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| **Committee:** | Southern Health and Disability Ethics Committee |
| **Meeting date:** | 09 February 2021 |
| **Meeting venue:** | ONLINE - Zoom Meeting |

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| **Time** | **Item of business** |
| 10:00am | Welcome | |
| 10:05am | Confirmation of minutes of meeting of 08 December 2020 | |
| 10:15am | New applications (see over for details) | |
| 10:15 – 10:40  10:40 – 11:05  11:05 – 11:30  11:30 – 11:55  11:55 – 12:20  12:20 – 12:50  12:50 – 1:15  1:15 – 1:40  1:40 – 2:05  2:05 – 2:15  2:15 – 2:40  2:40 – 3:05  3:05 – 3:30  3:30 – 3:55 | i 20/STH/167  ii 21/STH/16  iii 21/STH/9  iv 21/STH/12  v 20/STH/234  Lunch break  vi 21/STH/19  vii 21/STH/20  viii 21/STH/21  10-minute break  ix 21/STH/22  x 21/STH/23  xi 21/STH/24  xii 21/STH/25 | |
| 3:55pm | General business:   * Noting section | |

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| **Member Name** | **Member Category** | **Appointed** | **Term Expires** | **Apologies?** |
| Dr Sarah Gunningham | Lay (other) | 05/07/2016 | 05/07/2019 | Present |
| Dr Devonie Waaka | Non-lay (intervention studies) | 18/07/2016 | 18/07/2019 | Present |
| Assc Prof Mira Harrison-Woolrych | Non-lay (intervention studies) | 28/06/2019 | 28/06/2020 | Present |
| Dr Paul Chin | Non-lay (intervention studies) | 27/10/2018 | 27/10/2021 | Apologies |
| Professor Jean Hay-Smith | Non-lay (health/disability service provision) | 31/10/2018 | 31/10/2021 | Present |
| Mrs Helen Walker | Lay (consumer/community perspectives) | 19/08/2020 | 19/08/2021 | Present |
| Mr Dominic Fitchett | Lay (the law) | 05/07/2019 | 05/07/2022 | Present |
| Dr Pauline Boyles | Lay (consumer/community perspectives) | 05/07/2019 | 05/07/2022 | Present |

## Welcome

The Chair opened the meeting at 10:15am and welcomed Committee members, noting that apologies had been received from Dr Paul Chin.

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 10 December 2020 were confirmed.

## New applications

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| **1** | **Ethics ref:** | **20/STH/167** |
|  | Title: | Non-invasive lung imaging system |
|  | Principal Investigator: | Dr Kelly Burrowes |
|  | Sponsor: | University of Auckland |
|  | Clock Start Date: | 22 September 2020 |

Dr Kelly Burrowes was present via videoconference 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 an observational study testing a non-invasive lung imaging device in ventilated patients both in ICU and non-ICU. The hope is that it will to improve clinical care for people with COVID-19 and other patients.
2. The study seeks to evaluate a low-cost imaging system for continuous patient monitoring to improve clinical decision making. The device will use Electrical Impedance Tomography (EIT), a well-established technology that non-invasively measures changes in lung impedance as it fills with, and empties, of air. The new device aims to create more accurate images at lower cost.
3. The device will first be tested on ventilated non-ICU patients to evaluate the fit of the device within the clinical workflow, and in the final stage of testing ventilated patients within the ICU will be recruited (possibly with COVID-19).

Summary of resolved ethical issues

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

1. The Committee stated that most of the issues raised in the previous review of the application had been addressed.
2. The Committee asked if Māori consultation was underway, which the Researchers confirmed had been initiated. The Committee stated that the study cannot commence until Māori consultation has been completed.
3. The Committee asked if the Researchers had considered recruiting only from patients whose admission to ICU is previously anticipated, and who could provide consent before going into ICU. The Researchers stated that this was their intention, and explained that the initial plan was to get consent only from patients undergoing surgery or tracheostomized patients, but they decided to also include patients undergoing ICU (non-consenting) to better ensure that recruitment targets are met.
4. The Committee asked how participating in the study could be considered in the best interests of those recruited while in ICU. The researchers stated that participation would provide a benefit through the greater monitoring which the participants would receive. The Committee stated that whether study participation was in the best interests of an individual participant would need to be decided by the treating physician.

Summary of outstanding ethical issues

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

1. To address the previous query by the Committee about whether all participants would provide consent, the Researchers stated they had now modified the study and would be seeking informed consent from all participants. New PIS/CFs and other study documentation had been developed, however had been sent to the Secretariat after the agenda cut-off date.  
   Action requested: The Secretariat will upload the new PIS/CFs.

Decision

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

* The new Participant Information Sheet and Consent Forms will be uploaded by the Secretariat.

After receipt of the information requested by the Committee, a final decision on the application will be made by Dr Devonie Waaka and Dr Sarah Gunningham.

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| **2** | **Ethics ref:** | **21/STH/16** |
|  | Title: | Department of Medicine Tissue Bank |
|  | Principal Investigator: | Ms Fiona Hood |
|  | Sponsor: |  |
|  | Clock Start Date: | 28 January 2021 |

Amber Parry-Strong was present via videoconference for discussion of this application.

Potential conflicts of interest

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

Jean Hay-Smith declared a potential conflict of interest which the Committee decided was not significant and allowed her to remain and participate in the discussion of the application.

Summary of Study

1. The purpose of the tissue bank is to combine the tissue used for research from three research groups in the department of medicine at the University of Otago. It will be governed by some of the existing department leadership structures as well as its own operating procedures.
2. Individual research groups will seek consent for further research using the tissue bank at the time when consent for individual studies is sought.
3. The samples will only be used for research conducted by one of the three research groups.

