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| **Committee:** | Central Health and Disability Ethics Committee |
| **Meeting date:** | 26 November 2019 |
| **Meeting venue:** | Hawkestone Room, Thorndon Rydges Hotel, 24 Hawkestone Street, Thorndon, Wellington |

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|  | **Item of business** |
| 12:00pm | Welcome |
|  | Confirmation of minutes of meeting of 22 October 2019 |
| 12:30pm | New applications (see over for details) |
|  | i 19/CEN/181  ii 19/CEN/183  iii 19/CEN/184  iv 19/CEN/185  v 19/CEN/188  vi 19/CEN/189  vii 19/CEN/190  viii 19/CEN/194  ix 19/CEN/195  x 19/CEN/68 |
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|  | General business:  Noting section of agenda |
| 4:30pm | 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 |
| 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 Cordelia Thomas | Lay (the law) | 20/05/2017 | 20/05/2020 | Present |
| Dr Peter Gallagher | Non-lay (health/disability service provision) | 30/07/2015 | 30/07/2018 | Present |
| Ms Helen Davidson | Lay (ethical/moral reasoning) | 06/12/2018 | 06/12/2021 | Present |

## Welcome

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

The Chair noted that the meeting was quorate.

The Committee noted and agreed the agenda for the meeting.

## Confirmation of previous minutes

The minutes of the meeting of 22 October 2019 were confirmed.

## New applications

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| **1** | **Ethics ref:** | **19/CEN/181** |  |
|  | Title: | Child and adolescent inpatient mental health care in NZ |  |
|  | Principal Investigator: | Ms Julie Artus |  |
|  | Sponsor: | N/A |  |
|  | Clock Start Date: | 14 November 2019 |  |

Ms Julie Artus and Dr Gabrielle Jenkin 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. Dr Peter Gallagher identified a possible conflict of interest as he knew the two researchers, however the Committee allowed Dr Gallagher to take part in its review of the study.

Summary of Study

This study examines inpatient mental health service delivery for children and adolescents within the context of New Zealand’s mental health system, in order to develop an evidence-base to inform policy options for this age group.

Summary of resolved ethical issues

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

1. The Committee queried the age groups which will be captured in this study. The Researchers answered that the average age of admission is around 16, and that the upper-range of teenagers are most likely to participate. Some units admit children under the age of 14, and such children will be included if appropriate and assented.
2. The Committee inquired whether the ideal scenario for this study would be 1:1 interviews or group sessions. The Researchers replied that there is no preference but that this latter option is being considered as teenagers often form close bonds in this setting and may feel safer amongst their peers. The Committee questioned whether these two intervention options will be discussed with the participants. The Researchers answered that the consent form and process will be discussed 1:1 at the outset and will tailor the approach to the individual.

Summary of outstanding ethical issues

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

1. The Committee advised that there should be individual PISCFs for each of the 3 cohorts in this study: the service users, whānau members, and mental health staff.
2. The Committee stated that records of participant competence assessments must be retained.

The Committee requested the following changes to the participant information sheet and consent form:

1. Please add that participants will be assessed for Gillick competence, even participants that are at or above the age of consent.
2. Please review the HDEC template and expand the content on participants’ data. For example, there should be information on what happens to their data, how, where, and how long it will be stored, and who has access to it. There also needs to be an ACC statement; the template provides this, and helpful headings.
3. Please add a contact number for Māori support. The contact numbers should also be reformatted for readability.
4. Please add detailed safety information on what will happen if interviewees become distressed, such as the lead on-site clinician being contacted, and support offered.
5. Please remove that participation will be confidential.
6. Please include that a photo may be taken of the participant’s room and what will be done with that photo – e.g. state whether it will be reproduced in presentations and articles.
7. Please request permission from the participant to speak with their family and whānau about their mental health.

Notes

1. The Committee advised that an information sheet and consent form should be submitted as an amendment for additional ‘stakeholder’ participants once these become clear.
2. The Committee commended the detailed answer provided to question p.4.1 in the application form, in particular the statistics provided on the incidence of mental health disorders in Māori.

Decision

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

* Please amend the participant information sheets and consent forms, taking into account the suggestions made by the Committee. Please also provide an individual PISCF for each cohort in this study and ensure that records of competence assessments are retained. (*Ethical Guidelines for Observational Studies* para. 6.10).

