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| **Committee:** | Central Health and Disability Ethics Committee |
| **Meeting date:** | 27 February 2018 |
| **Meeting venue:** | Room GN.6, Ground Floor, Ministry of Health, 133 Molesworth Street, Wellington |

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| **Time** | **Item of business** |
| 12:00pm | Welcome |
| 12:05pm | Confirmation of minutes of meeting of 23 January 2018 |
| 12:15pm | General business:   * Noting section of agenda * Review of approved studies (see over for details) |
| 12:30pm | i 18/CEN/7  ii 18/CEN/17  iii 18/CEN/18  iv 18/CEN/20  v 18/CEN/22  vi 18/CEN/24  vii 18/CEN/25  viii 18/CEN/26  ix 18/CEN/27  x 18/CEN/29 |
| 4:35pm | Substantial amendments (see over for details) |
|  | i 15/CEN/224/AM03 |
| 5:00pm | Meeting ends |

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| **Member Name** | **Member Category** | **Appointed** | **Term Expires** | **Apologies?** |
| Mrs Helen Walker | Lay (consumer/community perspectives) | 01/07/2015 | 01/07/2018 | Present |
| Dr Angela Ballantyne | Lay (ethical/moral reasoning) | 30/07/2015 | 30/07/2018 | Present |
| Mrs Sandy Gill | Lay (consumer/community perspectives) | 30/07/2015 | 30/07/2018 | Present |
| Dr Patries Herst | Non-lay (intervention studies) | 27/10/2015 | 27/10/2018 | Present |
| Dr Dean Quinn | Non-lay (intervention studies) | 27/10/2015 | 27/10/2018 | Present |
| Dr Cordelia Thomas | Lay (the law) | 20/05/2017 | 20/05/2020 | Present |
| Dr Melissa Cragg | Non-lay (observational studies) | 30/07/2015 | 30/07/2018 | Present |
| Dr Peter Gallagher | Non-lay (health/disability service provision) | 30/07/2015 | 30/07/2018 | Present |

## Welcome

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

The Chair noted that the meeting was quorate.

The Committee noted and agreed the agenda for the meeting.

## Confirmation of previous minutes

The minutes of the meeting of 23 January 2018 were confirmed.

## New applications

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| **1** | **Ethics ref:** | **18/CEN/7** |
|  | Title: | Understanding Creatine for Neurological health in babies (UNICORN Babies) |
|  | Principal Investigator: | Dr Max Berry |
|  | Sponsor: | Hudson Institute of Medical Research |
|  | Clock Start Date: | 15 February 2018 |

Dr Max Berry 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.

Dr Angela Ballantyne declared a conflict of interest for this application. The Chair resolved that she could remain but not participate.

Summary of Study

1. The study investigates postnatal changes in cerebral, circulating and excreted creatine levels in preterm and term infants.

Summary of ethical issues (resolved)

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

1. The Committee queried if Guthrie cards will be used in this project. The Researcher explained that a card similar to a Guthrie card would be used, but that it is not an actual Guthrie card.

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 forms, taking into account the suggestions made by the committee *(Ethical Guidelines for Observational Studies para 6.10)*

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

1. Add that a karakia will be performed before samples will be sent overseas or when samples are returned to NZ for destruction.
2. Give the details of the Monash lab where samples will be sent.
3. Explain when and if tissue samples can be returned and when this is no longer possible.
4. Clarify that videos will be destroyed alongside all other study data.

Decision

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

* Please amend the information sheet and consent forms, taking into account the suggestions made by the committee *(Ethical Guidelines for Observational Studies para 6.10)*

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

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| **2** | **Ethics ref:** | **18/CEN/17** |
|  | Title: | Impact of checkpoint blockade immunotherapy on vaccine-induced T cell responses |
|  | Principal Investigator: | Dr Catherine Barrow |
|  | Sponsor: |  |
|  | Clock Start Date: | 15 February 2018 |

Dr Olivier Gasser was present in person for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. The study investigates the frequency and functionality of NY-ESO-1-specific T cell responses in patients who have received autologous dendritic cell vaccine in the adjuvant setting and require immunotherapy for metastatic disease and assess whether checkpoint blockade therapy has a quantitative and/or qualitative impact on vaccine-specific immune responses and seeks to determine the impact of checkpoint blockade therapy on the breadth of T cell responses, as assessed by T cell receptor (TCR-)sequencing.

