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| **Committee:** | Northern B Health and Disability Ethics Committee |
| **Meeting date:** | 04 September 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 07 August 2018 |
| 12:10pm | General business:   * Noting section |
| 12:30pm | New applications (see over for details) |
|  | i 18/NTB/140  ii 18/NTB/144  iii 18/NTB/145  iv 18/NTB/146  v 18/NTB/147  vi 18/NTB/148  vii 18/NTB/151  viii 18/NTB/150  ix 18/NTB/149 |
| 4:15pm | 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 | Apologies |
| Miss Tangihaere Macfarlane | Lay (consumer/community perspectives) | 20/05/2017 | 20/05/2020 | Apologies |
| 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 | 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, noting that apologies had been received from Stephanie Pollard, Leesa Russell, and Tangihaere Macfarlane.

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 07 August 2018 were confirmed.

## New applications

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| **1** | **Ethics ref:** | **18/NTB/140** |
|  | Title: | ATB200/AT2221 Pompe |
|  | Principal Investigator: | A/Prof Richard Roxburgh |
|  | Sponsor: | Amicus Therapeutics Inc |
|  | Clock Start Date: | 23 August 2018 |

A/Prof Richard Roxburgh 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. This study 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.
2. This application seeks to allow current participants in the trial, who currently must travel to Australia to receive infusions, to receive these infusions in New Zealand.

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 that the coordinating investigator update the details of the MEDSAFE approval to be under the coordinating investigator’s name.
2. The Committee noted that it is unclear if the study drug will continue for compassionate reasons to be available after the end of the study.
3. The Researcher asked if providing a stipend for New Zealand study visits would be appropriate. The Committee stated that yes as it would be unequitable to stop providing this stipend to NZ-based 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. 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. The National Ethics Advisory Committee guidelines state studies should not be terminated simply for reasons of commercial interest.
2. Please remove the section of the information sheet that requires written withdrawal.
3. Please clarify that study participation in New Zealand will be done under the supervision of University of Auckland staff.
4. Please add a separate heading for reimbursement and move reimbursement information into this section whilst clarifying that reimbursement is for travel arrangements and not for study visits etc.
5. Please amend the compensation wording to explain that the study sponsor will cover the participants.
6. Please clarify the frequency of pregnancy tests.
7. Please explain in the benefits section that participants may receive no benefits from participation.
8. Please add a yes/no tickbox to the consent form for participants to receive a lay summary of results of the study.
9. If safety bloods are part of the study then please include this in the information sheet.

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 Ms Maliaga Erick and Mrs Jane Wylie.

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| **2** | **Ethics ref:** | **18/NTB/144** |
|  | Title: | Low-Fat Versus Ketogenic Diet In Alzheimer's Disease |
|  | Principal Investigator: | Dr Matthew Phillips |
|  | Sponsor: |  |
|  | Clock Start Date: | 23 August 2018 |

Dr Matthew Phillips 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 pilot randomized trial on a population of 60 to 80 Alzheimer's (AD) patients so as to examine the plausibility and safety of maintaining a low-fat versus a ketogenic diet for 12 weeks, whether either diet group significantly improves in one or more of cognition, function, and quality of life, and whether one group shows greater improvements compared to the other.

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 there may be significant difficulty for the participants to adhere to the study protocol and diet. The Researcher explained that they have completed a previous study with Parkinson’s disease patients and these showed high retention rates despite the same concerns. The Researchers have developed a protocol where they produce weekly videos to help answer questions, email participants every 2 days, and the CI is available at any time. ;
2. The Committee asked if the ‘Keto flu’ was a problem in the previous study. The Researcher stated that it was not.