After receipt of the information requested by the Committee, a final decision on the application will be made by Dr Patries Herst and Mrs Sandy Gill.

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| **2** | **Ethics ref:** | **19/CEN/183** |  |
|  | Title: | Concussion Recovery in Children and Adolescents |  |
|  | Principal Investigator: | Dr Nicola Starkey |  |
|  | Sponsor: | University of Waikato |  |
|  | Clock Start Date: | 14 November 2019 |  |

Dr Amy Jones and Nicola Starkey 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 conflicts of interest were identified by any member.

Summary of Study

This is a longitudinal study of concussion recovery in 5 to 17-year-olds in three recruitment groups: Māori, Pacific, and non-Māori/non-Pacific. The study will provide detailed descriptions and understanding of acute symptoms (and management), typical patterns of symptom resolution, and long-term outcomes from concussion in children and adolescents in order to produce evidence-based guidelines. It will also identify and explore any inequities in outcomes.

Summary of resolved ethical issues

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

1. The Committee noted the large number of information sheets and consent forms and asked for clarification of the participant group. The Researchers explained that range of PISCFs was due to the varying ages of participants. Parents will be providing proxy consent for any participant under the age of 16 as well as consenting for themselves, and children over 8 will be assenting. The study requires that children and parents are recruited as pairs, so the various documents cover different possible pairing scenarios. Consent is also required from participants over 16 to approach their parents for inclusion. The Committee acknowledged this and agreed that it was appropriate for children under the age of 8 not to be asked to assent.
2. The Committee inquired after the study’s “multiple data collection points.” The Researcher answered that the protocol and timepoints are based on a study being run in Australia, and subsequently the interviews and assessments will occur 1-4 days post-injury, and then at 2 weeks, 1 month, 3 months, and 12 months. However, the study is also doing longer-term follow-up, as the HRC encouraged this in the Māori and Pacific communities involved; these participants may statistically be at greater risk and it is therefore appropriate to follow them for a longer period of time.
3. The Committee queried how the Researchers would ensure that they meet their recruitment targets of 1/3 Māori, 1/3 Pacific, and 1/3 Pākehā within this timeframe. The Researchers answered that they will be recruiting across multiple study sites and that there is a large Māori population in the Waikato region. Additionally, research shows that a reasonable number of Māori children will be recruitable through Waikato ED, and that Pacific participants can be recruited through Middlemore Hospital and accident and medical clinics in the South Auckland region. The study team is also consulting with a Māori and Pasifika advisory group which is engaging with these communities and will inform them of the research.
4. The Committee asked whether any statistics were available on Māori and concussion. The Researchers reported that for brain injuries as a whole, older Māori and females around 35 were at high risk when compared with Pākehā equivalents, but that with children there is no ethnic disparity.

Summary of outstanding ethical issues

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

1. The Committee commented that it may not be feasible for hard copies of study documents to be retained for 21 years. The Researchers are advised to retain this information in electronic form.

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

1. Please confirm that permission is being sought to access health information from hospitals and clinics about the particular injury under investigation and also subsequent injuries.
2. Please confirm that permission is being sought to approach the parent(s) of participants.
3. Please include in the PIS that if participants withdraw from the study their data collected to that point will continue to be processed, that participants are consenting to their GP being informed of the study, and that approved auditors may access existing records. This information is currently in the CF only.
4. Please explain the protocols for breaking data confidentiality when an individual is found to be at risk, such as what constitutes ‘risk’ and what will occur.
5. Please add that participants will be assigned a unique study code.
6. Please include participants’ rights to access and correct information as per the Health Information Privacy Code.
7. Please remove the statement under “What will my participation in the study involve?” about short memory tasks, which reads: “Most people find these tasks enjoyable.” This is suggestive.
8. On the 8-12-year-old information sheet, please add that there will assessments as well as answering questions.
9. Please relabel the parental PISCF as “parent or guardian.”
10. Please remove tick boxes in the consent form for aspects of the study which are not optional.
11. The Committee *suggests* removing mention of the 20-dollar voucher in the 8-12 document.

Notes

1. The Committee explained that statistics on Māori rates of brain injury would have been useful to include in the application form and asked that this be noted for future applications. Further, it should have been identified that the tapu nature of the head is a cultural issue for Māori on this topic, as is potentially whakamā, depending on how the injury occurred.