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 researchers were no longer collecting tissue for Future Unspecified Research purposes.
2. The Committee queried how the recruitment process for the study would work. The Researcher explained that they will be recruiting participants from the MELVAC trial and that they will target recruitment to suitable participants based on information gained in this trial.
3. The Committee noted that participants who cannot provide informed consent will not be recruited.
4. The Committee noted that 16-year olds are legally able to provide full informed consent.

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 forms, taking into account the suggestions made by the committee *(Ethical Guidelines for Observational Studies para 6.10)*

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

1. Add contact details for the CI, the HDC’s advocacy service and a Māori cultural support person.
2. Please remove the statement from the first paragraph that says ‘including’
3. Explain where samples will be sent overseas including the details/name of the laboratory.
4. Please remove any references to Future Unspecified Research
5. Explain that before samples are sent overseas a karakia will be performed.
6. Please add a table of study procedures that explains the time, date, and place of each study visit and what procedures will occur. For example, that there will be 4x 80ml blood draws.
7. Check that pembrolizumab is spelled correctly throughout.
8. Please add a footer which includes page numbers, the title of the ICF document, and the version.
9. Please provide more information on what kinds of questions will be asked in the questionnaire.
10. Explain that the researchers will be accessing medical records in accordance with the consent provided as part of the MALVEC study.

Decision

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

* Please amend the information sheet and consent forms, taking into account the suggestions made by the committee *(Ethical Guidelines for Observational Studies para 6.10)*

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

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| **3** | **Ethics ref:** | **18/CEN/18** |
|  | Title: | Sporting Physical Activity and Bone Health in New Zealand Adolescents and Young Adults |
|  | Principal Investigator: | Mrs Hansa Patel |
|  | Sponsor: | Victoria University of Wellington |
|  | Clock Start Date: | 15 February 2018 |

Mrs Hansa Patel was present in person for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. The study investigates the relationship between habitual sporting activity and bone health in adolescents and young adults.

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 Māori consultation is a requirement for all studies to receive final approval by HDECs. Please provide evidence that this has occurred. *(Ethical Guidelines for Observational Studies para 4.1 – 4.4.)*
2. The Committee stated that all health information or data created by the study must be retained for ten years in accordance with New Zealand law. Please amend the study protocol to reflect this. (*Ethical Guidelines for Intervention Studies* *para 5.41*)
3. Please amend the information sheet and consent forms, taking into account the suggestions made by the committee *(Ethical Guidelines for Observational Studies para 6.10)*

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

1. The Committee suggested that the length and complexity of the parental information sheet be checked to see if it can be simplified.
2. Please rephrase the section on withdrawal to more clearly explain that once participants have completed the questionnaire then their data will not be able to be withdrawn.
3. Please clarify if the ankle or heel are being measured in the information sheet and use the term consistently throughout the document. The Committee suggested a picture with an arrow.
4. Please add contact details for a Māori cultural support person.
5. Check that the correct ethics committee is referred to on all information sheets.
6. Please add a footer which includes page numbers, the title of the ICF document, and the version.

Decision

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

* Please amend the information sheet and consent forms, taking into account the suggestions made by the committee *(Ethical Guidelines for Observational Studies para 6.10)*
* Please amend the study protocol taking into account the suggestions made by the Committee. (*Ethical Guidelines for Intervention Studies* *para 5.41*)
* Please provide evidence of Maori consultation. *(Ethical Guidelines for Observational Studies para 4.1 – 4.4.)*

This following information will be reviewed, and a final decision made on the application, by Mrs Sandy Gill and Dr Melissa Cragg.

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| **4** | **Ethics ref:** | **18/CEN/20** |
|  | Title: | Reliability of swallowing assessment in neurodegenerative disease |
|  | Principal Investigator: | Ms Emma Burnip |
|  | Sponsor: | Rose Centre for Stroke Recovery and Research |
|  | Clock Start Date: | 15 February 2018 |

Ms Emma Burnip 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 reliability of swallowing outcome measures in Huntington's disease patients.

