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| **Committee:** | Northern B Health and Disability Ethics Committee |
| **Meeting date:** | 04 July 2017 |
| **Meeting venue:** | Novotel Ellerslie, 72-112 Greenlane Rd East, Ellerslie, Auckland |

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| **Time** | **Item of business** |
| 11:30am | Training on guidelines for genomic research and bio banking involving Maori |
| 12:15pm | Welcome |
| 12:20pm | Confirmation of minutes of meeting of 06 June 2017 |
| 12:30pm | New applications (see over for details) |
|  | i 17/NTB/134  ii 17/NTB/130  iii 17/NTB/121  iv 17/NTB/131  v 17/NTB/125  vi 17/NTB/127  vii 17/NTB/117  viii 17/NTB/120  ix 17/NTB/124  x 17/NTB/128 |
| 5:00pm | General business:   * Noting section |
| 5:10pm | 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 | Apologies |

## Welcome

The Chair opened the meeting at 12:15pm and welcomed Committee members, noting that apologies had been received from Mrs Jane Wylie.

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 06 June 2017 were confirmed.

## New applications

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| 1 | **Ethics ref:** | **17/NTB/134** |
|  | Title: | T2NOW |
|  | Principal Investigator: | Dr. Brandon Orr-Walker |
|  | Sponsor: | PRA Health Sciences |
|  | Clock Start Date: | 22 June 2017 |

Dr. Brandon Orr-Walker and Catherine Howie 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. This involves young people with diabetes.
2. The Committee commended the quality of the Participant Information Sheet and thanked the researchers for including a re-consent form for participants who turn 16 during the study.

Summary of ethical issues (resolved)

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

1. The Committee questioned whether it was a safety concern for participants to fast for 8 hours before blood draws, including those on morning insulin. The Researcher confirmed that it is not a concern.

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 questioned how pregnancy testing will be managed for young participants in this study. The Committee questioned which participants would be pregnancy tested, suggesting that it may be inappropriate to ask participants in front of their parents if they are sexually active and if only participants who indicate that they are sexually active are pregnancy tested if parents find out this is being done it could put the young participants at risk. The Researcher explained that it is intended to be left to clinician discretion which participants are pregnancy tested but they are not certain how this would be determined. The Committee asked for this to be confirmed, they suggested that the best way to protect participants is to require pregnancy testing for all female participants, this prevents parents knowing whether their child is sexually active while allowing participants to be pregnancy tested.
2. Further, the Committee noted that if young participants are pregnant or sexually active this could raise a welfare issue and they want to ensure that appropriate measures are in place to protect participants. The Researcher stated that there is a code of ethics for managing these kinds of situations in general care, although they are unable to provide details of this at the meeting. The Committee requested comprehensive details of the child protection policy are provided, including details about how various scenarios would be managed.
3. The Committee raised concerns regarding whether placebo arm participants may receive less than standard care. The Researcher explained that they do not believe that placebo participants will receive less than standard care as in standard care there is a very high hurdle to receive insulin therapy for these patients. The Researcher indicated that it is standard in diabetes trials for some participants to receive suboptimal care, to allow the study to show non-inferiority. The Committee agreed that this may be common practice but the difference in this case is that study participants are children. Intervention studies should be conducted only if the risk to vulnerable people is at an acceptable minimum (Ethical Guidelines for Intervention Studies paragraph 5.30). The Committee requested that further information is provided on the safety of study participation and at what stage participants in the placebo arm may be withdrawn from the study, the Committee stated that they need independent peer review of this aspect.
4. The Committee requested further justification of the study thresholds for altering participant’s care. Please provide a response from the study sponsor regarding the justification for this.
5. The Committee questioned whether some participants may already be on insulin before the study and then have this aspect of their care withdrawn to participate in the study. Please provide further information on this.
6. The Committee noted that generally study protocols specifically allow for researchers to deviate from the protocol to protect patient safety, however this study does not appear to have this capacity included. Please adjust the study protocol to allow clinician discretion to protect patient safety.

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

1. Please clarify in the Participant Information Sheet that participants will remain in the treatment arm they are assigned to throughout the study, this includes if they are assigned to the placebo arm.
2. Please clarify the pregnancy testing requirements for this study in the Participant Information Sheets.
3. Please revise the Participant Information Sheet to make it clear when participant’s data may be disclosed, currently it indicates that it may be disclosed for the care of other patients but it is not clear the reasons for this.
4. Please ensure it is clear in study advertising that participants may receive a placebo throughout the study.
5. Please clearly state in the advertising that participants will be reimbursed for travel costs, not that it depends on the site.
6. Please ensure that all material gives a rough indication of the length of the trial and the approximate number of visits and blood tests involved.
7. Please replace the Americanism of doctors "office" with a New Zealand specific term.
8. Please rewrite the instructions for the home pregnancy testing in a simple clear format.
9. Add a lay title to the Participant Information Sheets.
10. Please revise the following statement for clarity and accuracy: “1/3 will not receive either drug: 'Dapagliflozin and saxagliptin are the names of the study drugs that your child will take in this trial”
11. Please indicate he number of home and laboratory blood tests in the Participant Information Sheet.
12. Please clarify that follow up after withdrawal of the study drug is up to the participant.
13. Please revise the Participant Information Sheets to remove all typographical errors.
14. Currently the instructions on need for contraception in the Participant Information Sheet do not acknowledge that continued abstinence is regarded in the protocol, as sufficient
15. Please remove any reference to genetic testing from the Participant Information Sheet as this does not apply to this study.
16. Please remove duplicated sentences from the section on voluntary participation.
17. Please ensure it is clear in the Participant Information Sheet that the study won’t be stopped by the sponsor for purely commercial reasons.
18. Currently the child assent form indicates that participants’ emergency contacts may get to see participants’ personal data, please revise this.
19. Please make advice regarding pregnancy testing age appropriate.
20. Please remove any references to ‘treatment’ in the Participant Information Sheet to avoid implying a benefit from study participation.
21. Please ensure that the child information sheet explains all terms and concepts in an age appropriate way, for example the information on placebo needs clarification.
22. Please provide an age appropriate koha for the child participants, this should be stated in the child and adult Participant Information Sheets.
23. Please ensure that the Participant Information Sheets are accurate when addressing the reader, for example don’t refer to “my child” in forms that are not for parents.