Decision

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

* Please amend the participant information sheets and consent forms, taking into account the suggestions made by the Committee (*Ethical Guidelines for Observational Studies* para. 6.10).
* Please consider keeping study information in an electronic form (*Ethical Guidelines for Observational Studies* para. 8.3).

After receipt of the information requested by the Committee, a final decision on the application will be made by Dr Peter Gallagher and Mrs Helen Davidson.

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| **3** | **Ethics ref:** | **19/CEN/184** |  |
|  | Title: | Axial Spondyloarthritis: Evaluation of Upadacitinib in Adult Subjects |  |
|  | Principal Investigator: | Dr Douglas White |  |
|  | Sponsor: | AbbVie Pty Ltd |  |
|  | Clock Start Date: | 14 November 2019 |  |

No researchers were present for discussion of this application.

Potential conflicts of interest

The Chair asked members to declare any potential conflicts of interest related to this application. No conflicts of interest were identified by any member.

Summary of Study

This is a global, multicentre study with a common screening platform for determining eligibility into 2 separate studies: Study 1 involves participants with active axial spondyloarthritis (axSpA) who had an inadequate response to biologic disease-modifying antirheumatic drug therapy, and Study 2 involves participants with active axSpA. The objective of the double-blind period is to evaluate the efficacy of upadacitinib compared with placebo on reduction of signs and symptoms in adult participants with active axSpA, and to assess the safety and tolerability of upadacitinib in extended treatment in adult participants with active axSpA. The Open-Label Extension period objective is to evaluate the safety and tolerability of upadacitinib in extended treatment in adult participants with active axSpA.

Summary of outstanding ethical issues

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

1. The Committee noted that there is no safety plan in the event of a negative psychological reaction to the quality of life survey. This needs to be put in place and include details on what action will be taken, and how soon after completion the questionnaires will be reviewed and by who.
2. The Committee observed that HIV and TB testing will be done if warranted by blood testing, as per page 9 of the PIS, and questioned why this was not being undertaken as part of the screening process.
3. The Committee stated that it is unnecessarily intrusive for research staff to review all patient records within the clinic, without consent, to identify participants based on inclusion criteria. The Researchers should consider either in-clinic study advertisements or a member of the patient’s clinical team referring them to the study. Any advertisements should be submitted to the committee for review.
4. The Committee stated that data should not be sent overseas with study codes attached. These should rather be fully de-identified.

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

1. Please remove use of the phrase “fake drug” and replace it with an explanation, such as it will look like the real drug but not contain any active ingredients.
2. Please remove the qualifier on page 9 “if required in New Zealand.” The document should be aligned to New Zealand requirements. Please note that HIV and Hepatitis *are* notifiable diseases in New Zealand.
3. Please remove on page 13 the statement “blood collection may cause anaemia.” This seems unlikely in this study and may cause unnecessary alarm.
4. Please add study contact details to the pregnant participant document. Please also add a separate heading for the section to be signed following the birth of the child and note that access to data begins after birth not upon signing. Please state that tissue samples will be sent overseas. Additionally, please align the pregnancy risks content to the HDEC template, e.g. a barrier and oral method should be used in conjunction, and clarify whether it is important that a male participant not get his partner pregnant.
5. Please qualify what a “reasonable amount” is in terms of compensation.
6. Please clarify that long-term follow-up and pregnancy follow-up will continue to be undertaken only with the participants consent.
7. Please add that participants are consenting to their GP being informed about the study. This is in the CF but not the PIS.
8. Please add advocacy and study contact details to the pregnant participant form.
9. Please amend page 16 of the main PIS so that it refers to the Central HDEC.
10. Please amend the type on page of the optional biomarker research form which reads “Unites States.”

Notes

1. The Committee noted that the answers provided to questions p.4.1 and p.4.2 in the application form lacked detail and were patronising for Māori – Article 1 of the Treaty of Waitangi is not relevant to the question of Māori benefit from research. Some idea of the representation of the disease in Māori (incidence, mortality, etc.) should be outlined, and cultural issues such as data as taonga, sovereignty of tissue samples, the head as tapu, and whakamā should be acknowledged. Moreover, questions f.1.1 and f.1.2 should relate to ethnicities *other* than Māori.
2. The Committee commended the section in the PIS on information privacy and coding of data, which was very simple and clear.