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 potential participants would be identified. The Researcher explained that their local Huntingdon’s disease organisation’s clinical coordinator will identify and contact eligible people from their registry and refer them to the CI if they are interested.
2. The Committee noted that the research will be conducted at the ROSE centre and therefore participants will be in a safe environment that can manage any risks, such as choking, associated with the project.
3. The Committee noted that high quality of the responses addressing how the findings of this study might benefit Māori.

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

1. Please explain the pregnancy risks associated with the study are that it is not recommended for pregnant women to undergo an x-ray.

Decision

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

* Please amend the information sheet and consent forms, taking into account the suggestions made by the committee *(Ethical Guidelines for Observational Studies para 6.10)*

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| **5** | **Ethics ref:** | **18/CEN/22** |
|  | Title: | Comparison of Sotagliflozin versus placebo for bone safety in patients with type 2 Diabetes |
|  | Principal Investigator: | Professor Russell Scott |
|  | Sponsor: | Covance New Zealand Ltd. |
|  | Clock Start Date: | 15 February 2018 |

Ms Sarah Maeser and Dr Kerr were present via 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 26-week Randomized, Double-blind, Placebo-controlled, Parallel-group, Multicenter, Phase 3 Study with a 78-week Extension Period to Evaluate the Efficacy and Bone Safety of Sotagliflozin in Patients 55 years or Older with Type 2 Diabetes Mellitus and Inadequate Glycemic Control.

Summary of ethical issues (resolved)

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

1. The Committee asked if participants might be more likely to contract an infection due to higher levels of sugar in their urine. The Researcher explained that this is the case but they will be screening for this and have methods for treatment and education about this risk.
2. The Committee asked if participants would be newly diagnosed or those who have had their diagnosis for a while. The Researcher stated that all participants must have had their diagnosis for at least three months.
3. The Committee noted that the responses to questions relating to how the study might benefit Māori were inadequate given the prevalence of type 2 diabetes in Māori and recommended that the researchers be mindful of how whakamā could be significant for participants.
4. The Committee noted that the study drug has been shown to be very effective in persons with type 1 diabetes.

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

1. Add that there is a chance of infection and give any information you can on the risks of infection.
2. The Committee recommended a flowchart or table of study procedures to help break down what is happening in the study for lay persons. This could include the time, place, and what tests or other procedures will occur at each visit.

Decision

This application was *approved with non-standard conditions* by consensus. The non-standard conditions for this study 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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| **6** | **Ethics ref:** | **18/CEN/24** |
|  | Title: | Respiratory Health of Pacific Youth |
|  | Principal Investigator: | Dr El-Shadan Tautolo |
|  | Sponsor: |  |
|  | Clock Start Date: | 15 February 2018 |

Dr Catherine Byrnes, Dr El-Shadan Tautolo, and Dr Oscar Cañete were present by teleconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. The study investigates the impact of early-life and childhood events on the lung function and respiratory health of Pacific youth aged 18-19 years. These youth will be drawn from the Pacific Islands Families Study birth cohort born at Middlemore Hospital in South Auckland in 2000. By understanding risk and protective factors the researchers hope to inform the pacific community.

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 coercion to participate might be managed. The Researcher explained that the study builds on a birth cohort study and so they have a pre-existing relationship with the participants which may help mitigate this.
2. The Committee noted that as participants are aged over 18 years the initial research recruitment approach should be made to them, and not their parents.

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 will need the HDEC reference for an approved tissue bank if the researchers intend to collect tissue for future unspecified research and store it in New Zealand.
2. Please amend the information sheet and consent forms, taking into account the suggestions made by the committee *(Ethical Guidelines for Observational Studies para 6.10)*

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

1. Add the details of the HDEC-approved tissue bank where tissue will be stored to the future unspecified research PIS.
2. Explain that the chest x-ray and blood test are fully optional and provide the option for participants to consent to each item individually.
3. Please add contact details for a Pacific Islander cultural support person to all information sheets.
4. Amend timelines for data storage to be 10 years and explain if data might be shared or linked during this time.
5. Check all documents for blank spaces e.g. p3 of the main ICF talking about blood tests.
6. Add ‘as applicable’ to the statement about seeking ethical approval for future projects in the future unspecified research information sheet.

