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| **Committee:** | Northern B Health and Disability Ethics Committee |
| **Meeting date:** | 05 September 2017 |
| **Meeting venue:** | Novotel Ellerslie, 72-112 Greenlane Rd East, Ellerslie, Auckland |

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| **Time** | **Item of business** |
| 11:25pm | Welcome |
| 12:05pm | Confirmation of minutes of meeting of 01 August 2017 |
| 12:15pm | New applications (see over for details) |
|  | i 17/NTB/158  ii 17/NTB/159  iii 17/NTB/160  iv 17/NTB/161  v 17/NTB/162  vi 17/NTB/164  vii 17/NTB/165  viii 17/NTB/166  ix 17/NTB/167  x 17/NTB/169  xi 17/NTB/172 |
| 5:25pm | General business:   * Noting section of agenda |
| 5:55pm | 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 | Present |
| Mrs Stephanie Pollard | Non-lay (intervention studies) | 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 | Present |
| Mr John Hancock | Lay (the law) | 14/12/2015 | 14/12/2018 | Present |
| Mrs Jane Wylie | Non-lay (intervention studies) | 20/05/2017 | 20/05/2020 | Present |

## Welcome

The Chair opened the meeting at 12:00pm and welcomed Committee members.

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 1 August 2017were confirmed.

## New applications

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| **1** | **Ethics ref:** | **17/NTB/158** |
|  | Title: | RUBATO |
|  | Principal Investigator: | Doctor Kathryn Rice |
|  | Sponsor: | Covance New Zealand Ltd |
|  | Clock Start Date: | 24 August 2017 |

Dr Kathryn Rice was present in person 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 and efficacy of macitentan in adult and adolescent people with Fontan’s circulation.

Summary of ethical issues (resolved)

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

1. The Committee noted that the study drug may improve quality of life in participants.

Summary of ethical issues (outstanding)

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

1. The Committee requested further evidence of peer review. Please provide evidence of favourable independent peer review of the study protocol (*Ethical Guidelines for Intervention Studies* Appendix 1)
2. The Committee queried the need for a physical puberty assessment and pregnancy test in female participants aged 12 – 15 years. The Researcher explained that the study drug can have severe negative effects in individuals in this age range.
3. The Committee requested that all females be informed of the risks and be required to take a pregnancy test in order to avoid targeting of a specific demographic. This includes all female participants 12 or older being informed of the risks of getting pregnant and the need for contraception.
4. The Committee requested that the assent forms be simplified as the form would be too complex for young people.
5. Please create an information sheet and assent form for developmentally delayed participants.
6. 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 rephrase the adolescent PIS/CF for 16 year olds or over to make it clear that the teenager is giving consent and not the parent.
2. Please amend the PIS/CF for parents to clearly state that they cannot consent on behalf of any children aged 16 or older. They are only being informed.
3. Include an option in the consent form for participants to decide if data collected until withdrawal can be used for analysis.
4. Include that the drug will not be available post-study.
5. Please include more information about the future unspecified use and separate this out into a future unspecified use information sheet and consent form.

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 provide evidence of favourable independent peer review of the study protocol (*Ethical Guidelines for Intervention Studies* Appendix 1)
* Please amend the design so that all female participants 12 or older receive the same reproductive and contraceptive information and pregnancy screening.

This following information will be reviewed, and a final decision made on the application, by Mrs Maliaga Erick and Mrs Stephanie Pollard.

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| **2** | **Ethics ref:** | **17/NTB/167** |
|  | Title: | Pau te Hau. High intensity interval training for young adolescents |
|  | Principal Investigator: | Dr Nigel Harris |
|  | Sponsor: | Auckland University of Technology |
|  | Clock Start Date: | 24 August 2017 |

Dr Nigel Harris was present in person 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 feasibility of embedding a teacher-delivered high intensity interval training programme into the physical education curriculum at schools/

Summary of ethical issues (resolved)

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

1. The Committee noted that ethical issues that had led to this project being previously declined had been addressed such as the inclusion of a teacher information sheet and removal of a DEXA scan.

