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| **Committee:** | Northern B Health and Disability Ethics Committee |
| **Meeting date:** | 06 November 2018 |
| **Meeting venue:** | Novotel Ellerslie, 72-112 Greenlane Road East, Ellerslie, Auckland |

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| **Time** | **Item of business** |
| 12.00pm | Welcome |
| 12.05pm | Confirmation of minutes of meeting of 02 October 2018 |
| 12.30pm | New applications (see over for details) |
|  | i 18/NTB/173  ii 18/NTB/179  iii 18/NTB/180  iv 18/NTB/181  v 18/NTB/182  vi 18/NTB/183 (CLOSED)  vii 18/NTB/184  viii 18/NTB/190 (CLOSED)  ix 18/NTB/191 (CLOSED)  x 18/NTB/194 |
| 4.45pm | General business:  Noting section of agenda  Review of approved studies |
| 5.00pm | Meeting ends |

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| **Member Name** | **Member Category** | **Appointed** | **Term Expires** | **Apologies?** |
| Mrs Maliaga Erick | Lay (consumer/community perspectives) | 01/07/2015 | 01/07/2018 | Apologies |
| Mrs Stephanie Pollard | Non-lay (intervention studies) | 01/07/2015 | 01/07/2018 | Apologies |
| Mrs Helen Walker | Lay (consumer/community perspectives) | 01/07/2015 | 01/07/2018 | Present |
| Miss Tangihaere Macfarlane | Lay (consumer/community perspectives) | 20/05/2017 | 20/05/2020 | Present |
| Mrs Kate O'Connor | Lay (ethical/moral reasoning) | 14/12/2015 | 14/12/2018 | Present |
| Dr Nora Lynch | Non-lay (health/disability service provision) | 24/07/2015 | 24/07/2018 | Present |
| Mrs Leesa Russell | Non-lay (intervention studies), Non-lay (observational studies) | 14/12/2015 | 14/12/2018 | Apologies |
| Mr John Hancock | Lay (the law) | 14/12/2015 | 14/12/2018 | Apologies |
| Mrs Jane Wylie | Non-lay (intervention studies) | 20/05/2017 | 20/05/2020 | Present |
| Dr Peter Gallagher | Non-lay (health/disability service provision) | 30/07/2015 | 30/07/2018 | Present |

## Welcome

The Chair opened the meeting at 12:00pm and welcomed Committee members, noting that apologies had been received from Mrs Maliaga Erick, Mrs Stephanie Pollard,, Mrs Leesa Russell, and Mr John Hancock.

The Chair noted that it would be necessary to co-opt members of other HDECs in accordance with the Standard Operating Procedures. Mrs Helen Walker ( by teleconference) and Dr Peter Gallagher ( until the end of Application 18/NTB/191) confirmed their eligibility, and were co-opted by the Chair as members of the Committee for the duration of the meeting.

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 2 October 2018 were confirmed.

## New applications

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| **1** | **Ethics ref:** | **18/NTB/173** |  |
|  | Title: | Prelude BTK |  |
|  | Principal Investigator: | Associate Professor Andrew Holden |  |
|  | Sponsor: | Cagent Vascular |  |
|  | Clock Start Date: | 25 October 2018 |  |

Miss Elleni Takele was present in person and Associate Professor Andrew Holden was present via phone 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 Study

1. The study investigates safety and efficacy of the *Serranator®* PTA Serration Balloon Catheter in patients with distal lower limb peripheral artery disease.

Summary of resolved ethical issues

The main ethical issues considered by the Committee and addressed by the Researcher are as follows.

1. The Committee noted that blockages in arteries below the knee are difficult to treat and that this balloon may help patients in this group.
2. The Committee noted that it would be appropriate to include patients with critical limb ischemia in this study as doing so may help avoid amputation which might otherwise ensue.

