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| **Committee:** | Central Health and Disability Ethics Committee |
| **Meeting date:** | 26 May 2020 |
| **Meeting venue:** | Room GN.7, Ground Floor, Ministry of Health, 133 Molesworth Street, Wellington |

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| **Time** | **Item of business** |
| 12:00pm | Welcome |
| 12:15pm | Confirmation of minutes of meeting of 28 April 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 | 1. 20/CEN/113 (Helen W / Peter) 2. 20/CEN/108 (Sandy / Patries) 3. 20/CEN/106 (Helen D / Peter) 4. 20/CEN/109 (Cordelia / Patries) 5. 20/CEN/114 (Sandy / Peter) 6. 20/CEN/115 (Helen D / Patries) 7. 20/CEN/116 (Helen W / Peter) 8. 20/CEN/117 (Cordelia / Patries) 9. 20/CEN/118 (Helen W / Peter) 10. 20/CEN/119 (Helen D / Patries) |
| 4:40pm | General business:  Noting section |
| 4:45pm | 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 entire meeting was conducted via zoom and applicants also attended via zoom

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 28 April 2020 were confirmed.

## New applications

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| **1** | **Ethics ref:** | **20/CEN/113** |  |
|  | Title: | CA209-76U |  |
|  | Principal Investigator: | Dr Peter Fong |  |
|  | Sponsor: | Bristol-Myers Squibb |  |
|  | Clock Start Date: | 14 May 2020 |  |

Dr Peter Fong was 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 ethical issues

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

1. The Committee noted the PIS was very long but this would be mitigated by there only being a low number of participants and they will be well known to the Researcher. The Committee stated the grid was helpful and suggested the inclusion of a short title to the project.
2. The Committee requested the removal of the discussion of ‘survival follow-up’ on page 11 of the PIS as it infers the participant may not survive. The Researcher agreed to consult the Sponsor.
3. The Committee stated if a participant withdraws from the study it should not be assumed that they wish to remain in follow-up as page 29 implies. The Researcher stated if a participant withdraws, they would be asked if they wish to remain in follow-up or not and agreed to clarify the PIS.
4. The Committee requested the inclusion of information that samples will be sent overseas on the optional biopsy consent form and pregnant partner PISCF.
5. The Committee requested removal of the sentence on page 3 regarding study doctors jumping to conclusions.
6. The Committee requested a revision to check for typos e.g. ‘not’ instead of ‘note’ in the first paragraph of the PIS and two full stops on the final paragraph of page 27.
7. The Committee requested the inclusion of information on page 26 that participants have the right to access their information and correct it if necessary.
8. The Committee requested a cultural tissue statement be inserted into the optional genetic PIS acknowledging that whānau share DNA and this may have implications for genetic research.

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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| 2 | **Ethics ref:** | **20/CEN/108** |  |
|  | Title: | Signal study of lopinavir/ritonavir tablets vaginally in women with CIN 2/3 |  |
|  | Principal Investigator: | Dr Amanda Tristram |  |
|  | Sponsor: | Douglas Pharmaceuticals |  |
|  | Clock Start Date: | 07 May 2020 |  |

Ms Marina Dzhelali was 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 ethical issues

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

1. The Committee noted the response to question P.4.1. in the application and queried whether statistics on Māori with CIN2/3 compared to non-Maori were available. The Researcher stated the local data showed no higher incidence in the Wellington region. The Committee stated this sort of information is helpful and requested the Researcher be mindful of this for any future applications.
2. The Committee queried whether the Sponsor’s database would be located in New Zealand or overseas. The Researcher stated it was a cloud-based system operated by an overseas company. The Committee stated if there is any possibility of a participant’s data leaving New Zealand this must be adequately explained in the PIS along with the destination country (if known). The Researcher agreed to amend the PIS and clarified that only deidentified data would be added to the cloud system and all identified data would be kept on-site only.
3. The Committee noted the supplied insurance certificate was not study protocol specific. The Researcher stated they were in the process of acquiring this and would supply it when ready.
4. The Committee requested the term ‘dummy’ for placebo on page 10 be replaced with ‘inactive’ instead.

