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| **Committee:** | Central Health and Disability Ethics Committee |
| **Meeting date:** | 25 February 2020 |
| **Meeting venue:** | Room GC.3, Ground Floor, Ministry of Health, 133 Molesworth Street, Wellington |

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| **Time** | **Item of business** |
| 12:00pm | Welcome |
| 12:25pm | Confirmation of minutes of meeting of 28 January 2020 |
| 12:30pm | New applications (see over for details) |
| 12:30 – 12:55pm  12:55 – 1:20pm  1:20 – 1:45pm  1:45 – 2:10pm  2:10 – 2:35pm  2:35 – 3:00pm  3:00 – 3:25pm  3:25 – 3:50pm  3:50 – 4:15pm  4:15 – 4:40pm | i 20/CEN/4 (Cordelia/Peter)  ii 20/CEN/33 (Sandy/Patries)  iii 20/CEN/31(Helen D./Peter)  iv 20/CEN/34 (Helen W./Patries)  v 20/CEN/37 (Cordelia/Peter)  vi 20/CEN/36 (Helen D./Patries)  vii 20/CEN/35 (Sandy/Peter)  viii 20/CEN/38 (Helen W./Patries)  ix 20/CEN/41 (Sandy/Peter)  x 20/CEN/42 (Cordelia/Patries) |
| 4:40pm | General business:  Noting section  19CEN68 |
| 5:00pm | Meeting ends |

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| **Member Name** | **Member Category** | **Appointed** | **Term Expires** | **Apologies?** |
| Mrs Helen Walker | Lay (consumer/community perspectives) | 01/07/2018 | 01/07/2021 | 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 28January 2020 were confirmed.

## New applications

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| **1** | **Ethics ref:** | **20/CEN/4** |  |
|  | Title: | Meditative drawing for people with dementia and their care partners |  |
|  | Principal Investigator: | Ms Emma Febvre-Richards |  |
|  | Sponsor: | Massey University |  |
|  | Clock Start Date: | 13 February 2020 |  |

Ms Emma Febvre-Richards and Ms Emma Fromings were present in person and Dr Gary Cheung 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 research team has developed MindArt, a new group programme of drawing sessions that combine the principles of maintaining fine motor skills with the meditative qualities of drawing on paper and digital tablets. MindArt was specifically designed for people with dementia and their care partners. It comprises of eight weekly 90-minutes sessions. The programme was user-tested (and subsequently modified) with a group of eight care partners of people with dementia between July and September 2019. The research team is now ready to pilot test this dual care programme with 8 pairs of people with dementia and their care partners.
2. The first hypothesis is that MindArt will improve the quality of life and psychological well-being of people with dementia, which is consistent with the notion of living well with dementia. The second hypothesis is that MindArt will reduce carer stress and improve the quality of life and psychological well-being of care partners.

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 recruitment process. The Researchers stated it was more about informing people about the opportunity to participate. The Researchers stated they would make information available through the internet (Dementia Wellington website, Facebook), conversations and social groups.
2. The Committee queried whether people with dementia and their carers would be interviewed together or separately. The Researchers stated the carer would be asked to leave the room and the interview would be conducted privately.
3. The Committee queried the length of each session. The Researchers stated they were an hour and a half each. The Researchers stated the sessions included a welcome, context of the day, music and activities which last about 30 minutes. The Researchers stated individuals can go at their own pace as some may be absorbed and wish to continue or some may wish to finish sooner.
4. The Committee queried whether there would be a rest area as some participants may feel overwhelmed or fatigued. The Researchers confirmed there was a lounge area with water participants could relax in.
5. The Committee noted some questions about the relationship with the carer could be potentially controversial and depending on the level of dementia participants may give unusual answers or alternatively disclose caregiver abuse. The Committee queried what the Researchers would do in this scenario. The Researchers stated they would take any concerns seriously and the occupational therapist / social worker would channel it back to Dementia Wellington who have their own policies to manage this. The Committee queried how long that process would take. The Researchers stated it would happen the same day and if not during office hours the next day. The Researchers stated any imminent risk would be acted on immediately to protect the participant.
6. The Committee queried who would assess whether potential participants would be competent to provide consent. The Researchers stated they have a social worker and an occupational therapist with experience working with people with dementia. The Committee queried whether this was within their registered scope of practice. The Researchers stated only medical doctors and psychologists are registered with this within their scope of practice but what they have done in the past is to train non-medical health professionals to provide capacity assessments.