Summary of resolved ethical issues

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

1. The Committee asked if the previous tissue samples that were collected into the bank have been collected using the same PIS and for the same purpose. The Researcher stated that those samples have been collected using a stricter consent form, with specific consents for different uses of that tissue.
2. It was confirmed that one of the staff be responsible for moving tissue and will keep a record of what tissue is added and removed from the bank, which will be reported to the Head of Research.
3. The Committee asked how errors in information will be dealt with when identified. The Researcher stated that this would be dealt with by the staff responsible for the tissue and records.
4. The Committee asked if withdrawal of tissue will be only conducted by those managing the tissue bank and asked how research might be ‘led’ from overseas. The Researchers stated that tissue might be sent overseas for required tests, but would not be stored overseas.
5. The Committee asked if future research might include commercial research, which the Researcher confirmed, although she stated that the research group would seek to have one member as a lead reviewer.
6. The Committee asked if future genetic research was planned. The Researchers stated that they wanted to be able to conduct all kinds of research on the tissue, and as such wanted participants to consent to genetic testing including whole-genome analysis.
7. The Committee asked why options were not given for opting in or out of particular types of research, specifically genomic research. The Committee suggested that adding different options might increase the number of samples they will receive.

Summary of outstanding ethical issues

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

1. Further information requested: the Committee asked for greater detail around the management of tissue and data to be added either to the study protocol or to a separate tissue and data management plan. This should meet those requirements set out in para 12.15 of the National Ethical Standards. Please ensure that this plan includes information on how clinically significant results will be managed. For guidance, refer to the HDEC tissue and data management template (<https://ethics.health.govt.nz/system/files/documents/pages/hdec-data-tissue-management-template-oct2020.docx>)

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

1. Please state that tissue donated may be sent overseas. Please outline the cultural issues for Māori associated with sending tissue overseas, and state whether a karakia may be available when samples are destroyed.
2. Please revise the statement about future genetic research and expand on this information, explaining in lay language that partial genomic or whole genomic analysis might be undertaken, and the implications concerning genetic links with their relatives and the potential for re-identification / privacy breach.
3. The Committee suggested that the Researchers use the new HDEC PIS/CF template (https://ethics.health.govt.nz/system/files/documents/pages/participant-information-sheet-consent-form-template-sep20.doc). In particular, it is important to expand on the information concerning the management of participants’ data, and to add new sections for cultural issues for Māori and genetic testing.
4. Please review the ‘key points’ box for whether the ticks are appropriate (consider also using crosses where applicable).
5. Please mention that data will be linked with Stats NZ, and explain the risks associated with that.
6. Please add information on the risks involved in sending data and tissue overseas, risks associated with potential confidentiality breaches, and refer to wording in the HDEC template for guidance.
7. Please state whether participants will be able to receive their results. If yes, give the options for participants to opt in or out of receiving non-actionable clinically significant results, and actionable clinically significant results.

Decision

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

* Please address all outstanding ethical issues, providing the information requested by the Committee.
* Please update the Participant Information Sheet and Consent Form, taking into account the suggestions made by the Committee.

After receipt of the information requested by the Committee, a final decision on the application will be made by Dr Sarah Gunningham and Assoc Prof Mira Harrison-Woolrych.

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| **3** | **Ethics ref:** | **21/STH/9** |
|  | Title: | ICare-FASTER |
|  | Principal Investigator: | Dr Martin Than |
|  | Sponsor: |  |
|  | Clock Start Date: | 21 December 2020 |

Dr Martin Than and Alieke Dierckx was present via videoconference 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 a study evaluating the implementation of a new clinical care pathway for 30,000 patients in ED. The aim of the study is to determine if bedside troponin testing (taking 15 minutes) will reduce the time spent in ED for patients presenting with chest pain, compared with sending blood samples away to a lab (which can take more than one hour to get the result). There are also some secondary clinical endpoints.
2. The new point-of-care troponin test has been shown in previous studies to be as good as the 'traditional' laboratory one.
3. The analyses will compare patients in the new pathway with historical controls (those presenting in ED in the four-month period before the new pathway is introduced)

Summary of resolved ethical issues

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

1. The Committee asked for an explanation as to why the project should be considered as research rather than an audit/related activity. The Researcher said that, rather than audit, the project is more of a quality-improvement (QI) type activity. The Committee noted that as there is a clear hypothesis it could be viewed like research, while also being QI. Nonetheless, the Committee accepted the legal opinion provided by the Researchers that this is quality improvement.
2. It was clarified that HDEC review is required for this project independent of whether it is considered as research or not, due to it being funded by the HRC and unable to be reviewed by an HRC-accredited ethics committee.
3. The Committee stated that, if the project is to be considered as research, participant consent may be needed if there is an intervention element. It was confirmed that the troponin assays would enter the market independent of this project and would likely be introduced at the same centre, although in a less structured way and with less data collected. It was further confirmed that no new information would be collected (only secondary information), and as such patients would not need to be contacted.
4. It was clarified that, if consent were to be sought, it would only be sought for secondary use of data that is collected as part of standard care, as no change to the participants’ care will be made. Data will also be linked for quality improvement purposes; however, this is already done as part of ongoing quality improvement.
5. The Committee asked about the connection with research groups in other countries. The Researcher stated that the network is for the purpose of ensuring that all are following best practice, however no study data will be shared as part of that.
6. The Committee asked if there is any risk posed to patients in implementing the new point-of-care assay. The Researcher confirmed that the new assay is not a new test, but an advancement in the technology; a new version of the same test. It has been approved by the FDA for safety, but the value in terms of time saved has not been assessed.
7. The Committee stated that, as no consent is being sought in this study, the data collected should not be made available for future research. The Researcher clarified that de-identified data would only be made available for future QI activities.

Summary of outstanding ethical issues

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

1. The Committee asked for greater detail around the management of data to be added either to the study protocol or to a separate data management plan. This should meet the requirements set out in para 12.15 of the National Ethical Standards. For guidance, please refer to the HDEC data management template (https://ethics.health.govt.nz/system/files/documents/pages/data-only-management-template-oct2020.docx)

Decision

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

* A data management plan should be provided as described in point 11.

After receipt of the information requested by the Committee, a final decision on the application will be made by Mrs Helen Walker and Prof Jean Hay-Smith.