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

1. Add the complete phone number and extension for the Māori cultural support person.
2. Include that teacher participation is voluntary in the teacher information sheet.
3. Mention that children will be bussed into university and so teacher supervision will be required.

Decision

This application was *approved with non-standard conditions* by consensus. The non-standard conditions are:

* 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 offer teacher participants a copy of their interview transcript so that they may check for accuracy.

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| **3** | **Ethics ref:** | **17/NTB/169** |
|  | Title: | Open WATER Study |
|  | Principal Investigator: | Professor Peter Gilling |
|  | Sponsor: | Procept BioRobotics |
|  | Clock Start Date: | 24 August 2017 |

Ms Rachel Hamill 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 is a post-market study that investigates the efficacy of high speed water-based prostate ablation in the treatment of lower urinary tract obstruction in men aged 45 – 80
2. Results from this project will help produce data and safety information on the device.

Summary of ethical issues (resolved)

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

1. The Committee queried if the device is owned by the district health board or a private practice. The Researcher explained that the device is being provided to the District Health Board by the sponsor and will be checked by medical engineers before use.
2. The Committee asked if non-study patents will be able to receive treatment that uses the device. The Researcher stated that they would not unless the hospital was to purchase the device and that standard treatment is available to anyone declining to participate in the trial.

Summary of ethical issues (outstanding)

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. The Committee requested more information on the data safety monitoring arrangements for the study and requests details on that is in place and the terms of reference for the data safety committee.
3. Please use Statistics New Zealand's ethnicity classifications when collecting ethnicity data to ensure the options available are suitable for New Zealand participants. These classifications are: New Zealand European, Maori, Samoan, Cook Islands Maori, Tongan, Niuean, Chinese, Indian, Other (such as Dutch, Japanese, Tokelauan) please state.
4. Please provide confirmation that insurance cover will continue to be provided once the current insurance runs out on 10 Dec 2017.

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

1. Clarify in the information sheet that the water beam treatment will not be available outside of the study and that patients cannot decline study participation and receive the water beam treatment.
2. Please translate technical or jargon terms into lay explanations.
3. Include that travel is reimbursed and how to claim for reimbursements.
4. Include the Māori health services contact details
5. Clarify that any tissue collected is a standard care and no additional tissue will be collected.

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 use Statistics New Zealand's ethnicity classifications when collecting ethnicity data to ensure the options available are suitable for New Zealand participants. These classifications are: New Zealand European, Maori, Samoan, Cook Islands Maori, Tongan, Niuean, Chinese, Indian, Other (such as Dutch, Japanese, Tokelauan) please state.
* Please provide evidence of continuing insurance arrangements for the study.
* The Committee requested more information on the data safety monitoring arrangements for the study and requests details on hat is in place and the terms of reference for the data safety committee.

This following information will be reviewed, and a final decision made on the application, by Mr John Hancock and Mrs Stephanie Pollard.

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| **4** | **Ethics ref:** | **17/NTB/172** |
|  | Title: | Midodrine to prevent Orthostatic Intolerance after Hip and Knee Arthroplasty |
|  | Principal Investigator: | Dr Michal Kluger |
|  | Sponsor: |  |

Dr Michal Kluger was not present 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 is a randomised, placebo-controlled trial to determine the efficacy of oral midodrine hydrochloride to prevent Orthostatic Intolerance after Hip and Knee Arthroplasty.

Summary of ethical issues (resolved)

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

1. The Committee asked if the co-ordinating investigator had any relationship with the study drug’s manufacturer. The Researchers explained that they did not.
2. The Committee asked for the justification for using a placebo in this study. The Researchers stated that the placebo use is justified as this is a randomised controlled trial and that participants will receive current best practice standard care throughout.
3. The Committee noted that the dose size was at the limit of safety.