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 queried whether it would present a risk to the research team if staff would be asked to perform an assessment outside of their scope of practice and there was a subsequent complaint. The Researchers stated they would consult the DHB and provide an update.
2. The Committee queried whether the participant pairs’ status in the study was bound together and whether the withdrawal of one would pull the other from the study. The Researchers stated if one partner pulls out it would not necessarily eject the other, although it is desirable for them both to stay. The Committee requested the inclusion of a statement to the PIS advising that if one partner withdraws the other may remain if they wish to.
3. The Committee noted the response to question P.4.1. in the application form discussing how the study would benefit Māori was patronising. The Committee queried whether any statistics on the prevalence or incidence of dementia in Māori were available. The Researchers stated this was currently unknown and being worked on. The Committee recommended including any statistics (or an explanation if unknown) when answering P.4.1. for any future applications.
4. The Committee noted the response to P.4.2. on cultural issues did not include whakamā. The Committee recommended the Researchers consult a cultural advisor as whakamā is very likely to be present in a study of this nature.
5. The Committee queried how the Researchers would know whether any allegations were valid or due to the participant’s dementia. The Committee stated the Researchers would need a safety protocol to follow with disclosure in the PIS that if there are any concerns about X the research team will do Y. The Researchers stated they could ensure the assessment was done during office hours and have an immediate contact to report anything of concern. The Researchers stated potential participants will already have a relationship with Dementia Wellington. The Committee queried how large the potential study population pool is. The Researchers estimated about 200 people.
6. The Committee queried why these questionnaires were being used and the purpose of collecting this information. The Researchers stated they want to replicate what was done in France and capture the same data to compare. The Committee stated if one of the study objectives is to compare the New Zealand data with the results in France it should state so in the PIS. The Researchers stated it was not necessary and they were comfortable to remove it. The Committee stated all data collected should relate to a study objective and if it is not related to the main study question participants should not be asked about it. The Committee requested the Researchers revise the study objectives or remove the questionnaires.
7. The Committee advised that if the questionnaires will be used the PIS will need to contain information regarding the nature of some of the questions (e.g. do the participants with dementia enjoy spending time with their caregiver, do they like having their caregiver etc).

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

1. The Committee requested the statement on page 2 of the PIS advising that some questions ‘may’ be personal be changed to state some questions ‘are’ personal.
2. The Committee requested the statement advising that participants “do not need to answer all questions” be amended to state “do not have to answer any questions you do not want to”.
3. The Committee noted the care partner’s PIS refers to ‘your relative’. The Committee requested this be amended to simply state ‘care partner’ as the carer may or may not be related and could be a friend, professional carer etc.
4. The Committee noted a clause on the consent form consenting to staff taking information about participants health. The Committee queried what information the researchers intended to collect as this would need information in the PIS. The Researchers stated they were not collecting health information and would only record demographics (gender, ethnicity etc). The Researchers agreed to amend the consent form.

Decision

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

* Please update the participant information sheet and consent form, taking into account feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17).*
* Please provide a safety plan addressing the concerns raised by the Committee *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 11.25).*
* Please provide an update from the DHB on the scope of practice of the study team and who may perform the competency assessments. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.23a).*

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

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| 2 | **Ethics ref:** | **20/CEN/33** |  |
|  | Title: | Treatable traits for the management of asthma: a feasibility study |  |
|  | Principal Investigator: | Dr James Fingleton |  |
|  | Sponsor: | Medical Research Institute of New Zealand |  |
|  | Clock Start Date: | 22 January 2020 |  |

Dr James Fingleton was present by teleconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. This study is a feasibility study looking at personalised medicine for asthma. A planned full randomised controlled trial would test whether tailoring a patient’s treatment according to an algorithm based on their asthma symptoms, level of airway inflammation and airway narrowing gives better results than usual care.
2. Fifty participants will be recruited, 25 in New Zealand and 25 in Australia. Each participant will attend for 3 visits over 10 weeks and will have their medications adjusted according to the treatment algorithm specified in the protocol. All participants will receive inhaled steroid and long-acting bronchodilator medications in line with national and international guidelines. The difference is that the dose of inhaled steroid and whether or not participants are prescribed oral steroids (prednisone) will be adjusted according to the protocol algorithm rather than individual clinician's judgement.

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 any data would be sent outside of New Zealand. The Researcher stated all data will be stored on medical research institute encrypted servers but one of the servers is located in Australia. The Researcher explained while the data will be stored there it is encrypted and can only be accessed through a MRINZ terminal in New Zealand. The Committee requested the inclusion of information explaining this to the PIS.

Summary of outstanding ethical issues

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

1. The Committee noted the PIS does not explain how the process for adjusting medication. The Researcher explained they would measure volume capacity and airway narrowing and adjust medication or a second inhaler as necessary. The Researcher agreed to revise the section for a clear explanation.
2. The Committee noted the phrase ‘Can you help?’ could potentially be emotive and requested it be changed to ‘Would you like to be involved?’ to avoid any implication of people being unhelpful if they did not wish to participate.
3. The Committee requested the statement about patients ‘helping’ in the study be changed to state ‘involved’ or ‘enrolled’ in the study.
4. The Committee requested an additional option in the consent form for a participant to opt-in to receive a lay summary of results after the study conclusion
5. The Committee requested the inclusion of a cultural tissue statement to the PIS. 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/ whānau 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 before participating in research where this occurs. However, it is acknowledged that individuals have the right to choose.”

1. The Committee requested the schedule of procedures in the protocol be copied over to the PIS.
2. The Committee suggested the inclusion of a flow diagram as a helpful visual aid.