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 supply evidence of ACC-equivalent compensation available to all participants in the event of injury during the study. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 17.1).*

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

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| 3 | **Ethics ref:** | **20/CEN/106** |  |
|  | Title: | Glomuvenous malformation in the New Zealand population |  |
|  | Principal Investigator: | Dr Swee Tan |  |
|  | Sponsor: |  |  |
|  | Clock Start Date: | 14 May 2020 |  |

Dr Annelise Neal was 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 ethical issues

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

1. The Committee queried how the Researcher would identify and recruit participants. The Researcher stated the hospital has a database of plastic surgery patients who have previously consented to be contacted about research opportunities and they would telephone them to introduce the study.
2. The Committee noted the Researcher intended to recruit family members and queried this process. The Researcher stated the condition can run in families and participants in the study have the opportunity to invite family members to participate. The Committee expressed concern about participants being asked to identify family members who may have a condition as this would have privacy implications. The Committee suggested it would be more appropriate to supply participants with a ‘family flyer’ for a participant to give to a family member who may then contact the study team if they are interested.
3. The Committee advised that competency assessments would be required to consent participants under 16 and it would be simpler to revise to obtain their assent and parental consent. The Committee recommended splitting the assent forms into groups of 6 – 10 and 11 – 15 and to keep them simple.
4. The Committee noted some of the quality of life questions may produce distress in participants. The Researcher stated if this occurred, they would ask participants if they wish to discuss it and look at avenues to refer to an appropriate service. The Researcher stated support for this could not come through the plastic surgery department but participants could be referred to community mental health or to their GP.
5. The Committee advised a new form to reconsent participants when they reach 16 years of age will be necessary to continue to use their data.
6. The Committee requested the insertion of a statement advising that participants have the right to access and correct information held about them.
7. The Committee noted the consent forms mention auditor access but this is not explained in the PIS. The Committee advised the consent form cannot introduce new information and requested the Researcher ensure all clauses in the consent form have been explained in the PIS.
8. The Committee queried why the Researcher would request photos. The Researcher explained that any new family members would be asked to provide a photo to ensure the correct diagnosis but existing patients will already have photos on the system. The Committee requested information explaining this be added to the PIS.
9. The Committee recommended the if Researcher intends to publish any photos to send a copy of the image as it is intended to be published along with the consent form to double check a participant is still comfortable with it being used in this way.
10. The Committee noted if an NHI is stored on a database this is identifiable information and cannot be passed onto other Researchers without consent. The Committee explained that identified data cannot be disclosed to Researchers and requested a statement in the PIS advising that ‘data from this study may be made available to other researchers in a DEIDENTIFIED FORM’.
11. The Committee requested the Researcher devise a formal safety plan in the protocol to manage any participant experiencing distress or indicating suicidal ideation and add details of it to the PIS.
12. The Committee requested the consent clause about notifying the GP be amended to state participants would be happy for their ‘GP to be informed about any concerning responses or issues that may arise during the study”.

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).*

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/109** |  |
|  | Title: | BCT 1902 Neo-N |  |
|  | Principal Investigator: | Dr Marion Kuper-Hommel |  |
|  | Sponsor: | BCT |  |
|  | Clock Start Date: | 07 May 2020 |  |

Dr Marion Kuper-Hommel and Ms Wendy Thomas 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 potential conflicts of interest related to this application were declared by any member.

Summary of ethical issues

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

1. The Committee noted page 7 on the PIS was ambiguous on what biomarker and genetic research was related to the current study only and what was intended for future unspecified research.