Summary of ethical issues (outstanding)

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

1. The Committee queried the use of phone to screen participants in order to ensure competency to consent. The Researcher explained that medical histories will be checked prior to calling and that internal communication procedures will be in place with the research team. The Committee stated that they did not believe that the current screening process provides adequate safeguards to exclude patients with conditions that might effect their ability to provide informed consent. The Committee requested that the initial consult also include a specialist who can rule out patients who cannot provide informed consent. (*Ethical Guidelines for Intervention Studies* *paras 4.3 – 4.6*).
2. The Committee asked about the risks of orthostatic intolerance. The Researcher explained that they have a 22% incidence rate at their locality and thus 66% of participants will be randomised to the study drug (non-placebo) arm of the trial. The Committee noted that there are risks with administering the drugs and suggested that the randomisation be performed post-surgery, only randomising those with orthostatic intolerance on return to the ward .The Researcher explained that symptoms of orthostatic hypotension may have already developed at this stage and there is a risk of deep vein thrombosis. The Committee stated that benefit from the study drug would not be lost from waiting up to six hours and that by doing so the current level of risk would be better managed.
3. The Committee had concerns that the tool being used to diagnose orthostatic intolerance had not been validated and that it could over diagnose orthostatic intolerance.
4. The Committee asked if a patient would have to display all symptoms listed in the diagnostic tool to diagnose orthostatic intolerance. The Researcher explained that they would only have to exhibit a single symptom from the tool. The Committee stated that this was a significant scientific issue.

Decision

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

* The Committee had significant concerns about the scientific worth of the study. These include use of the diagnostic tool, the randomisation procedures for the study, and the randomisation ratio. (*Ethical Guidelines for Intervention Studies* *paras 3.3 -.36*).
* The Committee stated that the risks of the study, given the high dose and time of randomisation, were too high. (*Ethical Guidelines for Intervention Studies* *paras 3.8 – 3.11*).
* The Committee were not satisfied that there were sufficient screening procedures in place to adequately screen out vulnerable participants. (*Ethical Guidelines for Intervention Studies* *paras 4.3 – 4.6*).

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| **5** | **Ethics ref:** | **17/NTB/162** |
|  | Title: | Clinical Application of pharyngeal high resolution manometry. |
|  | Principal Investigator: | Dr Kristin Gozdzikowska |
|  | Sponsor: |  |
|  | Clock Start Date: | 24 August 2017 |

Dr Kristin Gozdzikowska 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 usefulness of pharyngeal high resolution manometry as an additive investigation to visual barium x ray evaluation of swallowing in patients with neurological injury. This will help establish if pharyngeal high resolution manometry is viable in practice.

Summary of ethical issues (resolved)

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

1. The Committee queried if patients who are unable to provide informed consent will be enrolled in this study. The Researcher explained that an independent clinician will be screening potential participants and determining their ability to consent. Patients who cannot provide informed consent will not be included.

Summary of ethical issues (outstanding)

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 document the competency assessment process in the protocol including all processes associated with informed consent.
3. Please amend the protocol to emphasise the researcher’s responsibility to ensure participant safety.
4. Please provide a universal trial number for this study.
5. Please provide the details on the data safety monitoring committee including the charter and terms of reference.
6. The Committee stated that Māori cultural review is required and requested the outcome of Māori cultural consultation.

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

1. Add that participant’s GPs will be notified and seek consent for this notification.
2. Include that this is a pilot study.
3. Amend the PIS to state that participant’s identities will not be made public at all.
4. Please include that the results of the manometry procedure can be used to improve participant’s care.

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 make the required changes to the study protocol.
* Please provide a universal trial number.
* Please provide the outcome of Māori consultation. (*Ethical Guidelines for Intervention Studies* *para 4.7*).

This following information will be reviewed, and a final decision made on the application, by Mrs Maliaga Erick and Mrs Stephanie Pollard.

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| **6** | **Ethics ref:** | **17/NTB/164** |
|  | Title: | CK-301-101: Phase 1 Study of CK-301 in Advanced Cancers |
|  | Principal Investigator: | Dr Dean Harris |
|  | Sponsor: | Checkpoint Therapeutics, Inc. |
|  | Clock Start Date: | 24 August 2017 |

Dr Dean Harris 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 is a Phase 1, Open-label, Multicenter, Dose-escalation Study of CK-301 Administered Intravenously as a Single Agent to Subjects with Advanced Cancers.