The Committee requested the following changes to the Participant Information Sheet and Consent Form:

1. Add a yes/no tickbox option to allow patients to explicitly consent for the post-study use of their information for other research.
2. Please more clearly distinguish between standard care procedures and study procedures on pages 2 & 3 of the information sheet.
3. Please remove the irrelevant risk statement about impregnating partners from page 3.
4. Please add an address for the sponsor to the initial page of the information sheet.
5. Please amend “your doctor is asking you if you would like to take part…” to “we are asking…”
6. Please clarify the “*your* doctor” vs “*the* doctor” distinction in the procedures section in the information sheet. It is unclear who will be doing what.
7. Please remove references to reimbursement as there will be no additional procedures or visits beyond standard care.
8. Please amend the HDEC reference to the correct reference number.

Decision

This application was *approved* by consensus, subject to the following non-standard conditions:

* Please amend the information sheet and consent form, taking into account the suggestions made by the Committee (*Ethical Guidelines for Intervention Studies* *para 6.22*).

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| **2** | **Ethics ref:** | **18/NTB/179** |  |
|  | Title: | A Study of the Efficacy and Safety of Guselkumab in Participants with Moderately to Severely Active Crohn's Disease Study to evaluate the safety and effectiveness of guselkumab in people with moderate |  |
|  | Principal Investigator: | Dr Michael Schultz |  |
|  | Sponsor: | Janssen-Cilag (New Zealand) Limited |  |
|  | Clock Start Date: | 18 October 2018 |  |

Dr Michael Schultz was not present for discussion of this application. Dr Daphne Chan and Ms Marie Schultz were present representing the sponsor by teleconference for the 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 Study

1. The study investigates the efficacy and safety of guselkumab in participants with moderately to severely active Crohn’s disease.

Summary of resolved ethical issues

The main ethical issues considered by the Committee and addressed by the Researcher are as follows.

1. The Committee noted that the MEDSAFE approval for this study does not cover the Phase III GALAXI studies and that HDECs will need to be provided the MEDSAFE approval for any phase III studies prior to their commencement.

Summary of outstanding ethical issues

The main ethical issues considered by the Committee and which require addressing by the Researcher are as follows.

1. The Committee noted that the long term extension (LTE) is identified as a separate study in the protocol but is not treated as such in the patient-facing documentation. The Researcher explained that there is an extension for every substudy and so any consent to the main participation will also cover the extension studies. The Committee noted that this was unacceptable as patients will not be able to provide informed consent to these extension studies as the decision will be made prior to any knowledge of the safety and efficacy being available. The Committee noted that the researchers will not be able to provide full information until all participants have moved into the extension studies.
2. The Committee requested that participants be provided with an extension study information sheet and consent form before the participants move into the extension study which contains the most up to date information available on the use of the drug including in Crohns disease and also clearly explains the dosing and rescue options in the LTE study. This should be submitted as a substantial amendment.(*Ethical Guidelines for Intervention Studies* *paras 6.22 & 5.41*).
3. The Committee noted that separate peer review will need to be provided for the extension studies when the amendment is submitted. y MEDSAFE approval for this part of the protocol will meet this requirement. (*Ethical Guidelines for Intervention Studies* Appendix 1)
4. Please amend the information sheet and consent form, taking into account the suggestions made by the Committee (*Ethical Guidelines for Intervention Studies* *para 6.22*).
5. The Committee stated that in the event that a participant becomes pregnant then they should be unblinded. Please explain in the information sheet that participants can request unblinding but this will end their participation. (*Ethical Guidelines for Intervention Studies* *para 6.22*).

The Committee requested the following changes to the Participant Information Sheet and Consent Form:

1. Explain that if during between week 50 – 80 of the LTE participants are failing and they are on 100mg of drug 8 weekly then they can be increased to 200mg 4 weekly.
2. Explain that if participants are in the 200mg 4 weekly arm then their rescue medicine will be a placebo.
3. Please explain in the information sheet that participants can request unblinding but this will end their participation.
4. Please create an information sheet for parental consent for a newborn child’s ongoing participation once the child is born alive. Under New Zealand law parents cannot consent for their unborn child’s participation and so must provide this consent after birth. When a child is in utero then the mother’s consent to participation covers collection of data about the pregnancy.
5. Please remove the statement about there being no genetic analysis in the study and explain that biopsy samples will be going for genomic analysis.
6. Please amend the statements on pages 9 & 10 about other therapies. Please just request that participants inform their study doctor if they are on any medicines that may weaken their immune system.