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 asked for further peer review from a geriatrician to confirm that it is possible for patients with a MOCA score of 16 to provide informed consent. (*Ethical Guidelines for Intervention Studies* Appendix 1)
2. The Committee noted that the Researcher would be asking for proxy consent from participant’s partners. The Committee stated that proxy consent is only legally acceptable for research participation in cases where the medical experiment would save the person’s life or prevent serious damage to the person’s health. The Committee noted that participant’s partners would also be considered participants and that they should receive their own informed consent forms. Likewise the protocol should be amended to reflect this (*Ethical Guidelines for Intervention Studies* *paras (5.41 & 6.22*).
3. The Committee noted that the study claims to be assessing the safety and plausibility of the diets but there are no outcome measures for these in the protocol. Please include some. (*Ethical Guidelines for Intervention Studies* *para 5.41*)
4. The Committee asked for further peer review of the project from a statistician to advise whether or not analysis should factor in the multiplicity of proposed primary outcome measures. Please provide evidence of favourable independent peer review of the study protocol (*Ethical Guidelines for Intervention Studies* Appendix 1)
5. Please upload the recruitment letter that may be sent to participant’s GPs.

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

1. Add some examples of the daily meals in the information sheets.
2. Please include that there is a slight cost discrepancy between the keto and the low fat diets.
3. Please add Māori cultural support person details to the information sheet.
4. Please explain technical terms such as APO genes and ketones.
5. Please check the statements on page for leading or coercive language. The language should be neutral as to the efficacy of low fat and ketogenic diets efficacy in this population as this is what the study investigates.
6. Clarify if home patients will be checking blood glucose and ketones with the home monitor as this is stated in the protocol and if so adjust the PISC to align with this.
7. Include information on travel cost reimbursement and that meal costs will not be reimbursed but the recipes are constructed to minimise cost.
8. Please ensure the ICF documents list the contact details for HDECS, the HDC patient advocacy service, and local Māori cultural support at the end of the documents.
9. Please remove the EPOA signature panels.
10. Please add a tickbox to the consent form for the option to receive a lay summary of results after the study ends.

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 and please provide suitable information sheets and assent forms for participant’s partners. (*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*)

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/145** |
|  | Title: | Acceptability of caring contacts by text messages. |
|  | Principal Investigator: | Miss Olivia High |
|  | Sponsor: |  |
|  | Clock Start Date: | 23 August 2018 |

Miss Olivia High 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 acceptability of supportive text messages (“caring contacts”) delivered to people who have been discharged from the Emergency Department (ED) following presentations for suicidal ideation or behaviour.

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 the high quality of the research application.
2. The Committee noted that 1 way text messages has been shown to be helpful.
3. The Committee asked how recruitment for the study would work. The Researcher explained that they will be in the hospital and awaiting referrals of patients who are due to be discharged that day.
4. The Committee asked if participants would have the opportunity to go away and think about their participation. The Researcher explained that they will not but that they can discuss with a family member or support person but once potential participants leave the hospital they will no longer be able to follow up.
5. The Committee noted that participants can opt out of the study at any time with a text message.

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 asked that the Researcher develop a data safety management plan for how study data will be held. *(Ethical Guidelines for Intervention Studies para 6.50).*
2. Please clarify what safety processes are in place to avoid retraumatisation of participants and if providing information on any history of mental health issues will be compulsory to participate. (*Ethical Guidelines for Intervention Studies* *para 5.41*)
3. 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 add that participants have the right to check and correct any information about themselves that is collected during the study.
2. Please use the standard HDEC ACC compensation wording for studies where participants are covered by ACC. This can be found on our website.
3. Please add contact details for Māori cultural support to the other details at the end of the information sheet.
4. Please remove tickboxes from the consent form for items where ticking no would exclude someone from participation.
5. Please note that all health information collected during the study must be held for ten years before it can be destroyed as per New Zealand law.

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 details of the Data Safety Monitoring plans *(Ethical Guidelines for Intervention Studies para 6.50).*

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

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| **4** | **Ethics ref:** | **18/NTB/146** |
|  | Title: | Kakano:Pilot study evaluation of an app to enhance parenting capacity and child wellbeing. |
|  | Principal Investigator: | Dr Stephanie Moor |
|  | Sponsor: |  |
|  | Clock Start Date: | 24 August 2018 |

Dr Stephanie Moor was present by teleconferencefor 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 acceptability and utility of the Kakano phone app for families and whānau parenting capacity and wellbeing.