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| **4** | **Ethics ref:** | **21/STH/12** |
|  | Title: | The CANTATA Study |
|  | Principal Investigator: | Professor Richard Troughton |
|  | Sponsor: | University of Otago |
|  | Clock Start Date: | 18 December 2020 |

Steve Chambers, Lorraine Skelton, and Chris Pemberton were present via videoconference 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 part of MBIE funding under the COVID-Accelerator program. It aims to create new tests for the serological detection of different classes of COVID-19 antibodies and to look at T-Cell functioning in the same patients. The Researchers will then apply those tests to participants who have had COVID and have since recovered, and then to conduct serological assessment in the general population.
2. The serological tests have now been developed which can detect different types of antibodies in the same sample.
3. The last aim of the study is to measure the spike protein of the COVID-19 virus,

Summary of resolved ethical issues

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

1. The Committee asked if the COVID-antibody test had been evaluated against other tests developed worldwide. The Researchers stated that they had not, as serological testing is not often done in New Zealand and as such COVID-19 patient plasma is needed to evaluate this test against others in the market. The Committee expressed concern that the results given to participants (about their immunity) may be misleading, as the test itself has not been evaluated. The Researchers clarified that the current study is intended as a feasibility to determine the validity of the antibody test. The Researchers further confirmed that they will not be informing patients of their immunity, but will be feeding the antibody results back through the participant’s clinician; all the researchers will be reporting is the patients’ serology results.
2. The Committee asked what would happen if it was determined that a participant who was not previously confirmed to have had COVID-19 had in fact been infected. The Researchers stated that the participant would be informed that they had had the virus but are no longer infectious, and that the information will be important for the government’s understanding of the population’s immunity and for planning their public health response.
3. It was confirmed that all participants will be recruited from the managed isolation facilities.
4. It was clarified that tissue will be added to an existing tissue bank, rather than establishing a new tissue bank.

Summary of outstanding ethical issues

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

1. Further information requested: the Committee asked for greater detail around the management of tissue and data to be added either to the study protocol or to a separate tissue and data management plan. This should meet the requirements set out in para 12.15 of the National Ethical Standards, and should include sufficient information about the linkage of data. Explain the breadth of follow-up data obtained through data-linking to the large number of services listed in the application. What is a 'COVID relevant diagnosis' and what does 'follow up events' mean? Why are blood transfusion services and pharmaceutical databases intended to be accessed? For guidance, please refer to the HDEC tissue and data management template (<https://ethics.health.govt.nz/system/files/documents/pages/hdec-data-tissue-management-template-oct2020.docx>)
2. Action requested: Please state in the protocol that participants will be recruited in the Auckland region.
3. The Committee stated that the questionnaire questions on alcohol are not easy to understand (e.g. current, number of drinks, and ex, number of drinks).  
   Action requested: please amend accordingly.

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

1. The Committee suggested that the study be explained in the following three steps:  
   1. Evaluating the new test;  
   2. Using those tests to determine the prevalence of COVID-19 immunity in the population;  
   3. Cardiac / other outcomes follow-up.
2. Please add greater information about the potential implications of the study (in particular, if a participant is found to have had COVID-19 infection).
3. Please add greater information about the potential future use of tissue.
4. A separate FUR PIS is needed. This should explain whether there is the possibility of any genomic research in the future.
5. Please add a section about data management, and how participant privacy and confidentiality will be protected – refer to HDEC template.
6. Please proof-read the entire PIS and adjust the language to make the PIS appropriate for a lay audience.
7. Please correct discrepancies in the timeframes given.
8. Page 2: please make the duration over which participants’ data may be accessed consistent with the protocol, and mention this in the consent form.
9. Page 2: the last three paragraphs on the page appear to belong to the previous section.
10. Page 3: please correct “16 years” to “10 years”.
11. The sentence "a simple questionnaire about your medical history and current medications" needs amending as it is not simple, and also includes questions about other aspects of health (e.g. exercise and alcohol) and also questions about their family.
12. Please explain the "MoH PHARMS " database.
13. Under the heading “what will the study involve”, please state that you will collect saliva and blood samples, how much, how often, and where - in a clinic, in a hospital, in an MIQ, at home?
14. Please clarify whether "In order to obtain maximum benefit from taking part in this study, access to your health records may be for up to 20 years" means you will access once and keep the data, or do you mean you will keep looking and collecting information for 20 years?
15. Please explain whether you can offer karakia if blood samples have been sent elsewhere, and whether elsewhere can include overseas.
16. Please amend "If you would like a copy of the results of the trial", as this is not a trial.
17. Please explain when any results might be available.
18. Overall: please use macrons where appropriate on Māori kupu, including the word Māori.
19. Please put into lay language the following sentences on both the study invitation letter and PIS: “new diagnostic tests to simultaneously detect antibody and viral antigens for COVID19”, “By testing with these assays”, “be achieved by reliable antibody assays”, and “NZ based commercial test component manufacturers”.

Decision

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

* Please address all outstanding ethical issues, providing the information requested by the Committee.
* Please update the Participant Information Sheet and Consent Form, taking into account the suggestions made by the Committee.

After receipt of the information requested by the Committee, a final decision on the application will be made by Dr Mira Harrison-Woolrych and Mrs Helen Walker.

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| **5** | **Ethics ref:** | **20/STH/234** |
|  | Title: | (duplicate) Learning from Adverse Events and Consumer, Family and Whaanau Experience |
|  | Principal Investigator: | Nurse Director Carole Kennedy |
|  | Sponsor: | Waikato District Health Board |
|  | Clock Start Date: | 10 December 2020 |

Carole Kennedy and Clare Simcock were present via videoconference 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 quality improvement-type study seeking to interview whānau who have had the distressing experience of a loved one dying by suicide whilst under the care of secondary mental health services. The primary aim is to learn more about their experiences of the MH & A services both before and after the suspected suicide.
2. The Researchers are specifically interested in their experiences of any review process relating to the suicide that they might have been involved in; and their thoughts about the current review process. The purpose of this study will be to learn how the review process can be improved to ensure that whānau are more involved.

