervention might assist in reducing the inequalities.

Compensation

- The Committee noted the certificate of insurance has not been included.

Maori Consultation

- The Committee noted the Maori review letter of support is pending.

Decision

This application was *provisionally approved* by consensus subject to the following information being received.

- Please amend the Participant Information Sheet to address the Committee's concerns above [*Ethical Guidelines for Intervention Studies para 6.22*]
- Please forward to the Committee the certificate of insurance.
- Please forward a copy of Dr Simon Dixon's peer review of the study protocol.

- Please forward a copy of the Maori review letter of support referred to in the study application.

This following information will be reviewed, and a final decision made on the application, by Dr Dean Quinn

5	**Ethics ref:**	**13/CEN/27**
	Title:	A clinical trial for children with low and intermediate risk Neuroblastoma
	Principal Investigator:	Associate Professor Michael Sullivan
	Sponsor:	Canterbury District Health Board
	Clock Start Date:	14 February 2013

Associate Professor Michael Sullivan was not present in person or by teleconference for discussion of this application.

Potential conflicts of interest

The Chair asked members to declare any potential conflicts of interest related to this application.

No potential conflicts of interest related to this application were declared by any member.

Summary of ethical issues

The main ethical issues considered by the Committee were as follows.

- The Committee discussed whether this is an intervention study or an observational study. B.2.1 page 12 talks about an observational study but the researcher ticked intervention study in section C. The Committee concluded this study may fall between the gaps.
- The key ethical issue raised concerned PIS and assent forms for children. P2.3 refers to children and young adult participants but only one generic PIS has been submitted. The Committee refers the researcher to the NEAC guidelines http://neac.health.govt.nz/streamlined-ethical-guidelines-health-and-disability[Section 2 page 46] "*Research involving children and young" and p47-48 "informed consent*". Older children (7-11) and young adolescence (12-16) are entitled to information targeted to their age and have the right to assent to research participation. The Committee noted in the cover letter that these documents should have been attached to the application but only the PIS and consent form for parents were received. Please either re-send the PIS/assent forms for children or draft these and submit.
- Page 14, p B.4.5 B.4.5.1 human tissue. The Committee noted this was an inappropriate response. The answer to B.4.5.1 for consistency should have been 'yes'. If tissue is stored for future unspecified use, a separate PIS and consent form must be supplied, and this must address Maori cultural issues regarding collection and tissue.
- Page 21, 1.2. The Committee notes the researcher answered 'yes' - all participants will give informed consent, but that this should read 'no'.
- Page 23. P.4.2 – The Committee notes the researcher responded there are "no cultural issues" are anticipated in this study. The Committee sought further information to satisfy the Committee Maori cultural considerations have been taken on board by the researcher.
- Page 23, 4.3. The Committee sought clarification on whether the Maori research review committee is Nga Tahu research Centre.

Decision

This application was *provisionally approved* by consensus subject to the following information being received.

- Please either re-send the PIS/assent forms for children or draft these and submit [*Ethical Guidelines for Intervention Studies para 6.22*]
- Please provide further information on "cultural issues anticipated" in this study [*Ethical Guidelines for Intervention Studies Section 4*]

- Please clarify whether the Maori research review committee is Nga Tahu research Centre[*Ethical Guidelines for Intervention Studies Section 4*]

This following information will be reviewed, and a final decision made on the application, by Paul Barnett

6	**Ethics ref:**	**13/CEN/28**
	Title:	Multi-sensory Integration and Tinnitus
	Principal Investigator:	Dr Grant D Searchfield
	Sponsor:	The University of Auckland (Grant Number: 3702601)
	Clock Start Date:	14 February 2013

Dr Grant Searchfield was not present in person or by teleconference for discussion of this application.

Potential conflicts of interest

The Chair asked members to declare any potential conflicts of interest related to this application.

Summary of ethical issues

The main ethical issues considered by the Committee were as follows.