1. The Committee requested the Researcher revise the section to clearly state “For this research study we will ask for ‘X’ to test ‘Y’” and under a separate heading to state ‘For future unspecified research we will ask ‘X.
2. The Committee requested the inclusion of a cultural tissue statement into the information on future unspecified research as well as the main 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 advised that in New Zealand verbal withdrawal is permitted and participants are not required to sign a form.
2. The Committee noted the written information in the PIS was repetitive and requested a revision to simplify it. The Committee complimented the Researcher on the flow chart and diagrams.
3. The Committee requested as part of the revision the Researcher ensure it is clear what is part of the main study and what is optional.
4. The Committee noted the consent form includes a clause to inform the participant’s GP but this is not explained in the PIS. The Committee requested information be added to the PIS.
5. The Committee requested the insertion of a statement advising that if participants do not agree to their tissue being used for future unspecified research it will be destroyed after the main study.
6. 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 of the prevalence of the disease in Māori (or an explanation if unknown) when answering P.4.1. for any future applications.
7. The Committee noted the response to P.4.2. in the application stated Māori participants would be encouraged to contact an advocacy service. The Committee queried what this was. The Researcher stated it was the local DHB’s Māori health service.
8. The Committee advised the Researcher that relevant Māori cultural issues for this research would include blood samples as tapu, information as a taonga and the potential for whakamā in participants. The Committee requested the Researcher become familiar with these concepts and be mindful of this for future applications.

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 Patries Herst.

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| **5** | **Ethics ref:** | **20/CEN/114** |  |
|  | Title: | (duplicate) Evaluating a model of care for patients with severe COPD |  |
|  | Principal Investigator: | Dr Amanda Landers |  |
|  | Sponsor: | University of Otago |  |
|  | Clock Start Date: | 14 May 2020 |  |

Dr Amanda Landers and Lutz Beckert 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 potential conflicts of interest related to this application were declared by any member.

Summary of ethical issues

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

1. The Committee requested a revision of the PIS to check for spelling errors and typos e.g. the section under the purpose of the study states ‘commission’ when it should read ‘committee’.
2. The Committee requested the removal of the ‘yes / no’ tick boxes from the consent form unless it is for a clause that is truly optional (i.e. the participant can answer ‘NO’ and still participate in the study).
3. The Committee requested a title on each PIS stating the group it is for.
4. The Committee queried whether Māori participants have a choice on whether they wish to participate in the Māori focus group or not. The Researcher confirmed it was their choice.
5. The Committee requested the removal of the statement implying participating would be of benefit to participants.
6. The Committee noted there was a specific Māori group and queried whether there could be a Pacific one if there are enough participants. The Researcher confirmed there would be and stated a Pasifika researcher on the team would lead that group.
7. The Committee queried whether the Researcher wished to talk to the participant’s family about the participant or what the experience for the family member was. The Researcher stated they were interested in the family member’s experience with the health sector caring for their relative. The Researcher agreed to amend the form for clarity.
8. The Committee requested the health professional PIS begin by stating ‘You have been chosen to participate because you take care of X’.
9. The Committee requested the insertion of a statement in the main participant information sheet advising that the study may invite their family member to report on their experiences as well and although it is not about the participant some information about them may be shared.
10. The Committee requested the insertion of a statement advising that participants have the right to access and correct information held about them.

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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| **6** | **Ethics ref:** | **20/CEN/115** |  |
|  | Title: | (duplicate) GastroIntestinal dysFunction in criTical illness(GIFT):Gut BiOmarker(BOx)study |  |
|  | Principal Investigator: | Ms Varsha Asrani |  |
|  | Sponsor: | University of Auckland |  |
|  | Clock Start Date: | 14 May 2020 |  |

Ms Varsha Asrani was 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 ethical issues

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

1. The Committee requested the Researcher supply a track-changes version of the protocol.
2. The Committee queried whether all participants would be unconscious or whether some could provide consent. The Researcher stated it would be a mixed group as the majority of critically ill unconscious patients would be captured, although some may be awake and alert.
3. The Committee stated there is not an issue with conscious participants who can provide consent for themselves but unconscious participants can only be enrolled into research if [Right 7(4) of 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/) is satisfied. The Committee advised that family members can give their opinion on whether they believe their relative would be ok with participation and a sample but they cannot provide proxy consent.
4. The Committee explained that under Right 7(4) of the Code a participant must be *better off* by participating in the research than if they did not. The Committee explained the Researcher cannot obtain retrospective consent but can obtain consent to use the sample and data going forward. The Committee advised that in the event of a participant’s death before they regain consciousness the Researcher may use the deceased participant’s data so long as it is deidentified.
5. The Committee queried whether the device placed on the abdomen was part of standard care or research. The Researcher stated it was part of the research and functions like an ECG of the abdomen. The Researcher explained the device can indicate a gut problem which would be referred to the participant’s doctor. Current scoring systems do not provide this type of information. The Committee noted if the device can communicate a gut problem which would otherwise be unknown then it may be in an individual’s best interest to be in the study and so enrolment under Right 7(4) may be possible.
6. The Committee recommended the Researcher consult with the DHB’s research office on Right 7(4) of the Code and enrolling unconscious participants into research.
7. The Committee requested a revision of the PIS to check for spelling and grammar consistency.
8. The Committee requested the Researcher insert the ACC statement from the [PIS template available on the HDEC website.](https://ethics.health.govt.nz/system/files/documents/pages/piscf-template-feb-2020-270220.doc)
9. The Committee noted a statement asking a family member about a blood sample and queried the purpose. The Researcher stated it was intended to ask the family member their viewpoint on obtaining a blood sample from the existing arterial line which would be collected but not analysed until consent is obtained.
10. The committee requests 3 different PISs each of these should be specific for the group they cover:

* For conscious patients
* For unconscious patients once they become conscious again (retrospective consent for use of samples already collected)
* For whānau with the intent to ask for their view on whether they think the participant would have participated if they had been conscious. Not to ask for their consent.

1. If a patient were to die before regaining consciousness, the blood sample could be analysed but if they do not regain consciousness before analysis takes place then their blood sample could not be analysed.
2. The Committee requested the Researcher ensure the language in all PISs is consistent with the Code.
3. The Committee requested the inclusion of a cultural tissue statement to the PISs. 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 removal of colourful language (e.g. ‘righteous’) and requested the use of plain English in the PISs.
2. The Committee requested consistency with font throughout the PISs.
3. 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 of the prevalence of the disease in Māori (or an explanation if unknown) when answering P.4.1. for any future applications.
4. The Committee explained that tikanga Māori is the Māori way of doing things and recommended the Researcher consult with a cultural advisor at the DHB. The Committee advised the Researcher that relevant Māori cultural issues for this research would include blood samples as tapu, information as a taonga and the potential for whakamā in participants. The Committee requested the Researcher become familiar with these concepts and be mindful of this for future applications.

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 revise the study protocol to ensure the process of obtaining consent from unconscious participants complies with all relevant legislation. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.70).*
* Please revise 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).*

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| **7** | **Ethics ref:** | **20/CEN/116** |  |
|  | Title: | Effects of Paravertebral blocks vs. Erector Spinae blocks on patients with rib fractures |  |
|  | Principal Investigator: | Dr Michael Hugh Ng |  |
|  | Sponsor: |  |  |
|  | Clock Start Date: | 11 May 2020 |  |

Dr Michael Ng was 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 ethical issues

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

1. The Committee queried how the recruitment would work. The Researcher explained when a patient is admitted to hospital and a rib fracture is identified (through CT scan or X-ray) the team will be referred to the pain service or discuss with the anaesthetist on call about appropriate analgesic. The Researcher stated in this study research nurses would also be alerted.
2. The Committee queried whether potential participants with a rib fracture would be in discomfort and whether they could provide consent. The Researcher stated they would be in discomfort and the aim is to identify the fracture early to give appropriate analgesia. The Researcher stated their experience over the past few years is the majority of patients are capable of consenting during this time. The Committee queried the time frame. The Researcher stated current data showed the median time between admission and the offer of intervention is 21 hours.
3. The Committee noted the application had answered that Māori consultation was not required. The Researcher stated Māori input has been sought through a Māori doctor colleague who has offered feedback. The Committee stated if research will potentially involve Māori participants then Māori consultation is required but as this has already been undertaken it is acceptable. The Committee requested the Researcher be mindful of this for future applications.
4. The Committee noted the peer reviewer had the same name as the CI and queried whether this was coincidental. The Researcher stated they were related so could get another colleague to review. The Committee advised that it should not be a colleague but an independent expert to provide in depth review of the scientific and statistical validity of the protocol as well as whether it is culturally appropriate for a New Zealand context. The Committee requested the Researcher undertake independent peer review and supply it.
5. The Committee requested the inclusion of more information under the ‘What does my participation involve?’ section. The Committee advised it should explain all measurements to be undertaken (e.g. pulmonary function) so participants are aware of everything that will happen in the study.
6. The Committee requested a general revision to check for spelling errors and typos.