Decision

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

* Please update the participant information sheet and consent form, taking into account feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17).*

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| 3 | **Ethics ref:** | **20/CEN/31** |  |
|  | Title: | EASY-AS |  |
|  | Principal Investigator: | Professor Ralph A H Stewart |  |
|  | Sponsor: | Auckland District Health Board |  |
|  | Clock Start Date: | 13 February 2020 |  |

Prof Ralph Stewart and Dr Jocelyne Benatar 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. Aortic stenosis (AS) is a common life-threatening condition in which one of the four heart valves becomes narrowed over many years. People with severe AS take years to develop symptoms, which include shortness of breath, chest pain, or even sudden death. Some patients may never develop symptoms at all. Heart surgery is a very good treatment for patients with symptoms but can cause complications and may be associated with prolonged recovery. The dilemma is therefore: should we operate in everyone when the AS is severe to avoid the risk of heart failure and death or wait until symptoms develop so that patients are spared unnecessary surgery? We will randomize 2844 patients with severe AS but no symptoms to either immediate aortic valve surgery or to careful monitoring with replacement of the narrowed valve when symptoms develop. This study will tell us whether patients with severe AS but no symptoms are better managed by early valve replacement rather than waiting for symptoms to develop and which strategy is more cost effective.

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 the response to question P.4.1 in the application form. The Committee queried whether any statistics on the prevalence or incidence of aortic stenosis in Māori were available. The Researchers stated this was currently unknown. The Committee recommended including any statistics (or an explanation if unknown) when answering P.4.1. for any future applications.
2. The Committee noted the response to P.4.2. in the application form and stated there were potentially serious cultural issues relevant to the research. The Committee advised that information is a taonga and there are cultural factors to consider with blood and tissue samples. The Committee also recommended the Researchers become familiar with the concept of whakamā as this may also be present and will need to be managed.
3. The Committee noted reimbursement was offered for travel and parking expenses for “specific visits”. The Committee queried which visits would be covered and which would not. The Researchers stated any appointments for regular clinical care would not be covered but visits for the study would be. The Committee requested the PIS be revised to make this explicitly clear.
4. The Committee queried whether the acronym was appropriate and whether a lay title should be used. The Researchers stated it was the Sponsor’s decision and out of their control but they could use the full title rather than the acronym.
5. The Committee noted the quality of life surveys and queried the process for if someone expressed extreme depression or suicidal ideation. The Researchers stated if they had any concerns with a participant’s responses they could discuss it with their treating cardiologist or GP. The Committee stated this would need to be explained in the PIS beforehand. The Committee advised that if the Researchers were going to collect any information on participants’ mental health they had a responsibility to ensure they act if a participant is at risk. The Researcher agreed and stated they have made contact with GPs and the CAT team in the past. The Committee requested the Researchers add an explanation to the PIS that if any concerns are raised the study team will act on them.
6. The Committee noted that blood samples would be sent overseas and queried where. The Researcher stated the location has not been finalised but would likely be the United Kingdom. The Committee stated the finalised location would need to be stated and requested the inclusion of a cultural tissue statement. 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/ whānau 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 before participating in research where this occurs. However, it is acknowledged that individuals have the right to choose.”

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

1. The Committee requested an additional clause in the consent form for participants to consent to their sample being sent overseas.
2. The Committee noted the risks section in the PIS was light and requested more detail about all potential risks of participating in the study above the default risks present during standard care.
3. The Committee requested a correction to page 5 of the PIS discussing the right to ask for updated information. The Committee advised that participants in New Zealand have the right to access and correct their information.
4. The Committee noted an option on the consent form agreeing to the participants GP being informed. The Committee requested the Researcher add information explaining this to the PIS.
5. The Committee requested an addition to page 2 advising the number of participants in the study, both worldwide and in New Zealand.
6. The Committee requested an amendment to page 3 where the PIS discusses blood sample storage for future studies. The Committee requested this be amended to include “with your consent” and advised a separate Future Unspecified Research (FUR) PIS would be necessary. The Researcher clarified that the intention was not FUR but for additional currently undetermined testing limited to the research question and related to this study. The Researcher agreed to revise the section for clarity.
7. The Committee requested the insertion of a statement advising that the study is paid for in part by the New Zealand Heart Foundation under the ‘Who pays for this study?’ section.
8. The Committee requested the addition of a statement to the PIS explaining that the GP would have access to study information.
9. The Committee requested the addition of information explaining why an auditor would access data and who they would be to the PIS.