Decision

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

* Please amend the information sheet and consent form, taking into account the suggestions made by the Committee (*Ethical Guidelines for Intervention Studies* *para 6.22*)
* Please amend the study protocol taking into account the suggestions made by the Committee. (*Ethical Guidelines for Intervention Studies* *para 5.41*)
* Please provide evidence of favourable independent peer review of the extension study protocol(s) (*Ethical Guidelines for Intervention Studies* Appendix 1)

This following information will be reviewed, and a final decision made on the application, by Mrs Kate O’Connor and Dr Nora Lynch.

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| **3** | **Ethics ref:** | **18/NTB/180** |  |
|  | Title: | A study into the effectiveness and safety of R131 vaginal ointment in women with cellular changes to the cervix |  |
|  | Principal Investigator: | Dr Amanda Tristram |  |
|  | Sponsor: | Douglas Pharmaceuticals Ltd, |  |
|  | Clock Start Date: | 18 October 2018 |  |

Dr Amanda Tristram was present in person along with other members of the research team and representatives of the sponsor 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 Study

1. The study investigates the effectiveness, tolerability, and safety of R131 vaginal ointment in women with low grade and high grade cervical intraepithelial neoplasia (CIN) who have been diagnosed with Human papillomavirus (HPV)

Summary of resolved ethical issues

The main ethical issues considered by the Committee and addressed by the Researcher are as follows.

1. The Committee queried earlier dose-tolerability projects and what information could be provided to participants. The Researcher explained that they have recently completed a trial using the full strength formulation and once they know the results then this will be used to inform whether or not this project will use a half or full strength formulation.
2. The Committee noted that the use of an ointment for this condition is unique internationally and is based on international evidence that the study drug is effective when used in a topical format.
3. The Committee asked why the study is in patients with high grade CIN and not in low grade. The Researchers explained that the two are different and they must test the drug in both groups due to the differences in the condition.
4. The Committee queried if participation in the study may cause a delay in treatment. The Researcher stated that participating in the study may cause a delay of up to six weeks but this will not pose a significant risk to patients as it will mean that participants will still receive standard treatment within a safe timeline if they still need it .
5. The Committee that noted that all participants who respond to treatment will still receive standard of care follow up.

Summary of outstanding ethical issues

The main ethical issues considered by the Committee and which require addressing by the Researcher are as follows.

1. The Committee asked that the data safety monitoring plans be added to the protocol. *(Ethical Guidelines for Intervention Studies para 6.50).*
2. Please provide an insurance certificate that confirms New Zealand as a policy territory.
3. Please explain in the study protocol who will be making the consent approach and when. (*Ethical Guidelines for Intervention Studies* *para 5.41*)
4. Please amend the information sheet and consent form, taking into account the suggestions made by the Committee (*Ethical Guidelines for Intervention Studies* *para 6.22*).

The Committee requested the following changes to the Participant Information Sheet and Consent Form:

1. Explain that after two cycles of treatment there is the option to be referred to your regular doctor for standard treatment.
2. Please explain that there will be no delay in receiving treatment through the public health system by participating in the study.
3. Please create an information sheet and parental consent form for the collection of data from any children born during the study.
4. Please add a picture of the applicator to the ICF.
5. Please explain that withdrawal does not have to be in writing.
6. Please add a statement that interpreters will be available to the main study ICF.
7. Please amend the contraception section to explain that participants must be on an effective contraceptive from the time of enrolment. Please note that while the oral contraceptive is acceptable but that participants must have been taking this for at least two weeks (14 days) prior to participation.

Decision

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

* Please amend the information sheet and consent form, taking into account the suggestions made by the Committee (*Ethical Guidelines for Intervention Studies* *para 6.22*).
* The Committee asked that the data safety monitoring plans be added to the protocol. *(Ethical Guidelines for Intervention Studies para 6.50).*
* Please provide an insurance certificate that confirms New Zealand as a policy territory.
* Please explain in the study protocol who will be making the consent approach and when. (*Ethical Guidelines for Intervention Studies* *para 5.41*)

This following information will be reviewed, and a final decision made on the application, by Mrs. Jane Wylie and Mrs Kate O’Connor.