Decision

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

* Please amend the participant information sheet and consent forms, taking into account the suggestions made by the Committee (*Ethical Guidelines for Intervention Studies* para. 6.22).
* Please provide a safety plan for the quality of life questionnaire, and justify the lack of HIV and TB testing during the screening process. (*Ethical Guidelines for Intervention Studies* para. 5.41)
* Please consider a different method of identifying participants than the systematic and blanket review of medical records without consent (*Ethical Guidelines for Intervention Studies* section 7).
* Please de-identify data being sent overseas, including the re-identifiable study code (*Ethical Guidelines for Intervention Studies* para. 7.3).

After receipt of the information requested by the Committee, a final decision on the application will be made by Dr Patries Herst and Dr Cordelia Thomas.

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| **4** | **Ethics ref:** | **19/CEN/185** |  |
|  | Title: | CO41101: STUDY OF IPATASERTIB IN COMBINATION WITH ATEZOLIZUMAB AND PACLITAXEL AS A TREATMENT FOR PATIENTS WITH LOCALLY ADVANCED UNRESECTABLE OR METASTATIC TRIPLE-NEGATIVE BREAST CANCER |  |
|  | Principal Investigator: | Dr Sheridan Wilson |  |
|  | Sponsor: | Roche Products (New Zealand) Limited |  |
|  | Clock Start Date: | 14 November 2019 |  |

Dr Sheridan Wilson, Sophie Goodger, and Ruth Lucas 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 conflict of interest was identified by any member

Summary of Study

This phase 3 study seeks to understand the effects of ipatasertib in combination with atezolizumab and paclitaxel versus a standard treatment in patients with metastatic triple-negative breast cancer.

Summary of resolved ethical issues

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

1. The Committee wished to confirm that 13 participants are planned to be recruited over 6 years. The Researchers confirmed these were the New Zealand-wide numbers. The Committee then asked after the survival period of patients with triple-negative breast cancer. The Researchers explained that this is under a year in New Zealand though this in slightly longer in the international figures. The Committee then queried whether participants would likely survive the 6-year length of the study, and what the age-range would be. The Researchers answered that it is unlikely participants will survive for this entire 6-year period and that the age-range for metastatic patients will be 40 years and over.
2. The Committee noted that the study will involve the EQ-5D-5L Health Questionnaire and inquired what safety processes were in place for participants who score highly for anxiety and depression. The Researchers replied that there is a standard of care pathway of referral to the cancer psychology support services, and this would be the approach used in the study. The Committee asked how quickly the multiple questionnaires which deal with depression are collated and assessed. The Researchers responded that these questionnaires are live and filled in at time of appointment; these are sent to the treating doctor who has the opportunity to act immediately. The Researchers emphasised that there is a very responsive team of psychiatrists attached to the oncology department.

Summary of outstanding ethical issues

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

1. If the pregnant partner and new-born health information authorisation consent documents remain targeted at the partners of men who may be recruited into the study, please ensure that the primary PISCF informs female participants that data may be collected on their pregnancy if they become pregnant during the study.
2. In both the pregnant partner and new-born health information authorisation forms, please state where data is being sent overseas.
3. Please ensure that all PISs include that samples will be sent overseas.
4. Please ensure that all information sheets are consistent and aligned with each other.

Note

1. The Committee complimented the grid in the PIS which clearly outlines study processes.
2. The Committee commended the statistics of the disease’s incidence in Māori which were provided in the application form.

Decision

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

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

After receipt of the information requested by the Committee, a final decision on the application will be made by Dr Peter Gallagher and Mrs Helen Walker.

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| **5** | **Ethics ref:** | **19/CEN/188** |  |
|  | Title: | Phase 3 Study of Pembrolizumab plus Docetaxel in mCRPC |  |
|  | Principal Investigator: | Dr Jim Edwards |  |
|  | Sponsor: | MSD |  |
|  | Clock Start Date: | 14 November 2019 |  |

**Closed minutes.**

Decision

This application was *provisionally approved* by consensus.

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| **6** | **Ethics ref:** | **19/CEN/189** |  |
|  | Title: | NeoGluCO Study |  |
|  | Principal Investigator: | Dr Chris McKinlay |  |
|  | Sponsor: | University of Auckland |  |
|  | Clock Start Date: | 14 November 2019 |  |

Dr Chris McKinlay was 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 conflicts of interest were declared by any member.

Summary of Study

This is a double-blinded, randomised controlled, two-arm, parallel trial of diazoxide versus placebo in neonates admitted to neonatal care with severe or recurrent hypoglycaemia in the first week after birth. The aim is to determine if early treatment with diazoxide improves glycaemic stability and metabolic transition.