Decision

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

* Please amend the information sheet and consent forms, taking into account the suggestions made by the committee *(Ethical Guidelines for Observational Studies para 6.10)*
* Please provide the details of the HDEC-approved tissue bank where samples will be stored for future unspecified research purposes. *(Standard Operating Procedures for Health and Disability Ethics Committees para 233 & Guidelines for the Use of Human Tissue for Future Unspecified Research Purposes para 30)*

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

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| **7** | **Ethics ref:** | **18/CEN/25** |
|  | Title: | BELIEVE 1 |
|  | Principal Investigator: | Ms Lynette Sadleir |
|  | Sponsor: | Zynerba Pharmaceuticals |
|  | Clock Start Date: | 15 February 2018 |

Ms Lynette Sadleir 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 an open label study to assess the safety and efficacy of ZYN002 administered as a transdermal gel to children and adolescents (3 to <18 years) with developmental and epileptic encephalopathy.
2. The formulation of the study drug is synthetic and pharmaceutical-grade with pre-existing data showing the drug is safe in adults.

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 Researchers would assess intellectual capacity. The Researchers explained that the children will have pre-existing neurological assessments that show moderate to severe intellectual disability.
2. The Committee stated that parents can consent for the participation of those under 16 and that guardians can do so for incompetent participants aged up to 18 years under the Care of Children p Act 2004.Competent young people can consent for themselves once they are 16 years.
3. The Committee asked what would happen if a participant showed suicidal tendencies. The Researcher explained that participants would be referred to the team psychiatrist.

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 noted that participants would be expected to complete the Columbia-Suicide Severity Rating Scale which may be distressing or too complicated for participants.
2. The Committee stated that, given the level of intellectual impairment, the information sheet for over 16s could be considered too complex.
3. The Committee had concerns about family members being expected to be able to identify signs of suicidal ideation in a population with an intellectual disability and stated that this assessment should be made by a qualified member of the research team.
4. The Committee stated that there are multiple issues with the information sheets and consent forms for the study. Please amend the information sheet and consent form, taking into account the suggestions made by the Committee (*Ethical Guidelines for Intervention Studies* *para 6.22*).
5. Please provide suitable information sheets and assent forms for 7-11-year olds. The Committee recommended that pictures be used.
6. Please provide a separate consent sheet for optional genetic testing.
7. The Committee stated that there should be no requirement for study withdrawal to be in writing.

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

1. Add a table of study procedures and diagram to the main information sheet and consent form.
2. Clarify that all travel for study-related procedures, including the collection of medicines, will be reimbursed.
3. Specify which types of contraception should be used and to only include those available in New Zealand.
4. Move the statement “I understand if I wish to discontinue…: from the consent form to the information sheet(s) as no new information should be introduced in the consent or assent forms.
5. Please make sure that the “I give permission for my child’s doctors to release information to…” is filled with local details and suggested the term researcher or study nurse be used.

Decision

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

* Suitable information sheets and assent forms for 7 – 11-year olds were missing. (*Ethical Guidelines for Intervention Studies* *paras 6.8 – 6.11*).
* The information sheets, consent, and assent forms require significant changes and were considered too complex. (*Ethical Guidelines for Intervention Studies* *paras 6.8 – 6.11*).
* The Committee stated that having untrained parents/family members/guardians assessing participant’s suicidality is not acceptable. (*Ethical Guidelines for Intervention Studies* *paras 3.8 – 3.11*).

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| **8** | **Ethics ref:** | **18/CEN/26** |
|  | Title: | The significance of post-streptococcal glomerulonephritis in New Zealand |
|  | Principal Investigator: | Dr Rachel Webb |
|  | Sponsor: |  |
|  | Clock Start Date: | 15 February 2018 |

Dr Rachel Webb 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 presence and severity of renal complications after childhood post-streptococcal glomerulonephritis (PGSN) by undertaking long-term follow-up of patients previously diagnosed with PSGN.