- Page 22, P.2.7. The Committee noted the answer provided relates to information received after completion of the study but what if information becomes available during the study. Clarification on this point was requested.
- Page 24, P.4.3. The Committee commends the researcher's reference to the head as tapu.
- The Committee requests GP approval before commencing the study because of possible health issues eg pre-existing hypo-natraemia (low sodium).
- The Committee noted several typos and requested the researcher proof reads all documents.
- Participant Information Sheet
- Please add footer and version number
- Please correct the name of the ethics committee
  Reference to ethics committee needs to be amended
- Exclusion criterion. Page 3, reference to people with claustrophobia will be excluded. Please ensure this information is included in the PIS/CF/exclusion notice.
- Case History Questionnaire
- Please review the case history questionnaire for readability. The Committee noted on page 2 of 3, paragraph 14 'tone' is the answer twice.
- Paragraph 22. Please make language understandable for a lay person.
  Peer review
- Page 14, 2.2 and document. The Committee noted that what has been attached is not evidence of favourable peer review. For guidance please refer to Appendix 1: *Joint Health Research Council and NEAC guidance on features of robust peer review for assessing the scientific validity of research*. http://neac.health.govt.nz/streamlined-ethical-guidelines-health-and-disability-research.

Decision

This application was *provisionally approved* by consensus subject to the following information being received.

- Please amend the Participant Information Sheet to address the Committee's concerns above [*Ethical Guidelines for Intervention Studies para 6.22*]
- Please amend the Case History Questionnaire as requested [*Ethical Guidelines for Intervention Studies para 6.22*]
- Please confirm the Committee request that GP approval is sought before commencing the study.

- Please clarify how information that becomes available during the study will be relayed to participants. [*Ethical Guidelines for Intervention Studies section 7*]
- Please provide evidence of peer review to the Committee.

This following information will be reviewed, and a final decision made on the application, by Paul Barnett

7	**Ethics ref:**	**13/CEN/30**
	Title:	Mothers and Babies Bodies.
	Principal Investigator:	Assoc. Professor Jane Coad
	Sponsor:	Massey University
	Clock Start Date:	15 February 2013

Associate Professor Jane Coad was not present in person or by teleconference for discussion of this application.

Potential conflicts of interest

The Chair asked members to declare any potential conflicts of interest related to this application.

No potential conflicts of interest related to this application were declared by any member.

Summary of ethical issues

The main ethical issues considered by the Committee were as follows.

- The Committee raised no specific ethical issues for this study.
- The Committee did raised some cultural issues regarding this study in regards to different cultural perceptions of size, noting some cultures, such as those in Pacific, place there is value on big babies and that these cultural differences should be acknowledged by the researcher.
- The Committee also noted the need for the researcher to undertake the measurements in a sensitive manner to avoid any potential to stigmatise new mothers.
- The Committee commended the researcher for providing an oral explanation of the study to participants in their own language.
- Page 13, B2.2.2. The Committee noted that what has been attached is not evidence of favourable peer review and requested evidence of an independent review. For guidance please refer to Appendix 1: *Joint Health Research Council and NEAC guidance on features of robust peer review for assessing the scientific validity of research*. http://neac.health.govt.nz/streamlined-ethical-guidelines-health-and-disability-research
- Page 23. P4.3. The Committee sought feedback on who provided Maori consultation?
- Page 17. R.3.9.1. The Committee the researcher provided an incorrect response which should read 'yes'.
- Please proof read all documents as several typos were noted by the Committee.

Decision

This application was *provisionally approved* by consensus subject to the following information being received.

- Please provide evidence of an independent review.
- Please advised the Committee on who provided Maori consultation [*Ethical Guidelines for Intervention Studies Section 4*]
- Please proof read all study documents

This following information will be reviewed, and a final decision made on the application, by Sandy Gill

8	**Ethics ref:**	**13/CEN/31**
	Title:	Acetazolamide to reduce lithium induced NDI
	Principal Investigator:	Professor Robert Walker
	Sponsor:	University of Otago
	Clock Start Date:	15 February 2013

Professor Robert Walker was not present in person or by teleconference for discussion of this application.

Potential conflicts of interest

The Chair asked members to declare any potential conflicts of interest related to this application.

No potential conflicts of interest related to this application were declared by any member.

Summary of ethical issues

The main ethical issues considered by the Committee were as follows.

- Page 23 (Protocol). The Committee noted the researcher does not acknowledge the protocol derives from the Netherlands that there is no letter from the original Dutch researchers to say this study protocol is allowed to be used in New Zealand. The Committee sought clarification on this from the researcher and a letter from the Dutch collaborators approving the use of their protocol in NZ.

- R1.5 /1.6 (application). The Committee notes these sections to do not exist in the protocol. Clarification is sought on whether the correct protocol has been uploaded. The researcher needs to check that all documents uploaded relate to this study.

- Page 21 (Protocol). Under 'compensation for injuries", the committee noted an incorrect reference to euros. This is not correct and needs to be amended.