Summary of ethical issues (resolved)

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

1. The Committee noted that this study is first in human but the study drug is closely related to another class of medicine that have been shown to effective and relatively safe.
2. The Committee asked if all previous lines of therapy need to have been trialled before a patient can enrol. The Researcher explained that this is not the case but that the Researchers would be following practice guidelines for choosing therapies.
3. The Committee queried the mandatory biopsy samples and how this would be managed for those patients who are physically inaccessible. The Researcher explained that these are highly desired but can be waived.

Summary of ethical issues (outstanding)

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 confirm that participants can return to a lower dose of the study drug if they begin to experience side effects as a result of escalation.
3. Please confirm in wiritng that patients who are in partial, stable remission will be able to take a drug free holiday and will be able to receive the drug if their disease comes back.
4. Please provide the updated insurance certificate as soon as practicable.

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

1. Please include Hodgkins lymphoma as an inclusion criterion.
2. Please amend the information sheet to include the information on returning to a lower dose if participants begin to experience side effects.
3. Please include disposal with karakia as an option for samples sent overseas.
4. Please include where samples will be sent overseas for testing and that overseas companies will be accessing samples for testing.
5. Please simplify and remove repetition where possible, and review for formatting. For example:
   * p.2: use a lay term for “non-clinical” studies
   * p.2 and p.5: specify that the expected patient numbers given are world-wide and/or give the expected participants in New Zealand.
   * p.7: format 3rd bullet point for “Radiation therapy…”
   * p.9: MRI - stated risks are lengthy and repetitive compared with CT scan.
   * p.13: funding by Checkpoint Therapeutics is stated twice.

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 confirm that participants can return to a lower dose of the study drug if they begin to experience side effects as a result of escalation.
* Please confirm in wriitng that patients who are in partial, stable remission will be able to take a drug free holiday and will be able to receive the drug if their disease comes back.
* Please provide the updated insurance certificate as soon as practicable.

This following information will be reviewed, and a final decision made on the application, by Mr John Hancock and Mrs Jane Wylie.

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| **7** | **Ethics ref:** | **17/NTB/165** |
|  | Title: | ATB200/AT2221 Pompe |
|  | Principal Investigator: | Dr Andrew Veale |
|  | Sponsor: | Amicus Therapeutics, Inc. |
|  | Clock Start Date: | 24 August 2017 |

Dr Andrew Veale and Mrs Carole Veale were present in person 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. This is a Phase 1/2 open-label study of single and multiple-ascending doses to assess if investigational new drugs, ATB200 and AT2221 are safe, given alone and in combination, to help adults with Pompe disease.

Decision

This application was withdrawn by the Co-ordinating investigator.

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| **8** | **Ethics ref:** | **17/NTB/166** |
|  | Title: | Neonatal conjunctivitis in the New Zealand Midland region (2nd application) |
|  | Principal Investigator: | Dr Samuel Newlands |
|  | Sponsor: |  |
|  | Clock Start Date: | 24 August 2017 |

Dr Samuel Newlands 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 neonatal conjunctivitis in the Waikato and Midland regions in the first 28 days of life. Specifically chlamydial and gonorrhoeal conjunctivitis will be examined.

Summary of ethical issues (resolved)

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

1. The Committee noted that issues raised in the previous Committee’s decline letter and those requested by the peer reviewers have been addressed.
2. The Committee were satisfied that the criteria laid out in the Ethical Guidelines for Observational Studies states at Paragraph 6.43 for non-consensual use of health information of the infant had been met.