Decision

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

* Please respond to the outstanding ethical concerns detailed above.
* Please provide further evidence of favourable independent peer review of the study protocol (*Ethical Guidelines for Intervention Studies* Appendix 1).
* Please amend the information sheet and consent form, taking into account the suggestions made by the Committee (*Ethical Guidelines for Intervention Studies* *paragraph 6.22*).

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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| **2** | **Ethics ref:** | **17/NTB/130** |
|  | Title: | Pau te Hau. High-intensity interval training for young adolescents |
|  | Principal Investigator: | Dr Nigel Harris |
|  | Sponsor: | Auckland University of Technology |
|  | Clock Start Date: | 22 June 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. This study investigate high intensity interval training for young adolescents.

Summary of ethical issues (resolved)

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

1. The Committee questioned how the practical aspects of the onsite clinic visits would be managed. The Researcher explained that they have discussed this in detail with the school and believe they have accounted for all the practical aspects, such as keeping the children entertained and protecting their privacy while they answer questionnaires. The Committee agreed that the practical aspects of this seem to have been well accounted for.
2. The Committee questioned the importance of the academic tests being done. The Researcher explained that they are not doing these tests anymore.
3. The Committee questioned how the consent process for the study will be managed. The Researcher explained that the children and their parents will be sent a letter regarding the study, the researcher will present to the class and answer their questions, and parents will be able to contact the researcher with any questions they may have. Consent and assent forms can then be returned to a drop off box at the school reception.
4. The Committee questioned what happens for children who don’t consent to being in the study. The Researcher explained that they won’t go to the clinic or do study specific assessments. The Researcher explained that they would still participate in either their standard PE class or the study specific HIT class, depending on their class allocation. The Committee questioned whether it was acceptable for participants who decline study participation to still receive the study intervention. The Researcher explained that the HIT class is within the current curriculum and it would be reasonable for them to receive this as determined by the school.
5. The Committee questioned the risks associated with HIT. The Researcher confirmed that the risks are similar to the risks of standard PE class.
6. The Committee questioned the risks of stigmatisation from the HIT for the children. The Researcher explained that they believe that HIT will be less stigmatising than other kinds of exercise participants could do in their PE class as all participants will be encouraged to start with the easiest option and will not be competing with their peers.

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 details about how the researchers will ensure that the control class receives a different curriculum than the study class, and whether the control class will be standardised in any way. The Researcher explained that the control class will follow their normal curriculum, which may vary between teachers and schools. The Committee stated that either this must be well controlled for or accounted for in the study analysis. Please provide further information on how this will be accounted for.
2. The Committee questioned whether teachers would be provided with training. The Researcher confirmed that they would be. The Committee requested details of this are provided.
3. The Committee noted that this study is quite burdensome for the participants. The Committee stated that although vulnerable people (including children) should have the opportunity to be included in high-quality studies, these must be on questions that might affect their health, and take in to account a number of factors (Ethical Guidelines for Intervention Studies paragraph 5.30).
4. Additionally, the interests of vulnerable participants must be protected, and these children must not be exploited for the advancement of knowledge (Ethical Guidelines for Intervention Studies paragraph 5.31).
5. Research procedures (including testing) which are not intended to be of direct benefit to the child participants, and are not intended to provide vital generalizable information on the child’s condition, may be undertaken only if the risk presented by the interventions to the child participant is minimal and commensurate with the importance of the knowledge to be gained (Ethical Guidelines for Intervention Studies appendix 2).
6. The Committee stated that study participation is quite burdensome for the children and the Committee are not convinced that the benefits of the research justify all of the proposed study procedures. The Committee specifically raised concerns about the testing which requires time out of school to visit the study site. The Committee requested further justification of all tests involved in this study, including the DEXA scans, noting that DEXA scans should not usually be done this frequently as the standard deviation of these scans reduces the usefulness of their results.
7. The Committee noted that this is a feasibility study and the primary outcomes are any changes to the fitness of the children and the acceptability of the training for children and the teachers. Because of this, testing such as DEXA scans and blood tests seem unnecessarily burdensome for child participants and the Committee feel they cannot be included in the study without significant further justification.
8. The Committee questioned whether the children would receive some kind of koha for their participation. The Researcher stated that there is no plan to provide this. The Committee stated that a small koha would be reasonable to thank the children for their participation. The costs of the study will reduce if the DEXA scans are removed and this may allow koha to be provided, please update the Committee regarding this.
9. The Committee questioned how study results would be communicated to study participants. The Researcher explained that they have not finalised their plans, but would likely give the results to children for them to give to their parents. The Committee raised concerns about this as without adequate explanation the results could cause anxiety for children and their parents. The Committee requested further details on which results would be returned to participants and their families and how these would be communicated.
10. The Committee questioned whether the researchers would be blinded when undertaking the study analysis. The Researcher stated they did not plan to be. The Committee explained that that is essential for the validity of the study and the protocol must be modified to ensure this.
11. Please provide more documentation regarding the focus group aspect of the study.