Decision

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

* Please update the participant information sheet and consent form, taking into account feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17).*

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

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| 4 | **Ethics ref:** | **20/CEN/34** |  |
|  | Title: | A study of trial drug BTX 1702 in patients with Papulopustular Rosacea |  |
|  | Principal Investigator: | Dr Dean Quinn |  |
|  | Sponsor: | Botanix Pharmaceuticals Limited |  |
|  | Clock Start Date: | 13 February 2020 |  |

Dr Dean Quinn and Ms Anna Montgomery were present in person for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. TBTX 1702 is being developed for the treatment of Papulopustular Rosacea.
2. This is a multi-centre (up to 12 sites), phase 1b study. Its primary objective is to determine the safety and tolerability of two dosage forms of BTX 1702 in patients with papulopustular rosacea.
3. Approximately 120 patients (≥ 18 years old) will be randomised 1:1:1:1 (30 patients to BTX 1702 5% (w/w) Solution, 30 patients to BTX 1702 5% (w/w) Gel, 30 patients to Vehicle Solution and 30 patients to Vehicle Gel) with papulopustular rosacea will be enrolled.
4. The study will last up to 64 days: screening period (up to 21 days), and 42 day treatment period. All subjects will apply study drug or vehicle (placebo) twice daily for 42 days.

Summary of outstanding ethical issues

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

1. The Committee requested the term ‘vehicle’ on page 2 of the PIS be replaced with ‘placebo’ to be more lay-friendly.
2. The Committee noted a typo in the bullet points on page 4 of the PIS. The second to last bullet point is missing the word ‘*OF’* after ‘severity’. The Researcher agreed to correct the error.
3. The Committee requested the statement cautioning participants to ‘avoid facial procedures’ be revised to explicitly instruct them not to do so.
4. The Committee queried whether there was evidence of scientific review. The Researcher confirmed a submission was going to SCOTT.
5. The Committee requested the addition of a ‘yes / no’ box on the consent form for participants to opt-in to if they wish to receive a lay summary of results. The Researcher agreed to add one.
6. The Committee noted the first half of the answer to P.4.1. in the application form was patronising and requested the Researcher be mindful of this for any future applications.
7. The Committee noted the pregnancy risks and a statement to remain in contact with the study until birth. The Committee queried whether the study intended to collect health information in the event of a pregnant participant/partner and subsequent birth of a baby. The Researcher stated it was not in the protocol. The Committee requested the Researcher either supply a pregnant participant/partner PIS or add an explanation in the PIS that health information will not be requested in the event of pregnancy.
8. The Committee requested the phrase ‘consent post the birth of my baby’ be amended to state ‘consent after the birth of my baby’ to be more lay-friendly.

Decision

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

* Please update the participant information sheet and consent form, taking into account feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17).*

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

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| 5 | **Ethics ref:** | **20/CEN/35** |  |
|  | Title: | Hamstring Avulsions and Measuring surgical Management against Early Rehabilitation: the HAMMER trial; a randomised controlled trial |  |
|  | Principal Investigator: | Dr Matthew D'Arcy |  |
|  | Sponsor: |  |  |
|  | Clock Start Date: | 13 February 2020 |  |

Dr Matthew D’Arcy 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. Proximal hamstring avulsions are a controversial injury with no agreed-upon best management protocol. This study will examine the outcomes for those operatively, against those non-operatively managed

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 the protocol was very brief, the study had not undergone Māori consultation, there was no independent peer review and an inadequate participant information sheet and consent form. The Committee stated it could not approve the application in its current form and recommended the Researcher consult their locality’s research office for assistance with resubmission.
2. The Committee offered the following feedback on the application form questions and requested the Researcher be mindful of this during resubmission.

* b.1.1. and b 1.3. If there is no difference between either type of management, please explain what this means for patients. Is surgery associated with a longer recovery, is it more expensive etc. Please explain what are the parameters that will decide whether surgery is better or worse.
* b.1.2 Please provide succinct answers to questions about the scientific basis of the study etc rather than referring to the protocol.
* b.3.1. Does the CI have any experience running RCTs? Please list any relevant experience.
* b.1.4.1. This is not of benefit to individual participants, they get either one or the other form of management. Please explain what benefit individuals would gain from their participation in the trial.
* r.1.1 The explanation reads like normal surgery not specific for the trial. What about the non-surgery patients, what does their management involve? A procedure does not have to be a surgical procedure.
* r.1.6. Is there a statistical plan for interim analysis? After how many patients will this be done? Please include relevant details.
* r.2.1. If potential participants health data will not be screened how will you know they fit the inclusion/exclusion criteria? Please revise.
* r.2.3 Please do not simply ‘refer to protocol’. Please take the time to succinctly explain this.
* r.2.4.1. Please explain where the will data be stored and who will have access to it.
* r.2.5 Health data must be stored for at least 10 years. Please revise.
* r.8.1. Please describe what the risks and benefits to the individual participants are.
* p.1.1. Please include much more detail here. Describe what the participants need to do or what is done to them for this trial. Presumably they need to meet with the study team to be told more about the trial, they are followed up at 3,6 and 12 months; they need be asked to fill in the questionnaires/evaluations; they will be examined etc. Please include all relevant details.
* p.2.1. the 1 page “patient questionnaire: is not as patient information sheet and consent form.
* p.2.3 Follow the [HDEC template for participant information sheets available on the website.](https://ethics.health.govt.nz/system/files/documents/pages/piscf-template-feb-2020-270220.doc)
* p.2.7 You need to advise participants of updates and anything that affects them and their participation in the trial. It is not up to the participants to do so. Please revise.
* p.2.9 You need to offer them a lay person summary of the outcome of the study.
* p.3.1. Who will approach the patients about the trial? The researcher or an independent person? If the former, how will the researcher ensure there is no coercion to participate? Please revise and describe the process.
* p.4.1. Are Maori more likely to get this type of injury? Please include any relevant statistics on the prevalence of the condition in Māori and whether the study may lead to more equitable outcomes.
* p.4.2. All health information is Taonga and needs to be treated as that.
* p.4.3 and p.4.3.1.ALL health research that does not specifically exclude Maori needs to undergo Maori consultation. Please contact your DHB’s Māori research office.
* f.2.1. Please do not simply ‘refer to protocol’. Please take the time to succinctly explain this.
* f.2.2 Please explain what risks may be present.
* f.3.2. Please do not simply ‘refer to protocol’. Please take the time to succinctly explain this.