Summary of ethical issues (outstanding)

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

1. This study, as presented in this application, involves accessing health information from patients, and speaking to their clinicians, without consent.

The Committee noted that participants have a right to know that their health information is being used in research. Right 6(1)(d) of the HDC Code of Rights states:

* 1. *Every consumer has the right to information that a reasonable consumer, in that consumer’s circumstances, would expect to receive, including … notification of any proposed participation in teaching or research, including whether the research requires and has received ethical approval.*

The Committee noted that they can approve access to identifiable health information without consent for research in certain circumstances. The Ethical Guidelines for Observational Studies states at Paragraph 6.43:

* 1. *Access to identified or potentially identifiable data for research without the consent of the people the data identifies or makes potentially identifiable may be justifiable when:*
     1. *the procedures required to obtain consent are likely to cause unnecessary anxiety for those whose consent would be sought; or the requirement for consent would prejudice the scientific value of the study; or it is impossible in practice to obtain consent due to the quantity or age of the records; and*
     2. *there would be no disadvantage to the participants or their relatives or to any collectives involved; and*
     3. *the public interest in the study outweighs the public interest in privacy.*

To approve a study involving access to health information without consent the Committee must be satisfied that these requirements are met by the study concerned. The Committee suggested that a letter be sent to the participants that explains that PGSN was a notifiable disease in the past.

1. Please amend the information sheet and consent forms, taking into account the suggestions made by the committee *(Ethical Guidelines for Observational Studies para 6.10)*

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

1. Add separate information sheets and consent forms for the optional sub studies.
2. Clarify that the koha will be a $20 grocery voucher.
3. Include that the ethics committee has given approval for the researchers to approach participants.
4. Explain that in the past PGSN was a notifiable disease and that this is how the researchers are obtaining participants’ contact details
5. Consider adding a pacific island cultural support person’s contact details if possible.

Decision

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

* Please amend the information sheet and consent forms, taking into account the suggestions made by the committee *(Ethical Guidelines for Observational Studies para 6.10)*
* Please justify the access to and use of data without consent. *(Ethical Guidelines for Observational Studies para 6.43)*

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

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| **9** | **Ethics ref:** | **18/CEN/27** |
|  | Title: | DIAMOND |
|  | Principal Investigator: | Dr James Taylor |
|  | Sponsor: | Janssen-Cilag (New Zealand) Limited |
|  | Clock Start Date: | 15 February 2018 |

Dr James Taylor 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 3 randomized, double-blind, placebo-controlled, multi-center study to evaluate the efficacy and safety of pimodivir in combination with the standard-of-care treatment in adolescent, adult, and elderly non-hospitalized subjects with influenza A infection who are at risk of developing complications.

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 participants will be recruited. The Researcher explained that eligible patients will be recruited through outpatient units, the emergency room, and through advertising material that has not yet been created.

Summary of ethical issues (outstanding)

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

1. Please amend the information sheet and consent form, taking into account the suggestions made by the Committee (*Ethical Guidelines for Intervention Studies* *para 6.22*).
2. The Committee stated that assent forms should be given to persons under age 16 only. (*Ethical Guidelines for Intervention Studies* *para 5.41*)
3. Please justify the inclusion of children and adolescents in the project as the study is a phase III trial but the investigator’s brochure indicates that there is no therapeutic benefit that has been shown in this population. (*Ethical Guidelines for Intervention Studies* *para 5.30*)

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

1. The Committee queried the lack of a Māori tissue statement in the Participant Information Sheet. The committee recommended the following statement: “*You may hold beliefs about a sacred and shared value of all or any tissue samples removed. The cultural issues associated with sending your samples overseas and/or storing your tissue should be discussed with your family/whanau as appropriate. There are a range of views held by Māori around these issues; some iwi disagree with storage of samples citing whakapapa and advise their people to consult prior to participation in research where this occurs. However, it is acknowledged that individuals have the right to choose.”*
2. Please add a statement about if contraception is necessary and that explains which types of contraception should be used. Please only use types of contraception commercially available in New Zealand.
3. Please use a different term to ward.
4. Please remove the statement about interpreters unless this service can actually be provided to all participants at the time of consent.
5. Please add a separate section that seeks consent for obtaining information post-birth for follow-up purposes.
6. Please clarify if the statement made on page 3 of 6 of the diagnostic information sheet about participants always having the right to ‘block personal data’ is true and amend this section so that it is clearer.
7. Please re-write or remove the explanation of genes on page 25 as it is unclear.
8. The Committee suggested a short, lay-friendly title.
9. Please make sure that all information sheets explain that samples tested in the study may be used for participant’s care.