Summary of resolved ethical issues

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

1. It was clarified that the answer to question ‘G’ on the application form was incorrect: the Researchers will be collecting health information.
2. The Committee asked if it is possible that for any participants, the loved one may have died in suicide or in a manner which would have gathered media attention, and as such whether information may be identifiable. The Researchers explained that no information about how the person died would be collected, and they would make sure not to collect any information that could indirectly identify individuals.
3. The Committee asked about the use of “completed suicide” in the PIS, which the Researchers explained is the currently accepted language.

Summary of outstanding ethical issues

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

1. Action requested: The Committee asked for the PIS to be given to interested individuals in advance of the interview, rather than just before it.
2. Further information requested: Please add greater detail on how any participant information will be managed.
3. The Committee asked if the Researchers had an at-home-visit safety protocol. The Researchers explained that they will go in pairs, will identify beforehand the koha which will be brought. This will be in accordance to the DHB at-home-visit safety protocol.  
   Action requested: please upload the at-home-visit safety protocol and ensure that research staff are aware of it.
4. Action requested: The Committee requested the following changes to the protocol:
   * Please specify the sample size
   * Please add any important eligibility criteria
   * Please clarify who is being interviewed (and ensure that all of those who might speak in the interview are consented).
   * Please add greater detail about the management of data. This should meet the requirements set out in para 12.15 of the National Ethical Standards. In doing so, please ensure that the data is de-identified prior to analysis. For guidance, please refer to the HDEC data management template (<https://ethics.health.govt.nz/system/files/documents/pages/data-only-management-template-oct2020.docx>).

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

1. Please clarify who specifically is being interviewed
2. Please add data management information according to the HDEC PIS template
3. Please state that data is kept for 10 years.
4. Please state how many whānau are participating in each interview.
5. Please state if the interviews can be conducted in Te Reo.
6. Please state where interviews will be conducted.
7. Please state whether the recording will be in audio or video format, or if notes will be taken. It should also state that participants can decline to be recorded.
8. Please add a section about potential risks for the participant, e.g. privacy/confidentiality breach, distress/anxiety, and how these will be managed.
9. Please state that the interviewer has the duty to disclose information in certain circumstances.
10. Please state that the sound recordings will be deleted after transcription.
11. Please add page numbers.
12. Please consider translating the PIS/CF into Te Reo Māori (note that the Committee does not have the expertise to review translations).
13. Please state who beyond the research team might have access to the study information and if it may be used for future research.

Decision

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

* Please address all outstanding ethical issues, providing the information requested by the Committee.
* Please update the Participant Information Sheet and Consent Form, taking into account the suggestions made by the Committee.

After receipt of the information requested by the Committee, a final decision on the application will be made by Mr Dominic Fitchett and Dr Devonie Waaka.

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| **6** | **Ethics ref:** | **21/STH/19** |
|  | Title: | LEAP: Improving self-regulation through play |
|  | Principal Investigator: | Dr Alison Leversha |
|  | Sponsor: |  |
|  | Clock Start Date: | 28 January 2021 |

Dr Alison Leversha was present via videoconference 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 seeks to adapt and test developmental games that were previously tested in the ‘ENGAGE’ trial to make them more appropriate for pre-schoolers. The games aim to improve self-regulation and language-learning, which in turn may improve long term health and social well-being.
2. The study takes the form of an open-cohort, parallel, non-randomised cluster trial, involving 330 participants in New Zealand. Those participants will be 5 and 6-year-old children from Tamaki, who will participate with their parents’ consent.
3. Participating schools have included the ENGAGE trial since 2020 in their usual classroom teaching to support the development of self-regulation skills in the children. Half of those schools will now move to the LEAP trial.
4. All children will be exposed to the intervention, but data will only be collected from children of consenting adults.

Summary of resolved ethical issues

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

1. The Committee asked if any risks were identified in the ENGAGE study. The Researcher stated that the main risks were in children not understanding the instructions, and consequently not obtaining the benefits from the games.
2. The Committee asked if any children had not wanted to participate, and if this would lead to findings of dysregulation. The Researcher stated that the games are quite simple, and a skilled teacher should be able to get students to engage. Where engagement drops off after an extended period, the adaptations are intended to make the games more appropriate for the child’s developmental level.
3. The Committee asked how developmental issues that are identified during the study would be managed. The Researcher stated that they would talk with the teacher and the family and explain their options and who they could be referred to.
4. The Committee asked how whanau, schools and community had been engaged with previously. The Researchers stated that there had been a hui with teachers from all of the schools and the whanau during the ENGAGE study, when the researchers received feedback. Additional workshops are going to be held just for the schools and community who will be beginning the adapted games (LEAP). The workshops are also used to show the parents how to run the games themselves.
5. It was confirmed that if the teacher declines to take part, it will prevent their students from taking part. The Researcher explained that an interest in taking part will be ascertained from the teacher beforehand, and the consenting process will simply formalise that, such that the children/parents are unlikely to consent and then be unable to take part.
6. The Committee asked how questionnaires will be sent to parents. The Researcher stated that questionnaires will be delivered online, to prevent paper copies from becoming lost.
7. The Committee asked if the questionnaire is available in other languages, which the Researcher confirmed, although it is not available in Te Reo Māori, Tongan or Samoan. They explained that an interpreter would be available for speakers of Te Reo.
8. The Committee asked why the same suite of objective and subjective measures were not being used in both the ENGAGE and LEAP studies. The Researcher stated that due to limitations in funding they are not able to do the controls, and are focusing on the primary outcome measure (the BASC and SDQ scores). A comparison will be able to be made for the ENGAGE study, but the LEAP programme will be evaluated with a before-after analysis.
9. The Committee asked if there was any risk of different families with children at the different schools might get together and tell each other about the programmes.

Summary of outstanding ethical issues

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

1. The Committee asked why schools are not being allocated to ENGAGE/LEAP programmes via randomization. The Researcher explained that the more engaged schools were being offered the LEAP programme. The Committee stated that this could potentially cause bias.   
   Action requested: please acknowledged this potential source of bias in the study reports.
2. Action requested: The Committee suggested asking the children for their own opinion about the value of the programme.