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 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).*

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

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| **8** | **Ethics ref:** | **20/CEN/117** |  |
|  | Title: | Relevance of metabolic profiles in children with cardiac disease |  |
|  | Principal Investigator: | Mrs Sandra Divanisova |  |
|  | Sponsor: |  |  |
|  | Clock Start Date: | 11 May 2020 |  |

Mrs Sandra Divanisova was 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 ethical issues

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

1. The Committee queried what sort of data the Researcher wished to collect. The Researcher stated it has already been collected and is stored on two databases (the Auckland cardiology group at Starship Hospital database and the new-born screening database) and they are seeking to combine the datasets.
2. The Committee requested the protocol be amended to specify that only new-borns from 2011-2019 will be included. The Researcher confirmed they were in the process of submitting an application to the new-born screening unit to use the data.
3. The Committee queried whether this was a retrospective study looking for correlations. The Researcher confirmed it was. The Committee queried whether patient medical records would need to be accessed without consent. The Researcher stated their records would not be needed only the diagnosis which is already in the database. The Researcher stated NHIs are used in the database but this would be replaced with a study-code.
4. The Committee noted the protocol did not include this information and requested the Researcher undertake a revision to describe exactly what sort of information is taken from where, what will be done with it, and its identifiability at all stages.
5. The Committee queried the process of clinically relevant findings. The Researcher stated the study-code could be relinked to NHI and the participant could be informed. The Committee noted study information would be deidentified and consent would not be sought and queried the legal basis for this. The Researcher noted all people on the new-born registry from 2011 onwards had consented to the data being used for research.
6. The Committee noted the application had answered that Māori consultation was not required. The Committee advised if research will potentially involve Māori participants then Māori consultation is required. The Committee requested the Researcher be mindful of this for future applications.
7. The Committee requested an update to the protocol to collect participant ethnicity as the research could potentially find a correlation between different ethnic groups.
8. The Committee requested the protocol be revised to include more detail about each stage of the project. A study protocol should be sufficiently detailed to allow another team of researchers unfamiliar with the project to replicate it.

Decision

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

* Please revise 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 of the revised study protocol. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.26).*
* Please supply evidence of Māori consultation to ensure the study is appropriate for a New Zealand context *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 3.7).*

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| **9** | **Ethics ref:** | **20/CEN/118** |  |
|  | Title: | ACcomplisH |  |
|  | Principal Investigator: | Prof Paul Hofman |  |
|  | Sponsor: | Pharmaceutical Solutions Limited |  |
|  | Clock Start Date: | 11 May 2020 |  |

Professor Paul Hofman was 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 ethical issues

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

1. The Committee noted the PIS very lengthy and potentially daunting and queried whether there would be a personalised consenting process as the study would only recruit three participants. The Researcher confirmed this would be the case. The Committee queried the potential participant pool in New Zealand. The Researcher stated approximately 15 – 20 people.
2. The Committee queried the involvement of participant’s families. The Researcher stated the participant reported outcomes would be done online and the Sponsor would provide participants’ families with a tablet for this purpose.
3. The Committee queried whether there was any intention for family members to be participants as the consent form implies they will be. The Researcher explained only as far as filling out the quality of life questionnaires. The Committee stated this was acceptable but would require the parents to consent for themselves and for their child separately.
4. The Committee noted the application stated ethnicity data would not be collected and queried why. The Researcher stated this was an error and ethnicity data would be collected.
5. The Committee requested the Researcher insert a statement advising that participants have a right to withdraw at any time although it is recommended to attend the visits.
6. The Committee requested a revision of the PIS to specify whether it is the parent or the child when the ‘you’ pronoun is used as currently it reads ambiguously.

Decision

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

* Please revise the participant information sheet and consent form, incorporating the feedback from the Committee.

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| **10** | **Ethics ref:** | **20/CEN/119** |  |
|  | Title: | Hookworm therapy for maintenance in ulcerative colitis |  |
|  | Principal Investigator: | Dr Stephen Inns |  |
|  | Sponsor: |  |  |
|  | Clock Start Date: | 19 May 2020 |  |

Dr Stephen Inns and Dr Tom Mules 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 potential conflicts of interest related to this application were declared by any member.