Summary of resolved ethical issues

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

1. The Committee queried whether it can be known in advance of birth whether a child has hyperglycaemia. The Researcher answered that risk factors such as maternal diabetes and infant size are known, but incidence cannot be predicted prospectively.
2. The Committee asked how long after birth the infants will be recruited into the study and mothers asked for consent. The Researcher replied that infants will likely be identified by ward staff, and the study team could be notified anywhere between 1-2 hours after birth through to the second or third day. The Committee noted that this could potentially be a stressful time for the mother to be asked for their child to participate in research. The Researcher answered that this is the case for any new-born stabilisation study, and that the study team is experienced in this area and used to recruiting participants after birth. It was stated that antenatal recruitment would not be feasible.
3. The Committee observed that this is a longitudinal study and not only being undertaken during the neonatal period. The Researcher confirmed this and explained that follow-up is always important for safety and consent will be sought for the study to link to routine outcome data.
4. The Committee noted that the study currently has seed funding with applications still pending with the HRC. It was asked what will happen if further funding is not secured. The Researcher replied that running costs are not high and there is sufficient funding to begin the study at a single site. HRC funding would simply allow recruitment to be undertaken more quickly at multiple sites.

Summary of outstanding ethical issues

The Committee requested the following changes to the participant information sheet and consent form:

1. Please add to the data section that participants have the right to access and correct their health information, as per the Health Information Privacy Code.
2. Please include in the PIS that consent is being sought to inform the participant’s GP of the study. This is currently only stated in the CF.
3. Please change the “declaration by caregiver” form to “declaration by parent or guardian.”
4. Please state where blood samples will be stored.
5. Please proof-read the document for typos.
6. Please consider removing the cultural paragraph, as all procedures on tissue will be standard of care.

Notes

1. The Committee noted that it was impressed with the quality of the answer provided in the application form to question p.4.2, which asks researchers to consider cultural issues arising for Māori.

Decision

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

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

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| **7** | **Ethics ref:** | **19/CEN/190** |  |
|  | Title: | Warm humidified insufflation study in acute surgical unit |  |
|  | Principal Investigator: | Professor John Windsor |  |
|  | Sponsor: | University of Auckland |  |
|  | Clock Start Date: | 14 November 2019 |  |

No researchers were present for discussion of this application.

Potential conflicts of interest

The Chair asked members to declare any potential conflicts of interest related to this application. No conflicts of interest were declared by any member.

Summary of Study

This is a randomised controlled, single-blind study to investigate the impact of warm humidified insufflation (administered using the HumiGard medical device developed by Fisher and Paykel Healthcare) on post-operative ileus in patients undergoing acute general surgical laparotomy. Specifically, it will determine whether warm humidified insufflation during surgery will reduce the length (in days) of post-operative ileus as defined by bowel function, improved gut dysfunction, and improved quality of life.

Summary of outstanding ethical issues

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

1. The Committee asked that the potential conflict of interest of a study surgeon approaching patients for participation be managed. If someone independent of the study cannot make the approach, then a research nurse not part of the clinical team should recruit patients.
2. The Committee requested that the issue of no-fault injury compensation be addressed. The application form indicates that this is not a commercially-sponsored trial and no insurance certificate or evidence of CI indemnity has been provided. However, the participant information sheet states that as the study is being conducted principally for the benefit of Fisher and Paykel Healthcare, participants will not be eligible for ACC compensation.
3. The Committee stated that a safety plan must be protocolised for negative psychological reactions to the quality of life index in the questionnaire.
4. The Committee asked for clarification of whether participants will be consenting, or asked to consent at a later date, to their tissue samples being used for future unspecified research, i.e. research which is not related to this study.

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

1. Please remove tick boxes on the consent form for aspects of the study which are not optional.
2. Please state that there are “no known risks” as opposed to “no foreseeable risks.”
3. Please ensure that it is the *Central* Health and Disability Ethics Committee which is referenced.
4. Please ensure that documents are consistent about the retention period of data in this study.
5. Please re-format the very detailed paragraph on what happens during the surgery for readability, such as using sub-headings. This could be stated more simply.
6. Please either ensure that the consent form obtains consent from participants to be contacted in order to obtain further consent for uses of their tissue not related to this study, or any further analysis is a part of this study ensure that references to future studies are removed. This relates to the Committee’s question about future unspecified research above.
7. Please clarify what will happen to already-collected data if a participant chooses to withdraw from the study.
8. Please state where data will be stored and who will have access to it.
9. Please include that an approved auditor may have access to study data. This is in the CF but not the PIS.
10. Please remove the statement “your participation will greatly contribute to advancing the knowledge on reducing post-operative ileus” which is overly promotional and emotive.