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

1. The Committee noted that no study data, such as health information, should be collected on the study Consent Form. Please ensure this form is revised to reflect this.
2. Please ensure it is clear in the Participant Information Sheet that all children will be randomised based on class, regardless of whether they consent to being in the study or not. It must be clear that this is a school decision and participation in PE is part of the regular school curriculum.
3. Please add a Māori cultural support person contact to the Participant Information Sheet.
4. Please add the area code to contact phone numbers in the Participant Information Sheet.
5. Please revise the risk and benefit section as these are currently coercive and not well explained.

Decision

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

* Please respond to the outstanding ethical concerns detailed above.
* Although vulnerable people (including children) should have the opportunity to be included in high-quality studies, these must be on questions that might affect their health, and take in to account a number of factors (Ethical Guidelines for Intervention Studies paragraph 5.30).
* The interests of vulnerable participants must be protected, and these children must not be exploited for the advancement of knowledge (Ethical Guidelines for Intervention Studies paragraph 5.31).
* Research procedures (including testing) which are not intended to be of direct benefit to the child participants, and are not intended to provide vital generalizable information on the child’s condition, may be undertaken only if the risk presented by the interventions to the child participant is minimal and commensurate with the importance of the knowledge to be gained (Ethical Guidelines for Intervention Studies appendix 2).
* Please amend the information sheet and consent form, taking into account the suggestions made by the Committee (*Ethical Guidelines for Intervention Studies* *paragraph 6.22*).

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

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| **3** | **Ethics ref:** | **17/NTB/121** |
|  | Title: | iCST delivered by trained volunteers |
|  | Principal Investigator: | Dr Gary Cheung |
|  | Sponsor: | The University of Auckland |
|  | Clock Start Date: | 22 June 2017 |

Dr Gary Cheung 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 Committee noted that this application was much improved compared to the previously declined application.
2. This study involves cognitive stimulation therapy being delivered by trained volunteers to participants with dementia in their own home.

Summary of ethical issues (resolved)

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

1. The Committee questioned whether participants would be able to provide their own informed consent. The Researcher explained that some participants would be able to consent for themselves, while others would be unable. The Researcher noted that participants with limited capacity would be supported to provide consent wherever possible.
2. The Committee questioned how capacity to consent would be determined. The Researcher explained the protocol for the enrolling clinician to determine capacity.
3. The Committee questioned whether participants unable to provide their own informed consent may be enrolled in the study, noting that inclusion of these participants must be consistent with Right 7(4) of the HDC Code of Rights. The Researcher explained that participants and their family would be consulted as much as possible regarding whether the participant would want to be in the study if they could provide informed consent, additionally the enrolling clinician would consider whether study participation was deemed to be in the best interests of the participant. The Researcher explained that they believe that study participation will be in the best interest of some participants as there is substantial evidence supporting the study intervention as beneficial for patients with dementia.
4. The Committee questioned whether all participants continue to receive standard care throughout the study. The Researcher confirmed they would.
5. The Committee questioned, and the Researcher explained the training process for the volunteers who will deliver the study intervention.
6. The Committee questioned whether there is a mix of ethnicities present among the volunteers to allow them to be matched with study participants. The Researcher explained that they will do their best to culturally match participants to volunteers and would try to get more Māori volunteers.
7. The Committee questioned whether the researchers will collect feedback from participants’ family members regarding their views. The Researcher stated that this was part of another study.
8. The Committee questioned whether ethnicity data will be collected. The Researcher confirmed that it will be and the NZ Census question will be used.
9. The Committee questioned the purpose of the report of welfare concern form. The Researcher explained that this was created in response to past feedback as a mechanism for volunteers to report any concerns they may have.

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 a copy of the video used in the consent process is provided.
2. The Committee requested further details are provided regarding the safety arrangements for the overall study and the safety protocol and the safety protocol for volunteers who will go to participants’ homes.
3. The Committee noted that the application form indicates that Māori consultation is not required for this study, however, Māori consultation is required for all studies involving Māori participants. As this study will involve Māori participants, cultural consultation is required, the Committee requested details of the planned cultural consultation for this study, especially considering that the study involves volunteers going to participants’ homes and this may raise cultural concerns.
4. The Committee questioned whether the volunteers would bring any snacks to share with participants, as participants may feel obligated to provide some refreshments to the volunteers and this may help address this. The Researcher agreed this was a good suggestion. The Committee requested the details of whatever is decided regarding this.

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

1. Please revise the Participant Information Sheet to remove all typographical errors.
2. Please clarify in the confidentiality section of the Participant Information Sheet what data is collected and that participants have the right to access and request changes to data collected about them.
3. Please include basic information on the inclusion criteria in the Participant Information Sheet.
4. Please revise the information sheet for family members, and provide a suitable consent form, to indicate that family carers are participants in their own right and will be asked to complete a questionnaire.
5. Please indicate in the information sheet that some questions in the questionnaire may be personal and participants do not need to answer all questions.
6. Please add a footer to the Participant Information Sheets and Consent Forms containing the study title, a document version number, and page numbers.
7. Please add the area code to the contact details in the Participant Information Sheet.
8. Please indicate in the Participant Information Sheet that some questions in the Participant Information Sheet are of a personal nature.
9. Please add a clause to the Consent Form regarding agreement to complete questionnaires and provide personal information
10. Please clarify in the Participant Information Sheets that treatment arm allocation is random, not a choice.
11. Please explain in the Participant Information Sheet what ‘usual treatment’ means.
12. Please add the compensation statement to the family information sheet.