Summary of ethical issues (outstanding)

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

1. The Committee stated that they had significant scientific concerns with the second part of the study. As presented the design of this section would lead to potential stigmatisation of groups as well as producing a skewed result of the rates of disease in these regions. The Committee recommended that researcher amend their study to only include the first part of the study and then resubmit the second part following consultation with public health researchers and other experts. *(Ethical Guidelines for Observational Studies paras 5.7 – 5.8)*

Decision

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

* Please amend the protocol to contain the first aspect of the study only and submit the second half as an amendment following consultation on the methodology of the second section. *(Ethical Guidelines for Observational Studies paras 5.7 – 5.8)*

This following information will be reviewed, and a final decision made on the application, by Mrs Maliaga Erick and Mrs Jane Wylie.

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| **9** | **Ethics ref:** | **17/NTB/159** |
|  | Title: | M15-991 |
|  | Principal Investigator: | Prof. Richard Gearry |
|  | Sponsor: | AbbVie |
|  | Clock Start Date: | 24 August 2017 |

Prof Richard Gearry was not present 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 is a randomised, double-blind, placebo-controlled investigation of the safety and efficacy of risankizumab in patients who have moderate to severely active Crohn’s disease and who have not responded to at least one prior biologic treatment.

Summary of ethical issues (resolved)

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

1. The Committee noted that the study had been submitted to the Standing Committee on Therapeutic Trials.
2. The Committee noted that there is an independent data safety monitoring committee for this study.

Summary of ethical issues (outstanding)

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

1. The Committee stated that there were hygienic and cultural issues with keeping stool samples in a fridge. The Committee stated that the sponsor should consider providing coolers or arranging a courier service to collect samples from participants. Please address how this issue will be managed as the current arrangement is not suitable. (*Ethical Guidelines for Intervention Studies* *para 4.7*).
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 remove references to flipping a coin when talking about randomisation or allocation.
2. Please make sure the contact numbers on the participant information sheet for using the electronic diary are local New Zealand numbers. Participants should not have to make an international phone call if they have concerns.
3. Please check the formatting of the page numbering.
4. Please consider using colonoscopy instead of endoscopy as this would be more in-line with New Zealand parlance.
5. Remove reference to separate pis/cf documents from the main pis/cf
6. Please re-write the risks section to explain risks in a lay friendly manner. This includes classifying the risks by severity, listing rate of occurance, and removing jargon terms such as reference to phase 2 studies, as lay participants will not understand these.
7. Explain what is meant by “paying for drugs according to hospital policy” or remove this statement.
8. Explain that the daily diary information will be de-identifiable.
9. Remove references to American law.
10. Explain that breaking the blind may lead to study termination.
11. Explain that participants can access and correct their health information at any time rather than having to wait until a defined point. This is in accordance with New Zealand privacy law.
12. Please index where Abbvie will store tissue samples.
13. Please include the option of moving to a maintenance study under the section “What happens at the end of the study.”
14. Please add yes/no tickboxes to the sections of the consent form for receiving a summary of study findings and informing a participant’s GP.
15. If there is no risk to a pregnant partner then please remove this from the information sheet.
16. Specify exactly what is meant by tissue in the optional study information sheet.
17. Please specify where tissue will be stored for the optional study.

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 address the cultural issues with this study. (*Ethical Guidelines for Intervention Studies* *para 4.7*).

This following information will be reviewed, and a final decision made on the application, by Dr Nora Lynch and Miss Tangihaere MacFarlane.

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| **10** | **Ethics ref:** | **17/NTB/160** |
|  | Title: | M16-000 |
|  | Principal Investigator: | Prof. Richard Gearry |
|  | Sponsor: | AbbVie |
|  | Clock Start Date: | 24 August 2017 |

Dr Richard Gearry was not present 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 is 52 week, randomised trial followed by an open-label extension study for participants with Crohn’s disease who responded to induction treatment in studies M16-006 or M15-991.

Summary of ethical issues (outstanding)

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. The Committee had concerns that those in substudy one who showed a response to placebo in the qualifying studies still needed to do another blinded year on placebo, with all required visits and tests. Please address why it would not be appropriate to break the blind prior to enrolling participants.
3. The Committee sought clarification for why those who respond to the placebo would be crossed over to the investigational product in substudy two. Please justify the 6 month monitoring cycle in the open label extension study and explain why this is not too infrequent.