Decision

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

* Please amend the participant information sheet and consent form, taking into account the suggestions made by the Committee (*Ethical Guidelines for Intervention Studies* para. 6.22).
* Please ensure that conflicts of interest arising during the recruitment process are managed (*Ethical Guidelines for Intervention Studies* para. 4.21).
* Please clarify the commercial nature of the study, or the lack thereof, and subsequent insurance requirements as requested by the Committee (*Ethical Guidelines for Intervention Studies* para. 8.5).
* Please ensure a safety plan is in place for the questionnaire, and please explain whether tissue samples may be retained for future unspecified research (*Ethical Guidelines for Intervention Studies* para. 5.41).

After receipt of the information requested by the Committee, a final decision on the application will be made by Dr Patries Herst and Dr Cordelia Thomas.

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| **8** | **Ethics ref:** | **19/CEN/194** |  |
|  | Title: | Proof of Principle BCG Trial |  |
|  | Principal Investigator: | Profesor Philip Hill |  |
|  | Sponsor: | University of Otago |  |
|  | Clock Start Date: | 15 November 2019 |  |

No researchers were present for discussion of this application.

Potential conflicts of interest

The Chair asked members to declare any potential conflicts of interest related to this application. No conflicts of interest were declared by any member.

Summary of Study

This is a proof of principle randomised trial of Bacillus Calmette Guerin versus placebo in medical and nursing students in one hospital in Bandung, Indonesia, to prevent conversion of an Interferon Gamma Release Assay over 12 months following the commencement of clinical training.

Summary of outstanding ethical issues

The Committee requested the following changes to the participant information sheet and consent form:

1. Please include a statement that makes clear the genetics research is not an optional part of the study.
2. Please either remove or amend the sentence which states that positive HIV and TB results will be both notifiable and kept confidential. It should rather be stated that such results will not be known to other study participants.
3. Please review the document for typos.
4. Please remove the advocacy number, as this service does not apply to studies conducted outside of New Zealand.
5. Please include in the PIS that the study co-ordinator will be aware of participation,
6. Please include information on insurance and cover in the event of injury.
7. Please include in the PIS that if the participant withdraws data collected to that point will remain in the study for analysis.

Decision

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

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

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| **9** | **Ethics ref:** | **19/CEN/195** |  |
|  | Title: | VIR-2482-3001: A study to assess the safety and effectiveness of VIR-2482, in the prevention of community-acquired influenza A illness. |  |
|  | Principal Investigator: | Dr Christopher Wynne |  |
|  | Sponsor: | Pharmaceutical Research Associates Ltd (NZ) |  |
|  | Clock Start Date: | 15 November 2019 |  |

Dr Chris Wynne, Dr Devonie Waaka, and James Swann 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 conflicts of interest were declared by any member.

Summary of Study

This is a 3-part study to assess the safety and effectiveness of VIR-2482, which is being developed for the prevention of influenza A illness (flu). Parts A and B will be conducted internationally and will inform the dosing levels of Part C which is conducted in New Zealand. The results of the study will help inform dose selection in future clinical trials of VIR-2482.

Summary of outstanding ethical issues

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

1. Please rewrite the risk section and ensure the information that is known about this medication and the parent drug is included in the PIS, and any information which has arisen out of part A and B of the study. Please also clarify whether there are restrictions on over-the-counter remedies as well.
2. Please include exclusion criteria which are important, and comprehensible to a lay readership.
3. Please clarify the section on compensation. For example, whether the payment sum includes travel and what constitutes “reasonable” travel expenses.
4. Please delete the sentence which states that all research in New Zealand involving humans is reviewed by an HDEC.
5. Please re-format the ‘What will happen to information about me’ section on page 14, as the text is currently very dense. Consider using sub-headings to break this information up. Sub-sections on de-identification and access could be employed.
6. Please revise language in the pregnant partner information sheet for clarity about what will happen to collected data if participation is withdrawn.

Notes

1. The Committee commented that information provided in the application form on consultation with Māori was comprehensive and well written.