Decision

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

* Please respond to the outstanding ethical concerns detailed above.
* Please amend the information sheet and consent form, taking into account the suggestions made by the Committee (*Ethical Guidelines for Intervention Studies* *paragraph 6.22*).

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

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| **4** | **Ethics ref:** | **17/NTB/131** |
|  | Title: | A study to examine the safety and tolerability of multiple doses of the trial drug Brincidofovir in healthy adults. |
|  | Principal Investigator: | Dr Chris Wynne |
|  | Sponsor: |  |
|  | Clock Start Date: | 22 June 2017 |

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 ethical issues (resolved)

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

1. The Committee questioned whether the Researchers expected any difficult recruiting only post-menopausal women and vasectomised men. The Researcher explained that they have not had serious issues recruiting for previous studies with these groups.
2. The Committee questioned whether sentinel dosing is needed for this study. The Researcher explained that it is not as this is not a first in human trial.
3. The Committee questioned the status of Māori consultation. The Researcher confirmed that it is currently underway.
4. The Committee noted that the taking and storage of tissue is not indicated as a potential cultural concern in the application form. Please ensure this is identified in future applications.
5. The Committee questioned which insurance certificate for the study sponsor is correct for this study, as two have been provided. Please ensure in future that only one insurance certificate is provided, or an explanation is provided if multiple insurance certificates are required.

Summary of ethical issues (outstanding)

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

1. The Participant Information Sheet includes information on the risks to participant’s partners if they become pregnant, but this is not relevant as participants are already vasectomised or post-menopausal and do not need to do anything additional to prevent pregnancy. Please remove this statement from the Participant Information Sheet.
2. The Committee requested that the Participant Information Sheet is revised to improve clarity.
3. Please state in the advertising that there are limits on smoking, alcohol consumption, and vigorous exercise for study participants.
4. Please clarify in the Participant Information Sheet that, although a reason may be recorded if participants decided to leave the study, participants do not need to provide a reason if they decide to leave the study.
5. Please state the Māori cultural contact person’s tribal and company affiliations in the Participant Information Sheet.
6. Please clarify in the Participant Information Sheet that participants do not need to withdraw in writing, they just need to let the study doctor know.
7. Please clarify in the Participant Information Sheet that participants who travel for screening but are not eligible for study participation will be reimbursed for travel costs.
8. Please spell out CMV with the full term.
9. Please clarify where the American labs are located.
10. Please clarify in the Participant Information Sheet that no genetic research is involved in this study.

Decision

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

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

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| **5** | **Ethics ref:** | **17/NTB/125** |
|  | Title: | Proof of Concept Study of Etrasimod in Patients with Pyoderma Gangrenosum |
|  | Principal Investigator: | Assoc. Prof Marius Rademaker |
|  | Sponsor: | Arena Pharmaceuticals Inc. |
|  | Clock Start Date: | 22 June 2017 |

Eileen Bisley, Anneke Marais, and Heather Logan 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 ethical issues (resolved)

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

1. The Committee questioned whether there are risks of heart symptoms detected in previous studies. The Researcher confirmed that there have been reports of lowered heart rates from participants in other studies, however, no participants will be included in this study who this could be a risk for.
2. The Researcher explained that the condition being studied is very rare and they already know of potential participants who they will approach directly. The Committee questioned whether it is acceptable in this case for potential participants to be approached by their treating clinician, as this may make them feel pressured to participate. The Researcher explained that all potential participants will have an ongoing relationship with the enrolling clinician and study participation would be discussed as an option for their ongoing care. The Committee agreed this is acceptable in this case.

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 questioned the reasons for STI screening. The Researcher indicated that it is part of the international protocol. The Committee stated that they require justification for these and clarification about the reporting protocol for notifiable diseases.
2. The Committee requested further information about whether participants are expected to have a lot of co-morbidities.
3. The Committee questioned how it will be determined whether participants will have a biopsy, as there are serious risks from biopsies in these participants. The Researcher confirmed that the biopsies are optional and will only be done if it won’t make the participant’s condition worse. The Committee requested details are provided regarding how it will be determined whether a biopsy may make the participant’s condition worse.
4. The Committee requested further details about the halter monitoring, including how the real time monitoring works and whether participants can wear the monitor in the shower.

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

1. Please state in the Participant Information Sheet that having the optional biopsy may make participants’ ulcers worse.
2. Please remove the references to Australia and the national statement from the Participant Information Sheet to make this New Zealand specific.
3. The Participant Information Sheet is inconsistent regarding whether study samples are only used in New Zealand or if they may be sent to the study sponsor, please clarify this.
4. Please add a table to the Participant Information Sheet to display the study visits and requirements clearly for participants.
5. Please clarify in the Participant Information Sheet the process for reimbursing travel expenses, including whether participants need to provide receipts.
6. Please clarify in the Participant Information Sheet that study participation may make it more likely for participants to get sick.
7. Please remove the yes/no tick boxes from the Consent Form for all statements that are not truly optional, meaning that a participant could respond ‘no’ and still participate in the study.
8. Please revise the information in the Participant Information Sheet to clarify how many people have previously received the study drug, not how many have received the placebo or study drug.
9. Please clarify that the driver required for the eye exams will be funded, or a taxi can be used.
10. Please use ‘influenza’ rather than ‘flu’.