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 how the app will work. The Researcher explained that the app will help with public health and parenting information. The current study is looking at the mechanism for delivering the information, or example basic behaviour management strategies.
2. The Committee asked how recruitment will work. The Researcher explained that when families are put on a waiting list for parenting or family help they will be given the information sheet for the study. Families will be told about the study as part of the in-home assessment that occurs when they go onto the waiting list.

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 needed more information about what the application would look like or what information will be provided to participants. Please provide this (*Ethical Guidelines for Intervention Studies Section 6)*
2. The Committee requested that the confusion around who is the coordinating investigator, i.e. the person responsible for the study conduct in New Zealand, be resolved and that their cv be supplied. (*Ethical Guidelines for Intervention Studies* *paras 5.36 & 5.37*).
3. 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. The Committee recommended the researchers use either the Otago University or HDEC information sheet templates as these help break down the information into the appropriate sections.
2. Please add details of a local Māori cultural support service for participants to call if needed.
3. Please note that survey results will be anonymous.
4. Please remove the statement by the principal investigator.

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 clarify who the coordinating investigator is and provide their CV. (*Ethical Guidelines for Intervention Studies* *paras 5.36 & 5.37*).
* Please provide further information on what the app will look like and what form the information will be presented in. (*Ethical Guidelines for Intervention Studies Section 6)*

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

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| **5** | **Ethics ref:** | **18/NTB/147** |
|  | Title: | M16-066 |
|  | Principal Investigator: | Professor Richard Gearry |
|  | Sponsor: | AbbVie Pty Ltd |
|  | Clock Start Date: | 23 August 2018 |

Professor 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 Multicenter, Randomized, Double-Blind, Placebo-Controlled 52-Week Maintenance and an Open-Label Extension Study of the Efficacy and Safety of Risankizumab in Subjects with Ulcerative Colitis Who Responded to Induction Treatment in the M16-067 or M16-065 projects.

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 asked that the researchers confirm if the trial has begun in any other countries and if there is any safety information from these countries that could be included in the information sheet. (*Ethical Guidelines for Intervention Studies section 6*).
2. Please justify placing participants who may have achieved a clinical response whilst on placebo in the feeder studies (M16-065 and 67) onto the active treatment for one year in substudy 2 and substudy 3. *(Ethical Guidelines for Intervention studies para 6.31)*
3. 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*).
4. The Committee noted that the certificate of insurance currency provided with this application is a national-level document, that there is no mention of this specific study protocol, and that the product is included in the liability. Please confirm in writing that participants in this study are eligible to apply to receive ACC-equivalent compensation from the study sponsor. Please also provide any additional insurance documentation that shows that the insurance documentation applies to this study. (*Ethical Guidelines for Intervention Studies section 8*).
5. The protocol states that substudy 3 will continue until discontinuation or approval and reimbursement (if applicable) for rizankizumab are available in the site’s jurisdiction. Please align information in the PISC with this. Currently the PISC says substudy 3 will continue for a maximum of 300 weeks.

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

1. Please check the future unspecified research information sheet’s section governing what happens to participants’ information for duplication.
2. Please clarify how many participants will go into the substudies 1 and 2 as different numbers are listed in the protocol and information sheet.
3. Please explain that there will be no rescue therapy for 16 weeks for participants on the placebo. These participants will be able to stay on standard therapy but cannot increase this or go onto new therapies.
4. Please create a lay title for the project and use this in the information sheet.
5. Please add ‘No live vaccines’ to the patient card as this is listed in the protocol but not in the card.
6. Please add the phone number of the clinic to the reminder card for participants.
7. Please consider creating a flowchart to help participants understand the study structure and processes.
8. Please remove any separate consents for HIV or Hepatitis testing and that the test results for HIV may need to be reported.
9. Please explain that reasonable travel costs will be reimbursed.
10. Please move the statement about Abbvie not being required to share profits and statement that tissue samples will be retained for 20 years, from the Main PISC to the future unspecified research information sheet.
11. Opt out consent for women who fall pregnant is not appropriate. Please amend this to an opt-in consent to be given when a pregnancy has been confirmed.
12. Make informing participants GPs non optional and explain this in the information sheet
13. Please express randomisation ratios as absolute figures (eg 2 out of 3 chances) rather than percentages which are less well understood.