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

1. Please amend the headings to more clearly distinguish between the ENGAGE and LEAP PIS documents.
2. Please simplify the PIS documents for children and parents and add pictures or diagrams where possible to make them more accessible.
3. Please amend “children will benefit from this” to “children may benefit”.
4. Please make clear to the parents that they have been assigned to either a LEAP or ENGAGE programme and cannot choose between them.

Decision

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

* Please address all outstanding ethical issues, providing the information requested by the Committee.
* Please update the Participant Information Sheet and Consent Form, taking into account the suggestions made by the Committee.

After receipt of the information requested by the Committee, a final decision on the application will be made by Mr Dominic Fitchett and Prof Jean Hay-Smith.

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| **7** | **Ethics ref:** | **21/STH/20** |
|  | Title: | INTERVENE |
|  | Principal Investigator: | Dr Travis Perera |
|  | Sponsor: | Australasian Leukaemia & Lymphoma Group |
|  | Clock Start Date: | 28 January 2021 |

Travis Perera was present via videoconference 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. INTERVENE is aimed at improving treatment for people aged >60 years with adverse risk and non-adverse risk AML who have not already received previous chemotherapy, or those people who are not able to receive intensive initial chemotherapy. It is hoped that the treatment will improve the initial response, prolong the duration of response and increase overall survival.
2. The study is in two parts – Part one assesses the overall safety of the combined dose, and part two splits the group into three and uses three different combinations

Summary of resolved ethical issues

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

1. The Committee asked how remote monitoring will be conducted. The Researchers stated that ARLG is Australian-based and will check in with the trial unit to see if there were any issues, but no data will be sent to the monitor as part of that.
2. It was confirmed that Novartis would not receive the raw data for the study, but only the study results.
3. The Committee asked how health information would be accessed in order to identify participants. The Researchers explained that clinicians will identify potential participants and only contact the research team once a potential participant has expressed interest in the study.
4. The Committee stated that the cultural issues section of the application form was answered in a fairly generic fashion and asked for further information on the prevalence of AML in Māori. The Researchers stated that AML is over-represented and has poorer outcomes in the Māori population, and as such the study may offer significant benefit for Māori.
5. The Committee asked how the questionnaire results would be reviewed and how any mental health issues identified from them would be followed up. The Researchers stated that the clinician reviewing the patient would review the questionnaire as part of the consultation at the first visit, and would follow up on any issues then.
6. It was confirmed that the study was not a commercial trial, and as such ACC compensation would apply.
7. It was clarified that participants will be over the age of 60.

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 raised the following issues relating to the study protocol:
   * samples sent outside of New Zealand should not be identifiable and carry participant number and year of birth at a maximum.
   * Ethnicity data should be collected from participants.

Action requested: please update the study protocol accordingly.

1. Further information requested: The Committee asked for greater detail around the management of tissue and data in the New Zealand part of the study to be added either to the study protocol or to a separate tissue and data management plan. This should meet the requirements set out in para 12.15 of the National Ethical Standards. For guidance, please refer to the HDEC tissue and data management template (<https://ethics.health.govt.nz/system/files/documents/pages/hdec-data-tissue-management-template-oct2020.docx>)

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

1. Please make clear that this is the first time that these three drugs have been tested together in human participants.
2. Please check that participants are referred to as over 60 years of age.
3. Please provide a short, lay-friendly study title to the document header.
4. Page 1:
   * provide an address for the study Sponsor
   * state that midostaurin is not approved for AML Rx in NZ
5. Page 4:
   * explain the chances of being in each Rx arm
   * delete 'teaspoons' and 'the AIDS virus'
6. Page 6: state that no inherited genetic information will be analysed.
7. Page 8: delete repetitive explanations of procedures, once they have been initially explained (procedures section).
8. Provide general frequencies for the risk categories (common, uncommon etc).
9. Make the mandatory inclusion in data bank clear.
10. Consent form: remove the optional tick-box from GP notification about study involvement (particularly given multiple con med restrictions etc).
11. Please remove the yes/no tick boxes from the consent form for all statements that aren’t truly optional, i.e. those where a participant could select ‘no’ and still participate in the study.
12. Please make it clearer that interested individuals will only be eligible for the study if they have already signed up to the registry.
13. Please submit a biobanking PIS/CF for review.
14. Please explain the “correlated research”.
15. Please ensure that all terms are explained in lay language the first time they are used, e.g. ‘correlative research', 'tumour lysis syndrome', ‘adverse and non-adverse karyotypes’.
16. Page 15 effective contraception: please add more information, and refer to the HDEC reproductive risks template for guidance <https://ethics.health.govt.nz/system/files/documents/pages/participant-information-sheet-consent-form-template-reproductive-risks-17apr20.docx>

Decision

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

* Please address all outstanding ethical issues, providing the information requested by the Committee.
* Please update the Participant Information Sheet and Consent Form, taking into account the suggestions made by the Committee.

After receipt of the information requested by the Committee, a final decision on the application will be made by Dr Devonie Waaka and Dr Sarah Gunningham.

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| **8** | **Ethics ref:** | **21/STH/21** |
|  | Title: | Review of the SACAT Act 2017 |
|  | Principal Investigator: | Ms Marnie Carter |
|  | Sponsor: | Ministry of Health |
|  | Clock Start Date: | 28 January 2021 |

Ms Marnie Carter was present via videoconference 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 will review the operation and outcomes of the Substance Addiction (Compulsory Assessment and Treatment) Act 2017. It is intended to show whether the Act is achieving its stated purposes and to identify areas where improvement can be made to the operation of the Act and outcomes for applicants, patients and whānau. The study includes multiple methods. These include:
2. (i) qualitative interviews with service providers, clinicians who deliver the Act, people who have been placed under the Act and their whanau;
3. (ii) descriptive analysis and multivariate analyses of data extracted from the NMDS and PRIMHD dataset and complementary data on health and social outcome measures;
4. (iii) documentary file review including review of case law and policy and process documents related to DHBs’ delivery system for the Act.