Decision

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

* Please respond to the outstanding ethical concerns detailed above.
* Please amend the information sheet and consent form, taking into account the suggestions made by the Committee (*Ethical Guidelines for Intervention Studies* *paragraph 6.22*).

This following information will be reviewed, and a final decision made on the application, by Mrs Leesa Russell and Mrs Kate O'Connor.

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| **6** | **Ethics ref:** | **17/NTB/127** |
|  | Title: | Efficacy of intravenous and submucosal dexamethasone in third molar surgery |
|  | Principal Investigator: | Ms Adelyn Lau |
|  | Sponsor: |  |
|  | Clock Start Date: | 22 June 2017 |

Ms Adelyn Lau 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 Committee noted that they prefer student researchers have their supervisor attend HDEC meetings with them to offer advice and support.
2. The Committee commended the high quality of the application.

Summary of ethical issues (resolved)

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

1. The Committee questioned whether this study has received any funding. The Researcher confirmed that they have applied for funding but not received any yet. The Committee noted that if funding is received that they would appreciate this submitted as an amendment to the study.
2. The Committee questioned whether the peer reviewer for this study is independent. The Researcher confirmed that they are.

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 participants going in the draw to receive $50 is not acceptable. The Committee requested that this is revised, they suggest that it would be more appropriate if all participants received a small koha, such as a coffee voucher. Please provide revised details for this.
2. The Committee questioned the plan for adverse event management, noting that adverse events are not generally reported to HDECs. Please provide details of the Data Safety Monitoring plans (Ethical Guidelines for Intervention Studies paragraph 6.50).
3. The Committee questioned the justification for the age thresholds in this study. Inclusion of participants in intervention studies must be equitable. Investigators may not exclude participants on the basis of sex, ethnicity, national origin, religion, education or socioeconomic status, except where such exclusion or inclusion is essential to the purposes of the study (*Ethical Guidelines for Intervention Studies* paragraph 5.26).

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

1. Please clarify in the Participant Information Sheet that although both treatments are standard care, in practice only one is used.
2. Please add an option to the consent form for participants to receive a summary of the study results.
3. Please revise the Participant Information Sheet to remove all typographical errors.
4. Please state in the Participant Information Sheet that participants will not be identifiable in any publication of the study result.
5. Please consider your Participant Information Sheet against the HDEC template to ensure all relevant sections are included.
6. The Committee requested that compensation wording is added for accuracy, they suggested the following statement: “If you were injured in this study, which is unlikely, you would be eligible to apply for compensation from ACC just as you would be if you were injured in an accident at work or at home. This does not mean that your claim will automatically be accepted. You will have to lodge a claim with ACC, which may take some time to assess. If your claim is accepted, you will receive funding to assist in your recovery. 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.”
7. Please explain randomisation in the Participant Information Sheet.
8. Please add any age thresholds for the study to the Participant Information Sheet and explain the justification for these briefly.
9. Please add version and page numbers to the footer of the Participant Information Sheet.
10. Please ensure that the correct HDEC is referenced in the Participant Information Sheet.
11. Please clarify in the Participant Information Sheet whether facial images will be stored separately from other study data to protect participants’ identity.
12. Please ensure that relevant contact details are provided, including for a Māori cultural support person.
13. Please add a witness signature box to the Consent Form.

Decision

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

* Please respond to the outstanding ethical concerns detailed above.
* Please provide details of the Data Safety Monitoring plans (Ethical Guidelines for Intervention Studies paragraph 6.50).
* Inclusion of participants in intervention studies must be equitable. Investigators may not exclude participants on the basis of sex, ethnicity, national origin, religion, education or socioeconomic status, except where such exclusion or inclusion is essential to the purposes of the study (*Ethical Guidelines for Intervention Studies* paragraph 5.26).
* Please amend the information sheet and consent form, taking into account the suggestions made by the Committee (*Ethical Guidelines for Intervention Studies* *paragraph 6.22*).

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

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| **7** | **Ethics ref:** | **17/NTB/117** |
|  | Title: | A study of MGA012 in patients with advanced solid tumors |
|  | Principal Investigator: | Dr Anne O'Donnell |
|  | Sponsor: | Macrogenics, Inc |
|  | Clock Start Date: | 22 June 2017 |

Dr Anne O'Donnell and Rosie Whitmore 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 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 long term follow up aspect of this study is unusual for a phase 1 trial. The Researcher explained that they believe there will be a number of long term survivors in this study and this is the reason for the follow up.
2. The Researcher explained that the New Zealand site will only come in to the study at the dose escalation phase of the study, which is more similar to a phase 2(a) study.
3. The Committee questioned why this study did not include sentinel dosing. The Researcher explained that this is because of the pre-clinical work already done on other drugs in this class. The Committee noted that this does not mean that there are not different risks associated with this drug. However, as this phase of the study is not being conducted in New Zealand the Committee felt that this as irrelevant to their discussion.
4. The Committee questioned the reason for doing this study, given the number of other drugs that exist in this class. The Researcher explained that it is because there is a market for more drugs in this class and this market competition may bring down the cost of these drugs.
5. The Committee questioned whether participants would still be able to receive the study drug after the end of the study. The Researcher explained that it is standard for this kind of therapy to stop after 2 years, as this is considered long term survival.
6. The Researcher questioned how they should approach communicating results to surviving participants, clarifying that usually they discuss the results with participants and provide a copy of any publication abstracts. The Committee explained that an optional tick box should be included in the Consent Form for participants to indicate whether they would like to receive a lay summary of the study results, this can also offer the option of results being returned to the participant’s family if the participant passes away before these are available.