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| **4** | **Ethics ref:** | **18/NTB/181** |  |
|  | Title: | Assessment of the trial drug CBL-514 in healthy adults. |  |
|  | Principal Investigator: | Dr Chris Wynne |  |
|  | Sponsor: | Caliway Biopharmaceuticals Australia PTY Ltd |  |
|  | Clock Start Date: | 18 October 2018 |  |

Dr Chris Wynne was present 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 Study

1. The study investigates the safety, tolerability, and preliminary efficacy of the drug CBL-514 as a treatment for reducing cosmetically unacceptable subcutaneous abdominal fat.

Summary of resolved ethical issues

The main ethical issues considered by the Committee and addressed by the Researcher are as follows.

1. The Committee noted that topical local anaesthetic will be provided to numb the skin of participants when they receive injections of the study drug although this will not necessarily eliminate discomfort from the drug as it enters the subcutaneous tissues..

Summary of outstanding ethical issues

The main ethical issues considered by the Committee and which require addressing by the Researcher are as follows.

1. Please amend the information sheet and consent form, taking into account the suggestions made by the Committee (*Ethical Guidelines for Intervention Studies* *para 6.22*).
2. Please add an independent cosmetic surgeon to the safety committee. *(Ethical Guidelines for Intervention Studies para 6.50).*
3. Please provide the administration manual to the committee.. (*Ethical Guidelines for Intervention Studies* *para 5.41*)

The Committee requested the following changes to the Participant Information Sheet and Consent Form:

1. Please explain clearly that there will be multiple injections and that there may be a risk of pain during the injections and of permanent scarring.
2. Please amend advertising materials to clearly explain that the study will involve needles.
3. Please clarify (p.10) that identifying data will not be used to label research specimens which are analysed overseas.
4. 9. Please amend the statement on the Consent form which states that samples will be labelled with initials and dob, to indicate this will not apply to samples going to Shanghai

Decision

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

* Please amend the information sheet and consent form, taking into account the suggestions made by the Committee (*Ethical Guidelines for Intervention Studies* *para 6.22*).
* Please update the Data Safety Monitoring plans *(Ethical Guidelines for Intervention Studies para 6.50).*
* Please provide the administration manual to the Committee. (*Ethical Guidelines for Intervention Studies* *para 5.41*)

This following information will be reviewed, and a final decision made on the application, by Dr Nora Lynch and Mrs Kate O’Connor.

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| **5** | **Ethics ref:** | **18/NTB/182** |  |
|  | Title: | HWEN at Korowai Manaaki: A Process Evaluation |  |
|  | Principal Investigator: | Dr Clare-Ann Fortune |  |
|  | Sponsor: | Victoria University of Wellington |  |
|  | Clock Start Date: | 18 October 2018 |  |

Dr Clare-Ann Fortune and Ms Molly Weenik were present 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 Study

1. The study evaluates the use of Dialectical Behavioural Therapy at Korowai

Manaaki through quantitative and qualitative methods to get a clear idea as to how the programme is being implemented and allow feedback to flow back through to the programme itself

Summary of resolved ethical issues

The main ethical issues considered by the Committee and addressed by the Researcher are as follows.

1. The Committee noted that the Researchers had consulted on the information sheet and consent forms with young people in the community and with a programme facilitator.
2. The Committee asked how the consent process works. The Researchers explained that facilitators will explain the project to potential participants and if the young person is interested then they will be passed on to the Researchers.

Summary of outstanding ethical issues

The main ethical issues considered by the Committee and which require addressing by the Researcher are as follows.

1. The Committee asked that the Researchers make reasonable attempts to contact participants and ask them to review their transcripts. While noting that there may be some difficulty in contacting participants the Committee felt it would not be equitable to provide the opportunity to staff members and not young people. (*Ethical Guidelines for Intervention Studies* *para 5.41*)
2. Please amend the information sheet and consent form, taking into account the suggestions made by the Committee (*Ethical Guidelines for Intervention Studies* *para 6.22*).
3. The Committee noted that a high percentage of the study population will be Māori and requested that they be provided the outcome of Māori consultation for this study.
4. The Committee agreed that the simpler information pamphlet produced by the research team may be easier for many participants to read themselves. However to ensure all appropriate information is available to potential participants, they asked that the Researchers read through through the full HDEC-templated information sheet aloud to participants so that they can confirm their understanding. Please amend the study protocol taking into account the suggestions made by the Committee. (*Ethical Guidelines for Intervention Studies* *para 5.41 & Section 6*)