Summary of resolved ethical issues

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

1. The Committee noted that the requests from the previous HDECs who had reviewed the application had now been addressed.
2. The Committee asked about the justification for accessing identifiable health information. The Researcher explained that the information will only be provided to the researchers in a de-identified form, however it was considered by a previous HDEC that due to the small population size it is potentially identifiable. To mitigate the risk of re-identification, a process has been put in place such that those accessing the quantitative data will not be able to access the qualitative data, and vice-versa.  
   It was further explained that consent is not being sought because to do so the researchers would need to obtain identifiable data, which would infringe on the patients’ privacy and potentially cause distress. Furthermore, as the target population tends to move location a lot, their details may have changed, and it is likely that consent will only be able to be obtained from a subset which would be a non-representative sample.
3. The Committee asked about the roles of various individuals mentioned in the protocol, and it was clarified that they were DHB staff and not considered as participants.

Summary of outstanding ethical issues

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

1. The Committee noted that the risk of re-identification is higher during the qualitative interviews involving up to 20 people. The Researcher stated that consent will be sought from those 20 participants who will be interviewed.   
   Further information requested: The Committee asked for greater detail to be added to the data management plan. This should include:
   * How the interview is recording
   * How the recording is transformed for analysis
   * Who has access to the data (recording and transcripts)
   * How it is de-identified.
   * How the data will be analysed

For guidance, please refer to the HDEC data management template (<https://ethics.health.govt.nz/system/files/documents/pages/data-only-management-template-oct2020.docx>)

1. The Committee asked why the participant should have the right to access the information provided about them by their family members. It was clarified that, as the information is about the individual’s opinion on the services accessed by their family member, it is not information about the individual and the right to access/correct that information would not apply.  
   Action requested: please update the PIS or other documents accordingly.
2. The Committee asked if the whanau members need to be related to the index cases, which the Researcher confirmed.   
   Action requested: please ensure this is stated in the protocol.

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

1. Please proof-read and reduce complexity if possible.
2. PATIENT PISCF:
   * Review for grammar, missing words etc (general), and complicated words / sentences that should be replaced with plain English, lay-friendly language (e.g. bullet points
   * Page 1: “if you stop taking part, the information you have given to us will be deleted”. Please make clear that information may only be deleted before it has been combined for analysis.
   * Page 2: replace 'You were selected' with 'you are invited to take part because'
   * Page 2: Include the identifiable information sub-heading as some source documents are necessarily identifiable (e.g. informed consent documents).
   * Page 3: explain what section 3 of the Act is.
   * Page 3/4 explains the interview well. However, it doesn’t say how the interview content is captured (e.g. recorded). What if someone does not want to be recorded? Can notes be taken instead? Is there a reason why there are two interviewers per interview?
   * Page 4: please correct hdc@hdc.org.nz to advocacy@advocacy.org.
   * Page 4: please put "there are no direct personal benefits from taking part in this Review" first, and add greater detail on how interview data is de-identified and stored (i.e. in what forms).
   * Delete the orphan header page 6.
3. FAMILY PIS
   * Page1: please explain “AOD”
   * Page 3: delete the orphan heading; and address the same issues as the patient PIS: HDC email on page 3, move the statement about no personal benefit, and add greater detail about the interview data.
4. CLINICIANS PIS
   * Please address the same issues, including email, orphan headings, benefits, interview data.

Decision

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

* Please address all outstanding ethical issues, providing the information requested by the Committee.
* Please update the Participant Information Sheet and Consent Form, taking into account the suggestions made by the Committee.

After receipt of the information requested by the Committee, a final decision on the application will be made by Professor Jean Hay-Smith and Mr Dominic Fitchett.

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| **9** | **Ethics ref:** | **21/STH/22** |
|  | Title: | Utility of DNA Methylation analyses in Meningioma |
|  | Principal Investigator: | Dr Fouzia Ziad |
|  | Sponsor: |  |
|  | Clock Start Date: | 28 January 2021 |

Dr Fouzia Ziad was present via videoconference 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 seeks to validate the findings of European studies showing correlation between meningioma tumour methylation profiles and tumour aggressivity; it is validating a test.
2. A retrospective cohort of 75 subjects with a diagnosis of WHO grade II meningioma and resected at Waikato Hospital during the period from 2007-2019 will be selected from the department of Pathology histology database. Pathology will be reviewed by an experienced neuropathologist to ensure they meet the criteria for WHO grade II as per the latest classification. Pathological data on microscopy findings including meningioma subtype, histological findings and immunohistochemistry will be recorded. Samples will then be sent to the Department of Surgical Sciences, University of Otago, for DNA methylation analysis.
3. Patient data collected will include age, gender, ethnicity, history of prior radiation, total/subtotal resection status, adjuvant radiation therapy. Follow-up data on time to recurrence, progression-free and overall survival will also be collected.

Summary of resolved ethical issues

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

1. The Committee asked about what the original consent for the tissue samples involved. The Researchers explained that the patients were consented by their surgeons prior to surgery, as part of the same consenting process. The consent was not specifically for genetic analysis.
2. The Committee asked about the genetic test. The Researchers explained that they will take the tumour samples and conduct genetic tests to see if there is any correlation between the tumour’s methylation profiles and their behaviour. This correlation has been indicated from studies in Europe, and this research will explore whether that is relevant in the New Zealand population, and if the methylation is well correlated with tumour behaviour then in the future it will be able to be used as an additional test on the pathology of the tumour.
3. The Committee asked if there are any genetic implications from this analysis for the participant or their family. The Researcher stated that there are not, as they are not looking at the epigenetics of the participants’ tissue but of the tumour sample. The Committee was satisfied that there are not likely to be any clinically significant findings from the study.
4. The Committee asked if whole-genomic sequencing would be necessary to do whole-genomic methylation analysis, and the Researcher clarified that it will not be.
5. The Committee raised the potential issue of establishing findings relevant for specific ethnicities, which might be relevant for the participants. The Researchers stated that the study will not be powered to make such findings; its primary aim is to validate the methylation test.
6. The Committee asked about Māori consultation. The researchers said that they have had preliminary, informal consultation, which was supportive, and are awaiting formal consultation.
7. The Committee was satisfied that the collection of data is also covered by the previously given consent for future unspecified research.
8. It was confirmed that samples sent for analysis will only be a part of the original sample.