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 add any safety information from any overseas sites that have commenced to the information sheet. (*Ethical Guidelines for Intervention Studies* Section *6*).
* Please justify placing participants who may have achieved a clinical response whilst on placebo onto the active treatment for one year. *(Ethical Guidelines for Intervention studies para 6.31)*
* Please confirm in writing that participants in this study are eligible to apply to receive ACC-equivalent compensation from the study sponsor. Please also provide any additional insurance documentation that shows that the insurance documentation applies to this study. (*Ethical Guidelines for Intervention Studies section 8*).

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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| **6** | **Ethics ref:** | **18/NTB/148** |
|  | Title: | M16-067 |
|  | Principal Investigator: | Professor Richard Gearry |
|  | Sponsor: | AbbVie Pty Ltd |
|  | Clock Start Date: | 23 August 2018 |

Professor 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 Multicenter, Randomized, Double-Blind, Placebo-Controlled Induction Study to Evaluate the Efficacy and Safety of Risankizumab in Subjects with Moderately to Severely Active Ulcerative Colitis Who Have Failed Prior Biologic Therapy

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 explain why participants who attend for 3 optional visits to provide blood for pk sampling will not be compensated for their time and if reasonable travel cost will be reimbursed. (*Ethical Guidelines for Intervention Studies* *paras 6.32 – 6.37*).
3. The Committee noted that the certificate of insurance currency provided with this application is a national-level document, that there is no mention of this specific study protocol, and that the product is included in the liability. Please confirm in writing that participants in this study are eligible to apply to receive ACC-equivalent compensation from the study sponsor. Please also provide any additional insurance documentation that shows that the insurance documentation applies to this study. (*Ethical Guidelines for Intervention Studies section 8*).
4. Commercial reasons are not an acceptable stopping criteria. Please remove these from the protocol and the ICF. (*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 why participants have been recruited – that they have failed biologic treatment and what that means
2. Please express randomisation ratios as absolute figures eg 2 out of 3 rather than percentages which are less well understood..
3. Please provide a space to enter the dose of i.v. rizankizumab that will be used in Substudy 2, Induction Period 1 and 2 as this will be available by the time the study is commenced and may be of interest to some participants.
4. Please consider a flow chart that explains how the study process works and when part two of the study will come into play.
5. Please explain the study risks in lay language
6. Please move the statement about Abbvie not being required to share profits derived from the results of research to the Future Unspecified Research information sheet.
7. Opt out consent for women who fall pregnant is not appropriate. Please amend this to an opt-in consent to be given at the time when a pregnancy is confirmed.
8. Make informing participants GPs non optional and explain this in the information sheet.
9. Please list example reasons for why the study might be terminated, e.g. safety concerns, and explain why these matter.
10. Please produce a participant card with relevant contact information.
11. Remove the final bullet point about the study sponsor not accepting compensation claims if an injury was caused by the study drug.
12. Insert the name of the NTB HDEC in the insurance section.
13. Please remove text about separate consent for HIV /hepatitis testing, and notification of positive HIV test as this is not relevant in NZ

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 confirm in writing that participants in this study are eligible to apply to receive ACC-equivalent compensation from the study sponsor. Please also provide any additional insurance documentation that shows that the insurance documentation applies to this study. (*Ethical Guidelines for Intervention Studies section 8*).
* Please explain why participants will not be compensated for their time and if reasonable travel cost will be reimbursed. (*Ethical Guidelines for Intervention Studies* *paras 6.32 – 6.37*).

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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| **7** | **Ethics ref:** | **18/NTB/151** |
|  | Title: | Staying Upright |
|  | Principal Investigator: | Prof Ngaire Kerse |
|  | Sponsor: | The University of Auckland |
|  | Clock Start Date: | 23 August 2018 |

Professor Ngaire Kerse 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 an exercise programme specifically designed for people with dementia in comparison to seated exercises to see if falls and injury from falls can be prevented.