Decision

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

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

After receipt of the information requested by the Committee, a final decision on the application will be made by Dr Peter Gallagher and Mrs Helen Walker.

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| **10** | **Ethics ref:** | **19/CEN/68** |  |
|  | Title: | whataboutme? |  |
|  | Principal Investigator: | Dr Deborah McLeod |  |
|  | Sponsor: | Ministry of Social Development |  |
|  | Clock Start Date: | 11 April 2019 |  |

Dr Debbie McLeod and Tom Roland were present in person for discussion of this application.

Potential conflicts of interest

The Chair asked members to declare any potential conflicts of interest related to this application. No conflicts of interest were identified by any member.

Summary of Study

This is a nationwide health and wellbeing survey of 14,000 young people aged 12-18 years. Youth will be sampled through secondary schools, kura kaupapa youth service providers, community organisations, and alternative education providers. This youth survey will inform policy, practice, programme development, implementation, and monitoring of trends.

The Researchers are responding to the previous provisional approval of this study by the Committee.

Summary of resolved ethical issues

The required changes to the study design which have been addressed by the Researchers, and the outstanding ethical issues responded to, are as follows:

1. The Committee was satisfied that the safety plan templates, which will be completed in discussion with the individual schools, constituted sufficient evidence of safety planning given the highly contextual nature of the research.
2. The Committee agreed that the study protocol and field manual provided met the Committee’s requirement for a general operational plan.
3. The Committee noted that the Researchers will provide parents with access to the questions of the survey, which justifies the opt-out consent model for the child participants.
4. The Committee noted that the Researchers have provided a final version of the survey for review, as requested as part of provisional approval.
5. The Committee agreed that the study can progress, without a preceding 3-school pilot study, but only with students 14 years of age and older.
6. The Committee queried how students who are unable, for reasons of physiological impairment, to complete the survey on their own will participate in the research – both logistically and ethically. The Researchers explained that for students with hearing impairments a New Zealand Sign Language video is available; for those with disabilities such as cerebral palsy hard copies and booklets are available; and for those with impaired vision an audio version will be provided. The Committee queried whether students receiving information and answering in this latter fashion will have their answers remain confidential. The Researchers confirmed that these students will be provided headphones and answer questions themselves on a specially-tailored tablet. All students, as a requirement, will complete the survey on their own. The Committee approved of this process, and that only children who could answer survey questions for themselves would participate in the research; that severely cognitively-impaired children will not be asked to complete the survey.

Summary of outstanding ethical issues

1. The Committee asked that signed locality approval from schools’ board of trustees be obtained before the study commences at each school. The Committee acknowledged that this can be sought in parallel to approaching the principal.
2. The Committee asked that the inclusion of students aged 12 and 13 be submitted as an amendment to the study once safety data is available from the early stages of the study. The Committee advised that pre-testing could be undertaken with focus groups outside of the study.
3. The Committee requested that a general and simplified information sheet be provided for students who require, for cognitive reasons, assistance to complete the survey on their own. For example, this could utilise pictures. It is understood that this will be supplemented by information appropriate to each context.
4. The Committee advised that legally-consistent language should be used on consent documents. The term ‘parent or whānau guardian’ was recommended.

Decision

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

* Once safety information is available from the early stages of the study, the addition of 12-13-year-old participants must be submitted as an amendment for approval by the Committee. Focus-grouping with this age-range could also produce qualitative evidence for the Committee to consider. (*Standard Operating Procedures for Health and Disability Ethics Committees* paras. 187 & 188).
* Please ensure that schools’ boards of trustees are contacted as part of the locality approval process, and signed approval given. This can be done in parallel with an approach to the school’s principal. (*Ethical Guidelines for Observational Studies* paras. 5.5 & 5.6).
* Please provide a generic information sheet for students with cognitive impairments (*Ethical Guidelines for Observational Studies* para. 6.10).
* Please use legally-consistent language on consent documents as advised by the Committee (*Ethical Guidelines for Observational Studies* para. 1.9).

## General business

1. The Committee noted the content of the “noting section” of the agenda.
2. The Chair reminded the Committee of the date and time of its next scheduled meeting, namely:

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| --- | --- |
| **Meeting date:** | 21 January 2020 |
| **Meeting venue:** | TBD |

1. **Problem with Last Minutes**

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

The meeting closed at 4:30pm.