Summary of outstanding ethical issues

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

1. The Committee asked for greater detail around the management of tissue and data in the New Zealand part of the study to be added either to the study protocol or to a separate tissue and data management plan. This should meet the requirements set out in para 12.15 of the National Ethical Standards. For guidance, please refer to the HDEC tissue and data management template (<https://ethics.health.govt.nz/system/files/documents/pages/hdec-data-tissue-management-template-oct2020.docx>)
2. Please provide evidence that formal Māori consultation has been completed.

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

1. Please upload a copy of the original consent form.

Decision

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

* Please address all outstanding ethical issues, providing the information requested by the Committee.
* Please update the Participant Information Sheet and Consent Form, taking into account the suggestions made by the Committee.

After receipt of the information requested by the Committee, a final decision on the application will be made by Assc Prof Mira Harrison-Woolrych and Mrs Helen Walker.

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| **10** | **Ethics ref:** | **21/STH/23** |
|  | Title: | STELLAR |
|  | Principal Investigator: | Prof Lutz Beckert |
|  | Sponsor: | PPD/Acceleron Pharma |
|  | Clock Start Date: | 28 January 2021 |

No member of the research team 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 Study

1. The study is a randomized double-blind placebo-controlled trial of sotatercept versus placebo plus standard of care for pulmonary arterial hypertension. There are 20 participants expected in New Zealand out of 248 worldwide.
2. The study duration is up to 108 weeks.
3. No ethics approval has been approved elsewhere in the world at this point.

Summary of resolved ethical issues

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

1. The Committee stated that the use of technical and non-lay language in the application form and other documents made assessing the application difficult.

Summary of outstanding ethical issues

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

1. The Committee asked for the use of placebo to be justified, given that there is no provision to cross-over to open-label Rx on failure to improve / deterioration, for an IMP where Phase II study results clearly indicated a benefit for sotatercept. Justify the 1:1 randomisation.
2. The Committee asked for clarification about tissue biopsy samples mentioned in response to question R.8.1, which are not mentioned in the PIS or elsewhere.
3. Please explain the mandatory use of blood samples for exploratory research, in particular whether the exploratory research is directly related to the current study, and whether any genomic research may be undertaken.
4. The Committee stated that access to results should include access to safety and screening tests.
5. The Committee asked for information on the incidence / prevalence and outcome of PAH in Māori compared with non-Māori New Zealanders. The answer provided in the application form is completely generic and does not answer the question asked.
6. The Committee stated in response to the answer for question R.1.6 that the study is not allowed to stop for commercial reasons.
7. The Committee asked for further information on how the EQ5LD depression questions will be monitored, how often, and how answers of concern would be followed-up.
8. The Committee asked for a new, valid indemnity certificate.

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

1. Please review for formatting etc. - the document is very poorly presented. The advertisement is however well-presented – consider using the flow diagrams to demonstrate some of the stages in the PIS.
2. Please give the PIS a meaningful lay title that is not suggestive.
3. Use appropriate macrons for Māori text.
4. Page 1: please include the sponsor’s address.
5. Page 1: state why the person has been approached or referred.
6. Page 4: add the number of participants anticipated in NZ.
7. Replace the table of assessments with a lay-friendly table (don’t drop straight from protocol).
8. Page 5 LTDB: Mention here that all participants will receive Sotatercept in the LTFU including those previously on placebo. Currently it appears suggestive of this. Perhaps explain that this will require a separate information and consent form which will be completed at XX visit.
9. Replace respiratory with breathing, pulmonary with lung etc. and write blood tests in lay terms (pp 11-12).
10. Pages 7/8, Table 1: please define all the abbreviations, both study procedures and those in the footnotes (EOT, EOS)
11. The risks of procedures and main procedures would be easier to read together, e.g. in a table.
12. Please re-write the biomarker section. Mandatory use of blood samples for exploratory research is highly problematic when not well explained, particularly given the fact that biomarker research is not listed as any sort of endpoint in the study protocol. Is there the potential for biomarker analysis to include genomic assays? Is the analysis related directly to this drug / PAH? If genomic analysis is planned or the biomarker is broader than inferred, this should be optional and should be presented in a separate PISCF
13. Amend the privacy and confidentiality section to separate information provided into identifiable and de-identified subsections, and include a section about future uses of data etc (see the HDEC PISCF template for guidance).
14. Notifying GP should be compulsory. Please explain this within the body of the PIS and it should not be optional in the consent form.
15. Please remove American contacts from the patient guide info.
16. The LTFU introduced at the end of the LTDB and Follow-up period is hard to understand and should be made clearer.
17. Pages 11/13: please give the length of time participants will be involved in each section of the study.
18. Page 15: please explain the purpose of the stored samples.
19. Add Maori health support details.
20. Please remove the yes/no tick boxes from the consent form for all statements that aren’t truly optional, i.e. those where a participant could select ‘no’ and still participate in the study.
21. PISCF PREGNANCY: These are no longer accepted for HDEC review unless a pregnancy is reported in a study participant or participant's partner.

Decision

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

* Please address all outstanding ethical issues, providing the information requested by the Committee.
* Please update the Participant Information Sheet and Consent Form, taking into account the suggestions made by the Committee.

After receipt of the information requested by the Committee, a final decision on the application will be made by Dr Sarah Gunningham and Dr Devonie Waaka.

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| **11** | **Ethics ref:** | **21/STH/24** |
|  | Title: | Venetoclax Extension Study |
|  | Principal Investigator: | Ms Eileen Grace Merriman |
|  | Sponsor: | AbbVie Limited |
|  | Clock Start Date: | 28 January 2021 |

Eileen Grace Merriman and Leo Gonzalez Perez were present via videoconference 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 3, open label, multicenter, extension study for patients with Chronic Lymphocytic Leukemia (CLL). The purpose of this extension study is to provide venetoclax and obtain long-term safety data for participants who continue to tolerate and derive benefit from receiving venetoclax in ongoing studies. The study is only looking at safety endpoints, and participants will be reviewed every 12 weeks for adverse events.
2. 17 participants will be recruited in NZ.