1. A series of references is not evidence of independent scientific peer review. Please use the [HDEC peer review template](https://ethics.health.govt.nz/system/files/documents/pages/HDEC-Peer-Review-Template.docx) and have it filled in by someone who is familiar with the field but not part of the research team.
2. The Committee advised that as this is an RCT there needs to be a participant information sheet that gives enough information for people to give informed consent. The current “patient questionnaire” is inadequate. Please follow the [HDEC template](https://ethics.health.govt.nz/system/files/documents/pages/piscf-template-feb-2020-270220.doc) to provide a participant information sheet and consent form.

Decision

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

* Please update the participant information sheet and consent form, taking into account feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17).*
* Please update the study protocol, taking into account the feedback provided by the Committee . *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.7).*
* Please supply an independent peer review for the updated version of the study protocol. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.26).*

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| 6 | **Ethics ref:** | **20/CEN/36** |  |
|  | Title: | Evaluating a model of care for patients with COPD in their last year of life |  |
|  | Principal Investigator: | Dr Amanda Landers |  |
|  | Sponsor: | University of Otago |  |
|  | Clock Start Date: | 13 February 2020 |  |

Dr Amanda Landers 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. Only 2 – 9% of patients with chronic obstructive pulmonary disease (COPD) ever receive the benefit of specialist palliative care. In our previous research, people with severe COPD identified six milestones that occur in a cumulative way as they get closer to death. These are loss of recreation, changes to the home environment, episodic acute care, long-term oxygen treatment, panic attacks, and difficulties with self-care. These milestones may represent opportunities to change the focus of care and plan future management. This research will evaluate the perspectives and preferences of patients, carers and members of the healthcare team involved in the care of people with advanced COPD using the six milestones. Our aim is to develop a detailed, integrated and resource-efficient model of care which enables positive experiences for all people with COPD in their last year 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 queried how the study would involve health professionals. The Researcher stated a separate ethics application involving health professionals as participants was submitted to the University of Auckland. The Committee stated it was unusual to split the project into smaller parts and submit to different ethics committees and it made it more difficult to assess the project as a whole. The Committee requested the Researcher re-submit the entire project to allow a proper assessment.
2. The Committee noted the response to P.4.2. on cultural issues did not include whakamā. The Committee recommended the Researchers consult a cultural advisor as whakamā is very likely to be present in a study of this nature. The Committee advised that information is also a taonga and requested the Researcher be mindful of this.
3. The Committee queried whether access to a psychologist or counsellor would be available to participants after visits if needed. The Researcher confirmed it would. The Committee requested the Researcher add a statement explaining this to the PIS.
4. The Committee queried who the external stakeholders with involvement in the study are. The Researcher stated there was a broad focus including community groups and organisations, emergency services, private ambulance services and district nursing services. The Researcher stated a diverse group are involved with care for COPD. The Committee noted the PIS does not explain this. The Committee requested additional information about the study, why it is being done, and how it will be managed. The Committee recommended an explanation in the PIS that the study wants to give patients a voice and is being done to ensure what is important to patients is addressed by health professionals.
5. The Committee queried whether participants would be able to receive and correct transcripts of the focus group discussions. The Researcher stated as it is a focus group and not individual data it would be more difficult. The Committee advised that if the focus group discussion will be transcribed but participants could not make corrections this would need to be stated in the PIS.
6. The Committee advised the resubmission would need a separate participant information sheet (PIS) for patients, carers and health professionals.

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

1. The Committee recommended the Researcher adapt the [PIS template available on the HDEC website.](https://ethics.health.govt.nz/system/files/documents/pages/piscf-template-feb-2020-270220.doc)
2. The Committee requested the inclusion of a statement advising participants of the types of questions that will be asked and the subject matter may be upsetting or cause distress and if that occurs support is available.
3. The Committee requested the addition of information explaining why an auditor would access data and who they would be to the PIS.
4. The Committee requested the addition of a ‘yes / no’ box on the consent form for participants to opt-in to if they wish to receive a lay summary of results. The Researcher agreed to add one.
5. The Committee queried a reference thanking participants for answering a survey. The Researcher stated this was likely an error and would remove it.
6. The Committee requested a statement in the PIS advising participants of their right to access and correct their study information.
7. The Committee requested a statement in the PIS advising participants that if they withdraw from the study a transcript of their group discussion will still be used.
8. The Committee suggested the inclusion of a flow diagram into the PIS outlining the study processes would be helpful.