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

1. Please provide more detail on the components of annual TB testing.
2. Please remove the statement about paying for all costs except some drugs.
3. Please move statements relating to future unspecified research (FUR) from the main PIS to the FUR PIS.
4. The Committee queried the lack of a Māori tissue statement in the Participant Information Sheet. The committee recommended the following statement: “*You may hold beliefs about a sacred and shared value of all or any tissue samples removed. The cultural issues associated with sending your samples overseas and/or storing your tissue should be discussed with your family/whanau as appropriate. There are a range of views held by Māori around these issues; some iwi disagree with storage of samples citing whakapapa and advise their people to consult prior to participation in research where this occurs. However, it is acknowledged that individuals have the right to choose.”*
5. The Committee requested the compensation wording is updated for accuracy, they suggested the following statement: *“If you were injured as a result of treatment given as part of this study, which is unlikely, you* ***won’t*** *be eligible for compensation from ACC. However, compensation would be available from the study’s sponsor, [x], in line with industry guidelines. We can give you a copy of these guidelines if you wish. You would be able to take action through the courts if you disagreed with the amount of compensation provided. If you have private health or life insurance, you may wish to check with your insurer that taking part in this study won’t affect your cover.”*
6. Please rewrite the risks of Risankizumab section on p.9-10 to clearly explain the risks of risankizumab. This includes rates of incidence (e.g. 1/1000) and a stratification of the risks by severity. These risks must be explained in lay-friendly language that avoids jargon.
7. Please include the risks for psoriasis.
8. Please include the details of the overseas lab where samples will be sent for testing
9. Please include that participants have the right to correct their health information at any time, as per New Zealand law but that this may break the blind and cause removal from the study.

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*).

This following information will be reviewed, and a final decision made on the application, by Dr Nora Lynch and Miss Tangihaere MacFarlane.

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| **11** | **Ethics ref:** | **17/NTB/161** |
|  | Title: | M16-006 |
|  | Principal Investigator: | Prof. Richard Gearry |
|  | Sponsor: | AbbVie Pty Ltd |
|  | Clock Start Date: | 24 August 2017 |

Dr Richard Gearry was not present 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 is a randomised, double-blind, placebo-controlled induction study that assesses the safety and efficacy of risankizumab in participants with moderate to severe Crohn’s disease. Two thirds of participants will not have failed a prior biologic treatment.

Summary of ethical issues (outstanding)

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. The Committee stated that failure to reimburse participants for a GP visit to discuss the study could be prohibitive for people with low-incomes or who face other barriers. Please justify not reimbursing participants for the GP visit or include reimbursement for this. (*Ethical Guidelines for Intervention Studies* *para 4.5*).

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

1. Please use the compensation wording option 2 in the information sheet and delete option 1.
2. The Committee queried the lack of a Māori tissue statement in the Participant Information Sheet. The committee recommended the following statement: “*You may hold beliefs about a sacred and shared value of all or any tissue samples removed. The cultural issues associated with sending your samples overseas and/or storing your tissue should be discussed with your family/whanau as appropriate. There are a range of views held by Māori around these issues; some iwi disagree with storage of samples citing whakapapa and advise their people to consult prior to participation in research where this occurs. However, it is acknowledged that individuals have the right to choose.”*
3. Please ensure that all contact details in the participants sheet explaining the use of the electronic diary, are New Zealand-based contact persons.
4. In Optional PIS, p.2/8, indicate how many samples and what quantity of blood is taken at the 3 extra visits.

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 justify not reimbursing participants for the GP visit or include reimbursement for this. (*Ethical Guidelines for Intervention Studies* *para 4.5*).

This following information will be reviewed, and a final decision made on the application, by Dr Nora Lynch and Miss Tangihaere MacFarlane.

## 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:** | 03 October 2017, 12:00 PM |
| **Meeting venue:** | Novotel Ellerslie, 72-112 Greenlane Rd East, Ellerslie, Auckland |

The following members tendered apologies for this meeting.

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.

The meeting closed at 5:55pm.