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 questioned whether participants whose disease progresses after the treatment is withdrawn at 2 years would be able to access ongoing treatment. The Researcher was uncertain whether it would be available. The Committee stated that if the study drug is providing benefit to participants then it should continue to be provided to them as long as they are receiving benefit from it. Please confirm with the sponsor that ongoing access will be available to the study drug for participants.
2. The Committee requested an un-redacted copy of the FDA permission to begin letter, as they are currently unable to see the FDA recommendations.
3. The Committee questioned whether participants can withdraw their samples from Future Unspecified Use of Tissue as the consent form indicates that they will not be able to. The Committee stated that the reasons they cannot withdraw their samples should be clear, and if their samples can be linked to them the Committee felt that participants should be able to withdraw their samples if they wish to. The Committee requested confirmation that this is the case.

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

1. Please revise the Participant Information Sheet to be more explicit regarding the lack of human testing to date for this drug.
2. Please revise the second paragraph of the purpose of the study section of the Participant Information Sheet, only the last two sentences talk about the purpose of the study, which is the topic of the paragraph. The benefit and contact information should be relocated elsewhere in the Participant Information Sheet.
3. In the section of the Participant Information Sheet regarding what participation involves please clarify that participants are assigned to one dose and frequency, and this is their dose and frequency for the whole study.
4. Please give a more realistic explanation of a CT scan in the Participant Information Sheet.
5. Please more the information on attending study visits from the risk and benefit section as this related to seeking advice on side effects and isn’t a study risk or benefit.
6. Please clarify which baby is being referred to in the pregnant partner Participant Information Sheet.
7. Please revise the Future Unspecified Use of Tissue Participant Information Sheet to ensure that the statements do not conflict with each other. For example, currently it indicates that both the tissue won’t be used outside the study without the participant’s permission and that they cannot confirm what type of research will be done on the tissue, but these statements seem to be in conflict.
8. Please clarify in the Participant Information Sheets whether samples may be used for profit.
9. Please revise the Participant Information Sheet to remove all typographical errors.
10. Please state in the Participant Information Sheet that some participants may have a biopsy taken.
11. Please remove all information on part 1 of the study from the Participant Information Sheet and include specific dosing levels, as part 1 is not being conducted in New Zealand.
12. Please revise the Participant Information Sheet to ensure this document is written in lay language.
13. Please clarify the reasons for following up people who withdraw from the study for 2 years in the Participant Information Sheet.
14. Please identify the study sponsor earlier in the Participant Information Sheets.
15. Please revise the Participant Information Sheets to state ‘ethics committee’ rather than ‘EC’.
16. Please ensure New Zealand spellings are used throughout the Participant Information Sheets.
17. Please add page numbers to the Participant Information Sheet and Consent Form.
18. Please ensure New Zealand spellings are used throughout the Participant Information Sheet and Consent Form.
19. Please add a lay title to the Participant Information Sheet.
20. Please alter the phrase “you will receive no penalty” to reflect the New Zealand way of speaking.
21. Please re-locate the Māori cultural statement to a more suitable section of the Participant Information Sheet, such as the section where information on what tissue is being used in the study.
22. Please clarify in the Participant Information Sheet that documenting the outcome of any pregnancy will only occur with the approval of the participant’s partner.
23. Please revise or move the following sentence as it does not belong in the ‘other treatments’ section, "By participating in this study, you may be delaying treatment with an approved therapy for your disease that has demonstrated an improvement in survival."
24. Participants are able to review information collected about them at any time, not just at the end of the study. Please revise the Participant Information Sheet to reflect this, it may be necessary to indicate that accessing this information may cause the participant to be withdrawn from the study (if this is necessary).
25. Please clarify this sentence as it may be intended to refer to patents rather than patients: “Any information derived directly or indirectly from this genetic research, as well as any patients, diagnostic tests, drugs, or biological products developed directly or indirectly as a result of this research, are the sole property of the sponsoring company and may be used for commercial purposes.”
26. The Committee questioned the statement in the Future Unspecified Use of Tissue Consent Form relating to participants identity being removed from their tissue. The Committee stated that it must be clear for participants whether any linking information will be retained in New Zealand that may allow them to withdraw their tissue.

Decision

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

* Please respond to the outstanding ethical concerns detailed above.
* Please amend the information sheet and consent form, taking into account the suggestions made by the Committee (*Ethical Guidelines for Intervention Studies* *paragraph 6.22*).

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

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| **8** | **Ethics ref:** | **17/NTB/120** |
|  | Title: | Cervical screening HPV self-test |
|  | Principal Investigator: | Dr Naomi Brewer |
|  | Sponsor: | Massey University |
|  | Clock Start Date: | 22 June 2017 |

Dr Naomi Brewer, Prof John Potter, Prof Jeroen Douwes were present by teleconference, and Dr Karen Bartholomew and Jane Grant 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.

Mrs Leesa Russell declared a potential conflict of interest. The Committee decided to allow her to remain in the room but not participate in the discussion of or decision making for this study.