Decision

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

* Please update the participant information sheet and consent form, taking into account feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17).*

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| 7 | **Ethics ref:** | **20/CEN/37** |  |
|  | Title: | IM011075: Long-Term Safety and Efficacy of BMS-986165 in Subjects with Psoriasis |  |
|  | Principal Investigator: | Dr Dean Quinn |  |
|  | Sponsor: | Bristol-Myers Squibb (NZ) Limited |  |
|  | Clock Start Date: | 13 February 2020 |  |

Dr Dean Quinn and Ms Anna Montgomery were present in person for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. This is a phase 3b study to characterise the safety and tolerability of long-term use of the study drug (BMS-986165) in participants with moderate-to-severe plaque psoriasis who have successfully completed the protocol-required treatment period in an applicable prior Phase 3 psoriasis study of BMS-986165 (ie, parent study). Applicable parent studies include, but are not limited to, IM011046, IM011047, IM011065 and IM011066.
2. For New Zealand the applicable parent study is IM011047 which has received both HDEC and SCOTT approval and is currently ongoing. HDEC reference 18/STH/241 and SCOTT reference TT50-10482 (2301) 18/SCOTT/107.
3. The intention is that the last study visit of IM011047 is also the first study visit of IMO11075.
4. Participants will receive open-label BMS986165 at a dose of 6mg once a day (QD). Participants will attend the clinic for assessments and routine safety follow-up on weeks 4, 8,16 and 24 then every 12 weeks for the remainder of the study.
5. The duration of the study is expected to be 96 weeks, with an additional 30 days for safety follow-up. The duration may be extended to a maximum of 240 weeks with continued assessments every 12 weeks to obtain further long-term evaluation of BMS-986165.

Summary of outstanding ethical issues

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

1. The Committee noted the pregnancy PIS does not contain the cultural statement present in the main PIS. The Committee requested this be copied over.
2. The Committee requested the phrase ‘consent post the birth of my baby’ be amended to state ‘consent after the birth of my baby’ to be more lay-friendly.
3. The Committee noted ambiguity under the section ‘Who pays for this study?’. The Committee requested the Researcher amend the section to state whether or not participants will receive reimbursement.
4. The Committee requested a revision to page 12 of the PIS when discussing withdrawal and the current statement that if the participant stops treatment the doctor will not presume withdrawal. The Committee requested this be revised for clarity and to comply with New Zealand law so that if a participant indicates they wish to withdraw they are removed from the study.
5. The Committee noted the information on page 2/15 of the FUR PIS was vague when discussing ‘causes of certain conditions’ and ‘treating certain conditions’. The Committee requested removal of the word ‘certain’. The Committee requested insertion of a statement advising that while it is FUR it will only be tested for things related to the original treatment etc.
6. The Committee advised that if tissue is sent overseas for future unspecified research then additional tests will not be reviewed or approved by HDECs. The Committee requested the statement implying this be removed.

Decision

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

* Please update the participant information sheet and consent form, taking into account feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17).*

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

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| 8 | **Ethics ref:** | **20/CEN/38** |  |
|  | Title: | OLIE Study |  |
|  | Principal Investigator: | Dr Mark Winstanley |  |
|  | Sponsor: | Eisai Limited |  |
|  | Clock Start Date: | 13 February 2020 |  |

Dr Mark Winstanley was not present for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. The study is a multicentre, randomised, open-label Phase 2 study to evaluate whether the study medication lenvatinib given in combination with chemotherapy agents ifosfamide and etoposide is superior to ifosfamide and etoposide alone in improving progression-free survival (PFS) in children, adolescents, and young adults with relapsed or refractory osteosarcoma. Outcomes will be evaluated by tumour response as measured by CT scan (or MRI if clinical indicated)) at intervals during the study using Response Evaluation Criteria In Solid Tumors [RECIST 1.1]. The primary outcome is the PFS rate at 4 months.
2. Approximately 72 eligible participants will be randomised internationally to one of the two treatment arms in a 1:1 ratio. Arm A will receive lenvatinib orally, once daily plus ifosfamide and etoposide intravenously, Day 1-3 of each 21-day cycle for a total of up to 5 cycles. Arm B will receive the same regimen as Arm A without lenvatinib. Participants in Arm A can continue on lenvatininb after completion of the chemotherapy cycles until disease progression or intolerable toxicity, or other stated reasons. This is estimated to be approximately 12 months. Participants who complete an off-treatment visit will be followed up for survival and tumour assessments every 3 months for up to two years after their end of study.
3. Safety and toxicity evaluations will be undertaken at regular physical exams and laboratory analyses and procedures such as cardiac monitoring by echocardiogram (ECHO).
4. Quality of Life questionnaires will be completed to allow comparison between the two treatment arms.
5. Samples will be taken for Pharmacokinetic (PK), pharmacodynamic (PD) and biomarker research.