The Committee requested the following changes to the Participant Information Sheet and Consent Form:

1. Please try to find a local independent Māori cultural support person as the current provider is very distant from the study site.
2. Please check that the correct you/your child pronouns are used in information sheet and consent and assent documents. The Committee requested that a specific parental guardian information sheet and consent form be created, separate from the assent document for young people under the age of 16..
3. Explain that participants will be given the opportunity to remove any statements from the transcript.
4. Please explain to staff that their participation will not affect their employment but due to the small number of staff then it may be possible for them to be identified based on their statements.

Decision

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

* Please amend the information sheet and consent form, taking into account the suggestions made by the Committee (*Ethical Guidelines for Intervention Studies* *para 6.22*).
* Please amend the study protocol taking into account the suggestions made by the Committee. (*Ethical Guidelines for Intervention Studies* *para 5.41*)
* Please provide the outcome of Māori consultation. (*Ethical Guidelines for Intervention Studies* *para 1.7*)

This following information will be reviewed, and a final decision made on the application, by Mrs Tangihaere MacFarlane and Dr Peter Gallagher.

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| **6** | **Ethics ref:** | **18/NTB/183** |  |
|  | Title: | Neonatal Ear Study |  |
|  | Principal Investigator: | Ms Gayl Humphrey |  |
|  | Sponsor: |  |  |
|  | Clock Start Date: | 18 October 2018 |  |

Decision

This application was *provisionally approved* by consensus.

**Closed Minutes**

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| **7** | **Ethics ref:** | **18/NTB/184** |  |
|  | Title: | Effortful decision making after stroke |  |
|  | Principal Investigator: | Dr Kelly Jones |  |
|  | Sponsor: | Auckland University of Technology |  |
|  | Clock Start Date: | 18 October 2018 |  |

Dr Kelly Jones was present 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 Study

1. The study investigates several computer-based decision-making tasks in stroke patients with fatigue.
2. Behavioural data (i.e. response times, correct/incorrect responses to stimulus target) will be recorded. These findings will directly inform measurement selection for a full-scale trial focusing on the management of post-stroke fatigue.

Summary of resolved ethical issues

The main ethical issues considered by the Committee and addressed by the Researcher are as follows.

1. The Committee noted that the study is a pilot study.
2. The Committee stated that the difference in compensation to staff for confirming medical details of the stroke to fulfil inclusion criteria versus the compensation to participants was unfair and should be made more equitable. The Committee requested that the Researcher attempt to do the study without having to compensate participant’s GPs for confirming their patient’s diagnosis.
3. The Committee acknowledged that this course of action may lead to difficulties and explained that the researchers would be able to amend their protocol to re-introduce compensation if the zero compensation option leads to the study not being practicable.
4. The Committee recommended the Researcher write to participant’s GPs and explain why the study is important.
5. The Committee noted that the proposed 2 hour computer session may be arduous for participants and would be best formally broken by a meal/rest break given that post-stroke fatigue was a necessary criterion for enrollment

The Committee requested the following changes to the Participant Information Sheet and Consent Form:

1. Please explain what food and refreshment will be provided to participants.
2. Please include that transport costs will be reimbursed in advertising and recruitment materials.
3. Please include contact details for a local Māori cultural support service at the end of the information sheet.
4. Please modify the ACC statement to state that participants would be eligible to APPLY for ACC in the event of injury

Decision

This application was *approved* by consensus, subject to the following non-standard conditions:

* Please amend the information sheet and consent form, taking into account the suggestions made by the Committee (*Ethical Guidelines for Intervention Studies* *para 6.22*).
* Please amend the study protocol taking into account the suggestions made by the Committee. (*Ethical Guidelines for Intervention Studies* *para 5.41*)

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| **8** | **Ethics ref:** | **18/NTB/190** |  |
|  | Title: | Novel passive stoma bypass device ('stoma-link') |  |
|  | Principal Investigator: | A/Prof Gregory O'Grady |  |
|  | Sponsor: | University of Auckland |  |
|  | Clock Start Date: | 18 October 2018 |  |

Decision

This application was *provisionally approved* by consensus.