- P3.2 page 20 – Should read 'yes' – add in paragraph on vulnerability.

- The Committee requests the researcher seeks approval from patient's GP/psychologist for their participation in the study before commencing the study.

Decision

This application was *declined* by consensus as the Committee did not consider that the study would meet the following ethical standards.

The Committee has considered you application and believe you have submitted an incomplete application as the protocol relevant to the NZ study was not supplied. As per section 5 of the NEAC Guidelines [July 2012]. Please note the Committee tried to contact you by phone [mobile and work number] but were unsuccessful.

Study question

5.1 Investigators should undertake studies that address important health and/or disability problems.

5.2 Investigators should develop clear study questions that identify the participant population, the intervention and the main outcome of interest. Normally the outcome(s) to be studied should be clinically significant.

5.3 Every study question should be based on a thorough review of the relevant literature.

Study design

5.4 The study design should be the one best suited to answer the study question, while minimising harm, maximising benefit and meeting other ethical standards.

5.5 Scientific soundness is ethically important. Projects without scientific merit needlessly expose participants to risk and misuse their time, and waste resources.

5.6 The intended number of participants in an intervention study should be sufficient to generate reliable study findings, and the consequent recruitment targets should be realistic. Statistical issues relating to trial design, sample size and analysis can be complex, and usually require expert advice.

5.7 The study protocol should contain an overview of the planned statistical analyses, and these planned analyses should be adhered to in conducting the study.

5.8 Assignment of participants to study groups is best done by randomisation. This process tends to make study groups reliably comparable and minimises biases, especially uncontrolled confounding. Quasi-randomised or non-random methods are generally less reliable in this regard because of their potential to allow other factors to influence the assignment of participants to study groups. Allocation concealment also improves study validity and design through preventing selection bias (see also 'Features of intervention studies', paragraphs 2.7–2.11).

5.9 Use of blinding is desirable in an intervention study design when it can be shown that it has methodological advantages and minimal risks (see also 'Blinding', paragraph 2.11).

5.10 Every effort should be made to ensure complete follow-up of all study participants. Incomplete follow-up means there is data missing from the study. This will be for non-random reasons and has the potential to compromise the reliability of the study findings (see also paragraph 6.20).

5.11 Peer review of the scientific validity of a study's protocols is beneficial, and is advised for all studies that pose more than minimal risk. Further advice about features of robust peer review is provided in Appendix 1.

Comparison groups

5.12 Investigators should treat actual and potential study participants fairly, both in relation to one another and in relation to similarly placed non-participants.

Best intervention standard

5.13 An intervention study meets the best intervention standard if the intervention(s) in the study are tested against the best proven intervention(s) available outside the study. In many settings there might be more than one intervention that is equivalent to the best, according to the current evidence.

5.14 All intervention studies should meet the best intervention standard, unless there are only temporary and minimal departures from the best intervention standard and the departure (and any risk posed) is justified in relation to the overall potential benefits of the study.

5.15 Withholding a proven intervention for a short time, whether or not it is replaced by a placebo, can sometimes be ethically justified to validate a measurement technique or to confirm the sensitivity of a therapeutic study design. An investigator who proposes any such approach should justify this to an ethics committee and explain how it can be undertaken without significant risk of harm to participants.

5.16 In some cases, one or more interventions provided in an intervention study are equivalent to the best proven intervention available locally outside the study but are known to be inferior to the best proven intervention available internationally. In such cases, the study can be justified only if the world-best intervention is unlikely to be available locally for the duration of the study and if the study can be justified in terms of its potential benefit to the community from which the participants are drawn. The same considerations apply to New Zealand-sponsored studies conducted in countries with less access to health interventions than New Zealand.

5.17 Investigators should ensure that participants understand that their participation in an intervention study is not designed to benefit them more than the benefit they would gain if they were instead receiving the best proven intervention available outside the study. (See also 'Equipoise standard', paragraphs 5.18–5.21.)

General business

1. The Committee noted the content of the “noting section” of the agenda.

2. The Chair reminded the Committee of the date and time of its next scheduled meeting, namely:

Meeting date:	26 March 2013, 12:00 PM
Meeting venue:	Clinical Trials Unit, Level 8 Ward Services Block , CCDHB, Wellington, 6011

3. **Problem with Last Minutes**

   The minutes of the previous meeting were agreed and signed by the Chair and Co-ordinator as a true record.

4. **Matters Arising**

5. **Other business**

6. **Other business for information**

7. **Any other business**

The meeting closed at 3.34pm