Summary of resolved ethical issues

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

1. The Committee did not identify or raise any ethical concerns with the proposed study.

Decision

This application was *approved* by consensus

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| 9 | **Ethics ref:** | **20/CEN/41** |  |
|  | Title: | CT19649 - A clinical research study that will look at whether SCO-792 is tolerated, how safe it is and whether it works for people with impaired kidney function due to type 2 diabetes. |  |
|  | Principal Investigator: | Prof Russell Scott |  |
|  | Sponsor: | SCOHIA PHARMA, Inc. |  |
|  | Clock Start Date: | 13 February 2020 |  |

Professor Russell Scott and Ms Virginia Grayling 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 study is being done to evaluate the safety, tolerability and efficacy of SCO-792 in paticipants with Type 2 diabetes and albuminuria. SCO-792, has been developed to block an enzyme, called enteropeptidase, which plays an important part in the digestion of proteins. It is hoped that blocking enteropeptidase will lead to better blood sugar control in type 2 diabetes and reduce the protein in urine.
2. The purpose of this study is to learn more about SCO-792, how it is tolerated, how safe it is and whether it works in people with impaired kidney function due to type 2 diabetes.
3. The total study duration is up to 17 weeks including: a screening period (Week -4 to Week 0), a treatment period (Day 1 to Week 12) and follow-up period (Week 12 to Week 13).Participants will be randomly assigned in a ratio of 2:2:1 to one of the following groups:
   * Group 1: SCO-792, 1500 milligrams (mg) per day
   * Group 2: SCO-792, 500 mg per day
   * Group 3: Placebo.
4. Participants will continue their stable does of RAS inhibitor throughout the study. They will be required to attend the study site for 7 visits for specific safety and efficacy assessments and will be required to fast for at least 8 hours prior to Visit 2, 4, 5 and 6.
5. Real time review of safety data will be performed by the investigator, and a Safety Monitoring Committee (SMC).

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 the answer to P.4.1. in the application form was patronising and requested the Researcher be mindful of this for any future applications. The Committee explained that the Treaty of Waitangi should not be cited as a health benefit and equal access to participate for Māori should not need to be stated as this is the default expectation. The Committee recommended including any statistics (or an explanation if unknown) when answering P.4.1. for any future applications.
2. The Committee requested the inclusion of a cultural tissue statement to the PIS. 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/ whānau 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 before participating in research where this occurs. However, it is acknowledged that individuals have the right to choose.”

1. The Committee queried whether the Researchers would be interested in health information of the baby in the event of a participant or their partner becoming pregnant. The Researchers stated they would if it did occur. The Committee advised that there would need to be an additional consent after the birth by a parent/guardian to accessing and using the baby’s health information. The Committee advised that a baby is not a legal person with human rights until after birth. The Committee recommended the addition of another signature box on the pregnancy PIS.
2. The Committee requested the pronouns in the pregnancy PIS be referred to also include ‘you’ for the event a participant herself becomes pregnant. The Committee requested a thorough revision of the pregnancy PIS to reflect this.
3. The Committee requested the references to an unborn baby’s personal data on page 2 of the pregnancy PIS be changed to state it is the mother’s health information and privacy.
4. The Committee requested a clause in the pregnancy consent form agreeing to information being sent overseas, as well as an appropriate explanation in the information sheet.
5. The Committee stated the information sheet’s explanation of the randomisation and placebo was confusing. The Committee requested a revision to clearly state that participants have a 4/5 chance of receiving the intervention drug and a 1/5 chance of receiving placebo. The Researcher agreed to rewrite the paragraph for clarity.
6. The Committee noted page 11 of the PIS states all research involving humans is reviewed an HDEC. The Committee noted this was not true as there are other institutional ethics committees and HDECs only review health and disability research of sufficiently high risk. The Committee requested an amendment to the sheet to simply state that ‘this study’ has received approval from the central HDEC.
7. The Committee requested the mention of ‘secret code’ on the optional urine sample FUR PIS be replaced with ‘trial specific code’.
8. The Committee noted a discrepancy in the ‘What are my rights?’ section. The sheet states that information from sample analysis will not be made available to participants and their doctor and then two paragraphs later it states participants have a right to access information. The Researcher stated it was unlikely for results to be returned as the data is normally analysed in aggregate in the future for pharmacogenetic reasons and not for individual participants. The Committee requested this be explained.
9. The Committee noted the information on page 6 of the main PIS that states if participants do not agree to the banking of their samples they can still participate in the main study. The Committee requested this be removed as there is a separate FUR information sheet for participants interested in participating in future research

**Provisional**

Decision

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

* Please update the participant information sheet and consent form, taking into account feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17).*

After receipt of the information requested by the Committee, a final decision on the application will be made by Ms Sandy Gill and Dr Peter Gallagher.