Summary of ethical issues (resolved)

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

1. The Committee questioned the recruitment process for the study. The Researcher explained that they would obtain the contact details of under-smeared women who meet the inclusion criteria and send them an invitation brochure explaining that unless they contact the researchers they will be included in the study and receive either a home testing kit or an appointment to have in clinic test (which may be by the traditional collection method or self-testing in the clinic).
2. The Committee discussed this opt-out enrolment method and determined that it is acceptable as participants still have to opt in to complete the actual test and can simply decline to participate by ignoring the invitation letters. The Committee further noted that this is what is likely to happen in the real world, assuming the study is successful, and the participants are not missing out on an aspect of standard care as to meet the inclusion criteria they must already be under screened.
3. The Researcher explained that one of the primary end points of the study is whether under screened women are interested in taking up this different screening method. The ‘opt-out’ component of the study is really only for the few women who do not want to be contacted at all.
4. The Committee noted the importance of having good support available for women who find they do have HPV.
5. The Committee noted that the inclusion of participants in intervention studies must be equitable. Investigators may not exclude participants on the basis of sex, ethnicity, national origin, religion, education or socioeconomic status, except where such exclusion or inclusion is essential to the purposes of the study (*Ethical Guidelines for Intervention Studies* paragraph 5.26). The Committee questioned the justification of inclusion criteria based on ethnicity. The Researcher explained that although screening rates between ethnicities may be comparable, the outcomes for Māori and Pacifica women are much worse and, therefore, it is important to investigate these groups in particular. Additionally, the Researcher explained that international studies have shown that this screening method is acceptable for Pakeha women, but no studies have investigated whether it is acceptable for Māori and Pacifica women. The Committee accepted that this exclusion based on ethnicity is essential for the study.
6. The Committee questioned why the invitation letters cannot be sent from the GP practices, as it is concerning for such personal information to be shared with a third party. The Researcher explained that GP practices do not have the capacity to send out the invitation letters and follow up with participants, and this is the reason the letters will not be sent from the GPs. In addition, in a real world situation invitations for this screening are likely to not come directly from GPs so this recruitment method reflects real world practice.
7. The Committee questioned whether the invitation letter will be co-signed by the participant’s GP practice. The Researcher stated that the invitation letters will be sent on letter head from the GP practices to make it clear that this project is being run in conjunction with these practices.
8. The Committee questioned whether participants may need to pay for any follow up visits or clinic appointments. The Researchers confirmed that they would not need to pay as they meet the definition of under screened.
9. The Committee questioned whether the study involves any Future Unspecified Use of Tissue. The Researcher confirmed that it does not and all use of tissue will be directly related to the study.
10. The Committee questioned whether the new test is as good as the old test. The Researcher confirmed that it is actually better, but they did not want to oversell it in the Participant Information Sheets.
11. The Committee questioned whether Pacifica cultural consultation will be obtained. The Researcher explained the consultation process, including that they have a Pacifica researcher involved in the project and an external Pacifica advisory group.

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 details are provided of the Data Safety Monitoring arrangements for the study *(Ethical Guidelines for Intervention Studies* paragraph 6.50).

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

1. The Committee stated that they require a copy of the invitation letters which make it very clear that participation is voluntary.
2. Please revise the wording in the invitation pamphlet to explain the ethnic targeting for this study.
3. Please clarify in the Participant Information Sheet that there are no costs associated with study participation.
4. Please clarify in the Participant Information Sheet how long tissue collected in this study may be stored for.
5. It is unclear from the Participant Information Sheet that participants do not have a choice regarding which study arm they are in.
6. Please clarify in the Participant Information Sheet that not all questions in the questionnaire relate to HPV.
7. Please revise the Participant Information Sheet to remove all typographical errors.
8. Please clarify in the Participant Information Sheet information about identifiable data being stored, currently this information is not clear enough for lay participants.
9. Please remove information on the HPV vaccination from the study brochure as this does not relate to the study specifically.
10. Please provide a detailed information sheet for participants in the home sampling group, to clearly state what they need to do and where and how their tests should be sent.
11. Please make it clearer under the confidentiality section of the Participant Information Sheet that although the research database will be partially de-identified, the National Cervical Screening Register and laboratory database will record identified data.

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* *paragraph 6.22*).
* The Committee requested details are provided of the Data Safety Monitoring arrangements for the study *(Ethical Guidelines for Intervention Studies* paragraph 6.50).

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

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| **9** | **Ethics ref:** | **17/NTB/124** |
|  | Title: | M15-925 |
|  | Principal Investigator: | Dr Daniel Ching |
|  | Sponsor: | AbbVie Pty Ltd |
|  | Clock Start Date: | 22 June 2017 |

Dr Daniel Ching 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 Committee noted that the application was well put together, however some questions in the application form request lay summaries but in this application the information provided is copied directly from the study protocol. In future, please ensure a lay summary is provided when requested.

Summary of ethical issues (resolved)

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

1. The Committee questioned whether participants will be able to access the study drug after the study if they are receiving benefits from it. The Researcher explained that they do not believe this drug will continue to be provided by the sponsor. The Committee indicated their strong preference that sponsors continue to provide a beneficial study drug to participants for as long as possible.
2. The Committee questioned whether ethics approval has been obtained in any other countries yet. The Researcher stated that they do not believe it has yet.
3. The Committee noted that although the application indicates that no unexpected findings are expected in the study they are still possible. The Committee questioned how any unexpected findings would be dealt with. The Researcher explained that they would discuss these with the participant and if necessary alter the study.
4. The Committee questioned whether the monitoring for participants will increase when they start the open label extension. Please revise the study protocol to reflect this.