Summary of resolved ethical issues

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

1. The Committee asked what type of tumours participants in this study might have. The Researchers stated that all participants will have CLL.
2. The Committee asked why efficacy data will not be collected in this follow-up study. The Researchers stated that the purpose of the study is essentially a compassionate supply, and safety data is being taken at the same time.
3. It was clarified that the study drug will be provided at no cost to the participants.

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 requested that the sponsor insurance certificate state that the insurance is specific to this study and that New Zealand is specified as the policy territory.   
   Action requested: please submit this as a post-approval form for confirmation with the Secretariat.

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

1. Please make it clear in the opening paragraphs that this study is for participants with CLL who are already in an on-going trial.
2. Please give a couple of examples of which vaccines are live vaccines.
3. The Committee suggested that the Māori cultural statement be removed, as no tissue is likely to be used in this study.
4. Please remove the information about reproductive risks, and use instead a simple statement along the lines of: “as in the previous study, you must ensure that you use contraception appropriately if you require it.”
5. Page 16: please remove the line “The Medical Officer of Health, if you return a positive test for [enter those tests applicable to your study].
6. Please add the Māori health support contact details.

Decision

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

* Please address all outstanding ethical issues raised by the Committee.
* Please update the Participant Information Sheet and Consent Form, taking into account the suggestions made by the Committee.

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| **12** | **Ethics ref:** | **21/STH/25** |
|  | Title: | Hydrolysed meat in residential aged-care |
|  | Principal Investigator: | Miss Xiaojing Wu |
|  | Sponsor: | The University of Auckland |
|  | Clock Start Date: | 28 January 2021 |

Xiaojing Wu was present via videoconference 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 will evaluate the benefit of a pureed meal using hydrolysed meat. Specifically, it will look at the nutritional and health outcomes of a high-protein pureed meal for aged-care residents with swallowing difficulties (dysphagia). This research will help to evaluate whether the high-protein pureed meal could improve resident health.

Summary of resolved ethical issues

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

1. The Committee asked who will be completing the Barthel questionnaire. The Researcher stated that she will be completing it using information from the aged-care records and checking that information with the nurses.
2. The Committee asked about the funding for the study. The Researcher explained that Zamati, which is the manufacturer of the hydrolysed meat, applied to Callaghan for funding in order to determine whether there is a benefit of the hydrolysed meat, however that funding is available for use only by researchers at the University. The contract between the University of Auckland and Zamati ensures that the study will be undertaken by researchers at the university and only the study results (not the dataset) will be shared with Zamati. The Committee was satisfied that Zamati would have no greater benefit from the study than any other manufacturer of hydrolysed meat, and therefore did not consider the study to be for the principal benefit of the manufacturer.
3. It was clarified that participants can ask for their samples to be returned to them at the end of the study.

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 stated that a best-interests justification is needed if non-consenting participants are to be included. It is not clear how this could be justified, given that the study could be conducted first in patients who have the full capacity to consent, and that the benefit claimed (improved nutrition) is also the outcome being evaluated in this study.  
     
   The Researcher explained that they wished to include non-consenting participants because most aged-care residents who are unable to consume regular foods, and around 80% of residents in aged care facilities, will have some cognitive impairment. The Researcher argued that participation would be in participants’ best interests as it would provide (non-vegetarian) patients with a meat alternative which they are expected to prefer, while also possibly providing greater nutrition. A previous study showed that the hydrolysed meat contains higher energy and protein, although it is not known that this will translate to greater nutritional uptake for this specific population group.   
     
   The Committee noted that aged-care residents with mild cognitive impairment would still be able to consent to their participation, if provided with adequate assistance, and asked for the study design to be adjusted so as to only include consenting participants. With this approach, the Researcher would not need to prove that the intervention is in participants’ bests interests.  
     
   Action requested: please amend the protocol, such that only patients who can consent and those who can be assisted to consent will be included in the study (*National Ethics Standards* para *6.7-6.8 & 6.10-6.11*)
2. The Committee noted that individuals who dislike hydrolysed meat will be withdrawn from the study, and asked whether this might bias the results. The Researcher explained that they would withdraw those participants to ensure that they obtain adequate nutrition on the standard food. The Committee suggested that those participants should be switched to the standard diet, but should still be included in the analysis under ‘intention to treat’.  
   Action requested: please amend the protocol accordingly (*National Ethics Standards* para *9.1*).
3. Further information requested: The Committee asked for greater detail around the management of data in the study to be added a separate data management plan. This should meet those requirements set out in para *12.15* of the National Ethical Standards. For guidance, please refer to the HDEC data management template (https://ethics.health.govt.nz/system/files/documents/pages/data-only-management-template-oct2020.docx)

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

1. Please simplify language where possible, explaining terms such as ‘hydrolysed’ and ensuring that all acronyms are explained.
2. Please proofread all information sheets, correcting grammatical/typological errors.
3. Please change the assent form into a participant information and *consent* form for residents with mild cognitive impairment but who are able to provide informed consent, such that it has all the information needed for participants to consent but in an easy to understand form.
4. Please make clear that there are two groups in this study: the ordinary diet treatment arm, and the hydrolysed meat treatment arm.
5. Please ensure that the wording does not imply any benefit from the hydrolysed meat, given that the benefit has not yet been determined
6. Resident PIS/CF: please ensure that all clauses in the consent form are first mentioned or explained in the PIS (e.g. incidental findings).
7. In re-submitting, please ensure that the PISs uploaded are the latest version, as some of the changes identified were not visible in the documentation.

Decision

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

## 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:** | 9 March 2021 |
| **Meeting venue:** | Online – note that the March meeting may need to be via Microsoft Teams. |

The following members tendered apologies for this meeting.

* Mrs Helen Walker

It was noted that an acting chair would need to be appointed for the meeting, and it was unanimously agreed that Dominic Fitchett would assume the role of acting chair.

1. **Review of Last Minutes**

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

The meeting closed at 4:00pm.