Decision

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

* Please amend the information sheet and consent form, taking into account the suggestions made by the Committee (*Ethical Guidelines for Intervention Studies* *para 6.22*).
* Please justify the inclusion of a potentially vulnerable a group in the study who will not benefit. (*Ethical Guidelines for Intervention Studies* *para 5.30*)
* 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 Dr Angela Ballantyne and Dr Peter Gallagher.

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| **10** | **Ethics ref:** | **18/CEN/29** |
|  | Title: | Early Start Denver Model (ESDM) in an Inclusive Preschool Setting |
|  | Principal Investigator: | Mrs Jessica Tupou |
|  | Sponsor: |  |
|  | Clock Start Date: | 15 February 2018 |

Mrs Jessica Tupou 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 is an evaluation of an inclusive preschool-based approach to early intervention for children with autism based on the Early Start Denver Model (EDSM).
2. The first study in this proposal involves an intervention delivered to children by an individual trained in EDSM.
3. The Second involves training teachers to use EDSM strategies with children in their classes.

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 Māori consultation had been completed for this study.
2. The Committee queried how participants would be identified. The Researcher explained that they have approached a kindergarten association of 19 pre-schools and each of these schools has around 1 student with a diagnosis of autism spectrum disorder.
3. The Committee asked how the results would be analysed and assessed. The Researcher explained that an independent observer will view videos and transcripts and check for agreement. The independent observer is another student with expertise in the EDSM.

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

1. Explain what EDSM is and what the coordinating investigator and teachers will be doing. This includes a brief explanation of procedures and techniques.
2. Please amend the non-participating child information sheets to state that the CI/teachers may be working with a young child in your child’s kindergarten. It is important that information about the participant’s diagnosis is not disclosed.
3. Remove the statement about anticipating improvement in the child’s behaviours as this leading.
4. Remove the statement about affecting their learning or ability to improve.
5. Explain to teachers in their information sheet that participation will qualify for CME points.

Decision

This application was *approved with non-standard conditions* by consensus. The non-standard conditions for this study 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*).

## Substantial amendments

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| **1** | **Ethics ref:** | **15/CEN/224/AM03** |
|  | Title: | School readiness |
|  | Principal Investigator: | Dr Alison Leversha |
|  | Sponsor: |  |
|  | Clock Start Date: | 12 February 2018 |

Dr Alison Leversha was present by teleconference for discussion of this amendment.

Potential conflicts of interest

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

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

Summary of Study

1. The study is a follow up study to the School Readiness/Welcome to School study. The research investigates the unmet need and long-term outcomes of the study cohort.

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 following up on unmet need was of high scientific value.
2. The Committee queried what happens if unmet need was discovered. The Researchers explained that by gathering the data they can improve services to try and meet the need of the study group.
3. The Committee asked what happens if unmet need is identified and support is not available. The Researchers explained that they would inform parents and other persons.
4. The Committee queried how families would be re-contacted. The Researchers explained that they have ongoing contact with the family or whānau of their participants or will recruit via schools.

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

1. Add a Māori cultural support person’s contact details.

Decision

This amendment was *approved* *with non-standard conditions* by consensus. The non-standard condition for this study is:

* Please amend the information sheet and consent forms, taking into account the suggestions made by the committee *(Ethical Guidelines for Observational Studies para 6.10)*

## 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:** | 27 March 2018, 08:00 AM |
| **Meeting venue:** | Room GN.6, Ground Floor, Ministry of Health, 133 Molesworth Street, Wellington, 6011 |

The following members tendered apologies for this meeting.

The meeting closed at 5pm.