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| 10 | **Ethics ref:** | **20/CEN/42** |  |
|  | Title: | Hypertriglyceridaemia |  |
|  | Principal Investigator: | Dr Minesh Prakash |  |
|  | Sponsor: |  |  |
|  | Clock Start Date: | 13 February 2020 |  |

Dr Minesh Prakash 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. Medical and Surgical patients get admitted to ICU for intensive care and require mechanical ventilation. For mechanical ventilation, sedative agents are infused continuously for endotracheal tube tolerance. Propofol is the most common sedation used as it has early onset and off-set with minimal side-effects. The most common side-effect is hypertriglyceridaemia from the high lipid load of the drug which has been shown to cause hypertriglyceridaemia and also pancreatitis if used more than 48 hours. The aim of the study is to identify the incidence of hypertriglyceridaemia and pancreatitis from a small sample of patients (15 patients) admitted to Waikato ICU.
2. Inclusion criteria: Participants above the age of 16 years who have propofol infusion for more than 48 hours. Patients known to be on medications for hypercholesterolaemia and known to be hypothyroid would not be excluded.
3. Exclusion criteria: Patients less than 16 years of age.

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 queried why the Researcher would not be able to obtain consent before the intervention. The Researcher explained because potential participants would be trauma patients or transferred from the operating theatre and they would be sedated on arrival. The Committee queried whether the Researcher could obtain consent before the surgery. The Researcher explained elective patients are transferred to a different unit and they only receive unexpected arrivals in the ICU.
2. The Committee stated it was unlikely the research would comply with the [Code of Health and Disability Services Consumers' Rights](https://www.hdc.org.nz/your-rights/about-the-code/code-of-health-and-disability-services-consumers-rights/), specifically right 7(4). The Committee explained the Code requires that if a person is not competent the provider may provide services (including participation in research) if to do so is in their best interests. The Committee queried whether the Researcher had obtained a legal opinion. The Researcher stated they had not. The Committee recommended the Researcher consult their DHB and obtain a legal opinion.
3. The Committee explained that New Zealand law does not generally allow proxy consent for people over 18 years. Right 7(4) provides the provider must consult with suitable persons who are available to advise the provider but the person consulted does not give consent..
4. The Committee noted the protocol was unclear about how many blood samples would be taken, what tests would be performed and what the safety monitoring would be. The Committee requested the Researcher revise this for resubmission.
5. The Committee noted the paper supplied for scientific review was a comparison of Māori versus non-Māori visits to the doctor. The Committee queried how this was relevant to the research. The Committee requested the Researchers get an independent expert to fill out the [HDEC peer review template](https://ethics.health.govt.nz/system/files/documents/pages/HDEC-Peer-Review-Template.docx) for the re-submission. The Committee advised the purpose of independent peer review is to evaluate the methodology of the study and whether it is feasible, along with if it is appropriate for a New Zealand context.
6. The Committee advised that health information is required to be kept for a minimum of ten years and not five.
7. The Committee advised that participants’ blood test results cannot be given to their family without the participant’s consent.
8. The Committee noted the application form indicated identifiable information may be made available to other researchers. The Researchers stated it would be for other ICU doctors as they would need to know the patient they were treating was a trial participant. The Committee stated it was acceptable for their treatment team to know but making identified data available for the purposes of research would require consent.

Decision

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

* Please update the participant information sheet and consent form, taking into account feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17).*
* Please supply an independent peer review for the current version of the study protocol. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.26).*
* Please seek and supply a legal opinion on whether the proposed research complies with New Zealand law governing research on adults who cannot provide consent*(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.75).*

## Review of approved studies

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| **1** | **Ethics ref:** | **19/CEN/68** |
|  | Title: | whataboutme? |
|  | Principal Investigator: | Dr Deborah McLeod – Malatest International |
|  | Sponsor: | Ministry of Social Development |

Summary

1. Malatest International and TOMM have been commissioned by the New Zealand Government to design and deliver a national survey of youth health and wellbeing (whataboutme?) The study is funded by the Ministry of Social Development.
2. The Committee approved the application on 10 December 2019.
3. A condition of the approval was that participation was restricted to students aged 14 and above.
4. The Committee received a request from the Researchers to review the approval and include 13-year-old students who are part of a year 10 class with students aged 14.
5. The Committee noted point 8 in the HDEC approval letter for the study stated that 13 year old participants could be considered for inclusion upon submission of an amendment once safety data is available:

“8. 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.”

1. The Committee noted the Researcher’s request to clarify how evidence of the Board of Trustees approval can be provided. The Committee recommended the Researchers upload these as ‘supporting documents’ with annual progress reports. These can also be uploaded via the amendment-pathway. The Committee confirmed that minuted discussions with the Board are appropriate evidence, as well as any written documentation confirming the Board’s approval.

Decision

This request was *declined* by consensus. The Committee recommended the Researchers submit an amendment to include younger participants once preliminary safety data is available.

## 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:** | 24 March 2020, 12:00 PM |
| **Meeting venue:** | Room 1S.5, Level 1, Ministry of Health, 133 Molesworth Street, Wellington, 6011 |

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.

1. **Matters Arising**
2. **Other business**
3. **Other business for information**
4. **Any other business**

The meeting closed at 5:00 pm.