**Closed Minutes**

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| **9** | **Ethics ref:** | **18/NTB/191** |  |
|  | Title: | The use of the RACER-PAP during exercise in normal healthy adults |  |
|  | Principal Investigator: | DR Julie Reeve |  |
|  | Sponsor: |  |  |
|  | Clock Start Date: | 18 October 2018 |  |

Decision

This application was *provisionally approved* by consensus.

**Closed Minutes**

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| **10** | **Ethics ref:** | **18/NTB/194** |  |
|  | Title: | TRCA-303 Study |  |
|  | Principal Investigator: | DR Kannaiyan Rabindranath |  |
|  | Sponsor: | Tricida, Inc |  |
|  | Clock Start Date: | 18 October 2018 |  |

Dr Kannaiyan Rabindranath was present 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 Study

1. The study investigates the efficacy and safety of TRC101 in delaying chronic kidney disease progression in people with metabolic acidosis.

Summary of resolved ethical issues

The main ethical issues considered by the Committee and addressed by the Researcher are as follows.

1. The Committee queried if the use of a placebo in the study was justified. The Researcher explained that sodium bicarbonate is the standard treatment at their institution but this is not universally used and that often there is no treatment. Participants were able to enter the study on bicarbonate providing they still had a significant level of metabolic acidosis meaning the standard of care had failed.

Summary of outstanding ethical issues

The main ethical issues considered by the Committee and which require addressing by the Researcher are as follows.

1. The Committee stated it was unclear if there will be future unspecified research in this study. Please confirm this and amend the protocol and information sheets accordingly. (*Ethical Guidelines for Intervention Studies* *paras 6.22 & 5.41*).
2. Please amend the information sheet and consent form, taking into account the suggestions made by the Committee (*Ethical Guidelines for Intervention Studies* *para 6.22*).

The Committee requested the following changes to the Participant Information Sheet and Consent Form:

1. Please explain that depending on how participants are randomised then they may be on the placebo for a long time.
2. Please explain that there will be no compassionate extension for the study.
3. The Committee stated that all three information sheets are very long and repetitive and asked that they all be checked over for ways to be shortened without compromising on the level of information provided.In the Optional Bone Density substudy, for example, it is acceptable to refer back to information in the Main PISC rather than repeat it again verbatim. It should be possible to explain the study, which involves 3 DEXAs over 3 years, without running to 15 pages. Add details of time required to undertake a DEXA.
4. Please shorten the section of the information sheet about the European Union data protections. It is important that participants understand that data sent overseas will be held according to the laws of the country the data will be sent to. However an in-depth explanation of the GDPR is not necessary and may overwhelm participants.
5. In the Prescreening PISC, remove reference to using the data “after the study” as they have not yet signed up for anything other than the Prescreening phase.
6. In the Main PISC, remove the paragraph on Prescreening p.6 as that phase has already passed
7. 11. State which countries offshore will undertake specimen analysis and what analyses will be done ie biochemical/genetic/ other?
8. Remove the reference to the “Ministry of Health “ being able to access study data. Refer to more specifically to Medsafe if this is what is meant
9. Ensure all PISCs have the 4 standard contacts

Decision

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

* Please amend the information sheet and consent form, taking into account the suggestions made by the Committee (*Ethical Guidelines for Intervention Studies* *para 6.22*).

1. Please confirm if there is future unspecified research in this study and amend the protocol and information sheets accordingly. (*Ethical Guidelines for Intervention Studies* *paras 6.22 & 5.41*).

This following information will be reviewed, and a final decision made on the application, by [insert name(s) of member(s) or the secretariat].

## Review of approved studies

## 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:

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| **Meeting date:** | 04 December 2018, 12:00 PM |
| **Meeting venue:** | Novotel Ellerslie, 72-112 Greenlane Road East, Ellerslie, Auckland |

1. **Problem with Last Minutes**

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

1. **Matters Arising**
2. **Other business**
3. **Other business for information**
4. **Any other business**

The meeting closed at 5pm.