Summary of ethical issues

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

1. The Committee noted that the potential flareup may result in 20% of patients having to be withdrawn from the study and queried whether this would affect the validity of the results. The Researcher stated it was a pilot study and would answer questions on the feasibility of patients taking hookworm therapy. The Researcher stated there was a healthy volunteer study at the Mallaghan Institute but it has not been properly tested in patients. The Researcher stated part of the study would examine whether participants would take it, what the drop out rate is and difficulty in recruitment. The Researcher stated a major endpoint is having a disease flare which would be an exit point for the study. The Researcher stated they did not believe a high dropout rate would be an issue because that is a primary outcome and the study would analyse the difference between patient flaring in each group. The Researcher stated the study’s hypothesis is that participants with the worms should not flare as much but all flare-ups would be included in the analysis.
2. The Committee queried the turnaround time on the questionnaires that ask participants about depression and anxiety and if there is a safety plan for the event of a participant indicating severe distress or suicidal ideation. The Researcher stated the department has an IBD nurse who is experienced with psychosocial distress and did not believe anything in the study could trigger a worsening of a participant’s mental state but the safety net would be the standard referral process (e.g. to the participant’s GP or community mental health). The Researcher stated as it is a small pilot study, they would have a good handle on data as it comes in so would be able to identify any deviations quickly. The Committee requested the protocol be amended to include a safety plan for managing any participants experiencing mental distress.
3. The Committee requested the removal of the word ‘exciting’ in the letter sent to participants and the PIS as this may over incentivise participation.
4. The Committee requested the removal of the statement that placebo is a ‘fake’ treatment and suggested simply stating its an application of gauze without the worms.
5. The Committee requested the statement in the PIS informing participants that the study has received HDEC approval be clarified to specify it has received ethical approval from the Central HDEC, as HDECs do not have the mandate to validate the scientific aspect.
6. The Committee requested a general proof-read of the PIS to check for spelling and grammatical errors.
7. The Committee requested the insertion of a statement on the questionnaire advising participants they do not have to answer any questions they do not wish to.
8. The Committee requested an additional statement to the potential benefits on page 7 advising that participants ‘may not receive any benefit’.
9. The Committee noted the ‘Who pays for this study?’ section does not disclose the funder. The Researcher stated they have applied for a grant from the HRC and if this is unsuccessful they may be able to secure funding from the Mallaghan Institute. The Committee requested the Researcher add this information when available.
10. The Committee requested the inclusion of a cultural tissue statement into the main PIS as well as the sheet for future unspecified research. 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 addition of a local Māori health contact to the PIS.
2. The Committee noted the consent form contained clauses that had not been explained in the information sheet (e.g. informing the GP). The Committee requested the Researcher ensure everything referred to in the consent form has been explained in the PIS.
3. The Committee noted the consent form referred to a pregnancy risk and queried if this was accurate. The Researcher stated pregnant participants would be excluded and did not believe the hoomworms would affect a developing foetus. The Researcher stated if a participant did become pregnant on the trial they would have a discussion with them on whether they wish to continue or receive deworming treatment. The Committee requested information explaining this be added to the PIS and a revision to the phrase in the consent form.
4. The Committee recommended the removal of the apostrophe from “Dr. Stephen Inn’s”.
5. The Committee noted page 7 mentioned the costs for treatment of mild or severe symptoms would be covered by the study team and queried if moderate symptoms would be covered. The Researcher stated this was an oversight and it should read ‘mild TO severe symptoms’.
6. The Committee noted if a participant decides to withdraw part way through the study the PIS does not explain whether deworming is available. The Researcher stated it was covered in the protocol and participants would be dewormed and / or have their previous treatment restarted. The Committee requested information explaining this be added to the PIS along with a statement advising participants that if they wish to withdraw they ought to get dewormed.
7. The Committee advised that ‘Lower Hutt Hospital’ should simply be called ‘Hutt Hospital’.

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 revise the GP letter to use neutral language when describing the study.

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

## 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:** | 28 July 2020, 12:00 PM |
| **Meeting venue:** | GC.3, 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 4:45pm.