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 how participation in the project would be in a participant’s best interests. The Researcher explained that all participants will be receiving individualised assessments and will be engaging with fall prevention classes differently. The additional assessments will be on top of standard care assessments and could help identify other issues.
2. The Committee asked who will determine if participants are able to provide informed consent. The Researchers stated that they will be looking at the various factors surrounding a person such as if they have activated their EPOA and the views of clinical nurse manager and the person’s family. The Researchers will also use InterRAI assessment data to help with the decision.
3. The researcher stated that the plan to video participants as a method of standardising intervention delivery, had been changed and this would not be happening

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 they need to see the physiotherapy manual and the BUPA sham manual.
2. The Committee asked if there is any accreditation required for the sham volunteers. The Researchers stated they will follow up on this. *(Ethical Guidelines for Intervention Studies para 5.36).*
3. 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*).
4. Please add an independent statistician to the Data Safety Monitoring Committee. *(Ethical Guidelines for Intervention Studies para 6.50).*

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

1. Please create a simplified assent script for those who have diminished ability to consent. The Committee also suggested signature blocks for staff to sign to show the script has been delivered and an assent signature block for the person.
2. Please add some Māori cultural support service contact details
3. Please explain more about the sessions for example who will be there, how long they last, if there will be breaks.
4. Please explain that a rest home may withdraw from the project and what this means for participants.
5. Please remove references to consent from the care home managers documents. The Committee suggested the term permission.
6. Please make sure the clinician’s ‘best interest’ statement explains what the clinician’s role is.
7. Please upload the correct consent form for competent participants.

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 accreditation information on the sham arm volunteers. (*Ethical Guidelines for Intervention Studies* *para 5.36*).
* Please add an independent statistician to the Data Safety Monitoring Committee. *(Ethical Guidelines for Intervention Studies para 6.50).*
* Please provide the physiotherapy manual and the BUPA sham manual. (*Ethical Guidelines for Intervention Studies* *para 5.41*)
* Please upload an amended protocol which does not describe video assessment of participants

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

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| **8** | **Ethics ref:** | **18/NTB/150** |
|  | Title: | Cimetidine for Reducing Oxaliplatin Neurotoxicity (CITRON) |
|  | Principal Investigator: | Professor Mark McKeage |
|  | Sponsor: | The University of Auckland |
|  | Clock Start Date: | 23 August 2018 |

Dr Mark McKeague 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 randomized, double-blind, placebo-controlled, cross-over, phase Ib clinical trial.
2. In combination with oxaliplatin, patients will be randomized to receive either a Cimetidine capsule(s) of 200, 400 or 800 mg 30 minutes prior to Cycle 1 chemotherapy or a matching blank capsule(s).
3. It is hypothesised that this will help reduce the neurotoxicity of the chemotherapy drugs.

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

1. Please do not refer to cimetidine as a treatment as it has not yet been substantiated. Please use the term study drug instead.
2. Please remove any tick boxes from the consent form for items where ticking no would exclude someone; these are not-optional so do not require separate consent.

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*).

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| **9** | **Ethics ref:** | **18/NTB/149** |
|  | Title: | Study of VIR-2218 in Healthy Volunteers and Patients with Chronic Hepatitis B |
|  | Principal Investigator: | Professor Edward Gane |
|  | Sponsor: | Novotech (New Zealand) Limited |
|  | Clock Start Date: | 23 August 2018 |

Professor Ed Gane 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 1/2, Randomized, Placebo-Controlled Study to Evaluate the Safety, Tolerability, Pharmacokinetics, and Antiviral Activity of VIR-2218

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 the value of the study and asked if healthy volunteers would begin before hepatitis participants on the study drug. The Researcher confirmed that they would.
2. The Committee asked that the Researcher check that reimbursement for travel costs are consistent across the study and noted that different arms may receive different time reimbursements due to differing length of stay.

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

1. Please amend the advertising material for accuracy as they currently mention excluding all persons who are on medication.

Decision

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

* Please amend the study advertisement material to be consistent with the study inclusion and exclusion criteria.

## 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:** | 02 October 2018, 12:00 PM |
| **Meeting venue:** | Novotel Ellerslie, 72-112 Greenlane Road East, Ellerslie, Auckland |

**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 4:15pm.