Summary of ethical issues (outstanding)

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

1. Provide details of the Data Safety Monitoring plans, including the charter (*Ethical Guidelines for Intervention Studies* paragraph 6.50).

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

1. Please clarify in the Participant Information Sheet whether the chest x-rays in the study are additional to standard care.
2. Please explain in the Participant Information Sheet how any incidental findings may be dealt with.
3. Please revise the Participant Information Sheet to shorten this and reduce repetition.
4. Please add a lay title to the Participant Information Sheet.
5. Please revise all technical terms and jargon to be in lay language.
6. Please clarify the use of placebo in the Participant Information Sheet.
7. Please provide more information on what reasonable travel expenses will be reimbursed.
8. Please ensure New Zealand spellings are used in the Participant Information Sheet.
9. Please identify the location of BioStorage Technologies in the Participant Information Sheet.
10. Please revise the information on hepatitis and HIV testing to be applicable to New Zealand law.
11. Please clarify in the Participant Information Sheet when participants may need to use male or female condoms.
12. Please clarify in the Participant Information Sheet what medications participants may need to pay for, noting that participants should not incur any costs from study participation.
13. Please clarify whether the genetic studies referred to are the only optional PG studies.
14. Please clarify that participants are not paid to attend study visits, they are reimbursed for travel costs and inconvenience instead.
15. Please clarify in the Participant Information Sheet that participants can access, and request correction of, any data collected about them, although this may mean that they will be withdrawn from the study if blinding is broken.
16. Please remove references to US law from the Participant Information Sheet.
17. Please add more detail on sample handling and disposal to the Participant Information Sheet, including who may use the samples.
18. Please add contact details for a suitable Māori cultural support person to the Participant Information Sheet.
19. Please add to the Participant Information Sheet that participants’ GPs will be informed of their study participation.
20. Please clarify in the routine bloods section whether testing will be conducted in New Zealand or overseas.
21. Please remove references to Crohns disease from the Participant Information Sheet.
22. Please clarify where samples from the optional genomic sub study will be stored, stating a ‘safe place’ is not acceptable.
23. Please ensure the contact number on the participant information card is a local 24/7 number.
24. Please include the compensation statement in full in all Participant Information Sheets, do not refer back to the main Participant Information Sheet.
25. Please revise the Participant Information Sheets to clearly state that information on pregnancy will only be collected with express permission of the pregnant woman.

Decision

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

* Provide details of the Data Safety Monitoring plans, including the charter (*Ethical Guidelines for Intervention Studies* paragraph 6.50).
* Please amend the information sheet and consent form, taking into account the suggestions made by the Committee (*Ethical Guidelines for Intervention Studies* *paragraph 6.22*).

This following information will be reviewed, and a final decision made on the application, by Mrs Stephanie Pollard and Mrs Kate O'Connor.

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| **10** | **Ethics ref:** | **17/NTB/128** |
|  | Title: | A study of AL-034 in healthy participants |
|  | Principal Investigator: | Prof Edward Gane |
|  | Sponsor: | Novotech (New Zealand) Limited |
|  | Clock Start Date: | 22 June 2017 |

Prof Edward Gane and Shuruthi Balachandran 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 ethical issues (resolved)

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

1. The Committee questioned whether there is a risk to a baby in utero, given that men with a pregnant partner are asked to use a condom. The Committee stated that if there is a risk to the baby then men with pregnant partners should be excluded from the study, even if the risk is quite low. Please respond to this with either an explanation of why they should not be excluded or amended study documents excluding this group.
2. The Committee questioned why the Participant Information Sheet did not indicate that some participants have died in studies of similar drugs. The Researcher explained that they do not believe this risk applies to this study as participants will receive a much lower dose.

Summary of ethical issues (outstanding)

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

1. The Committee requested that a copy of the Future Unspecified Use of Tissue Participant Information Sheet is provided.
2. Please label each Participant Information Sheet more clearly as it is unclear which study group each Participant Information Sheet is for.
3. Please re-format the risk and benefit sections of the Participant Information Sheet to increase clarity.
4. Please clarify the compensation arrangements in the Participant Information Sheet, as some participants will receive more compensation due to attending two clinic stays.
5. Please clarify the instructions for the halter monitoring in the Participant Information Sheet, including information such as whether participants can shower while wearing this.
6. Please ensure New Zealand specific spelling is used in the Participant Information Sheet and Consent Form.
7. Please revise the Participant Information Sheet to remove all typographical errors.
8. Please emphasise the information in the Participant Information Sheet relating to this being the first time the study drug is used in humans.
9. Please identify the location of the central laboratory and clarify who the authorised representatives of the study sponsor may be.
10. There is a contradiction within the genetic sub0study Participant Information Sheet as to whether the tissue will be used for commercial purposes. On p. 2, "Your genetic material will not be used to produce new tissues or for any commercial purpose” On p.3 "It is possible that results from this genetic research may lead to discoveries and inventions (e.g., patents) or other commercial benefits. All the rights to these will belong to Alios BioPharma and/or their partners". Please address this discrepancy.
11. Please add additional subheadings to the Participant Information Sheet on page 13 where a variety of topics are covered in successive paragraphs.

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* *paragraph 6.22*).

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

## 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:** | 01 August 2017, 12:00 PM |
| **Meeting venue:** | Novotel Ellerslie, 72-112 Greenlane Rd East, Ellerslie, Auckland |

The following members tendered apologies for this meeting.

* Mrs Jane Wylie

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 5:20pm