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| **Committee:** | Southern Health and Disability Ethics Committee |
| **Meeting date:** | 13 October 2020 |
| **Meeting venue:** | Video conference (Zoom) |

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| **Time** | **Item of business** |
| 11:30am | Welcome |
| 11:35am | Confirmation of minutes of meeting of 08 September 2020 |
| 11:45am | New applications (see over for details) |
| 11:45 – 12:10  12:10 – 12:35  12:35 – 1:00  1:15 – 1:40  1:40 – 2:05  2:05 – 2:30  2:30 – 2:55  2:55 – 3:20  3:30 – 3:55  3:55 – 4:20  4:45 – 5:05  5:05 – 5:30 | i 20/STH/163  ii 20/STH/159  iii 20/STH/160  [15 minute break]  iv 20/STH/161  v 20/STH/164  vi 20/STH/162  vii 20/STH/165  viii 20/STH/166  [10 minute break]  ix 20/STH/168  x 20/STH/169  xi 20/STH/170  xii 20/STH/173 |
| 5:30pm | General business:  Noting section |
| 5:40pm | Meeting ends |

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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 | Apologies |

## Welcome

The Chair opened the meeting at 11:45am and welcomed Committee members, noting that apologies had been received from Dr Paul Chin and Dr Pauline Boyles.

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 08 September 2020 were confirmed.

## New applications

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| **1** | **Ethics ref:** | **20/STH/163** |
|  | Title: | Impact of inflammation on the Cxbladder test in detection of urothelial carcinoma |
|  | Principal Investigator: | Mr. Tony Lough |
|  | Sponsor: | PACIFIC EDGE LIMITED |
|  | Clock Start Date: | 14 September 2020 |

Mr. Tony Lough 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 a NZ observational study of 500 patients who have submitted a urine sample (via their urologist) to Pacific Edge Ltd (a commercial company) for testing for bladder cancer. This study will use both samples already collected and frozen (since 2019) and samples prospectively submitted from 2020 onwards until 500 have been obtained. This study aims to analyse those urine samples with a high proportion of inflammatory cells, which have been deemed not to pass Quality Control, in order to: 1) perform an audit/observational study of the incidence of bladder cancer in samples with a high proportion of inflammatory cells; 2) use an alternative methodology to determine the risk of bladder cancer in these previously unusable samples.

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 clarification as to whether the test is available for patients to self-refer to. The Researchers confirmed that this is possible, but that most samples would come from urology clinics or GPs.
2. The Committee asked for clarification about how consent is given for the tissue to be used in the study. The Researchers clarified that the samples have been or will be collected in clinical care with verbal consent for the standard of care test. The Committee explained that as the study is research, it must be treated separately from the clinical use of the samples, and that this applies to both retrospective and prospectively collected samples.
3. The Committee asked what patients whose samples are failed will be told. The Researchers explained that currently, if the test fails, the GP is notified of that failure. The aim of this study is to return a result to those patients.
4. The Committee queried whether the analysis in the first part of the study could produce clinically relevant findings, however it was clarified that this would not be possible. The first part will involve using data from the standard of care test and patient’s clinical records to analyse the incidence of cancer in patients whose samples received a failed test result. As this involves only the data produced by the samples, rather than the samples themselves, it cannot produce new clinical findings. The Committee accepted the justification provided by the researcher for the use of data without consent for the purposes of this study, provided the results of the analysis are made available.
5. The second part of the study will involve re-running samples which were unable to yield a result. The Committee asked whether a positive result (indicating cancer) would be communicated back to the urology centre or GP, so that the patient can be informed. The Researchers explained that the test is for the *absence* of cancer, such that lower scores equate with a very low or low risk of cancer. In the event of a higher score or failed result, cancer has not been ruled out and further standard clinical work-up is required. Whether a patient who receives a high or very high gene expression score is tumour-positive would then have been determined as part of their standard clinical workout. Furthermore, the study is a validation process; and as such, the test will not be valid until the study is completed.

Summary of outstanding ethical issues

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

1. For the prospective arm of the study which involves re-running the test on those samples which produce a failed result, the Committee queried whether it would be feasible to seek consent from participants. The Researchers acknowledged that it would be possible to seek consent over the phone from patients whose samples return a failed result. The Researchers argued that, as the participants had sought a test on their samples to begin with, they could be expected to be interested in participating in this study. The Committee emphasized the distinction between a test as part of clinical care and for the purposes of research. The Researchers agreed to seek consent from participants via email.

Further action requested. Please amend the protocol to include the methods for seeking consent for the use of tissue for research purposes in the prospective component of the study. Please also clarify that archival samples will not be analysed in this study.

1. The Committee stated that the publishing of results should not be restricted for commercial reasons, especially for the observational component of the study which is described by the researcher as an audit of current practice. The results of the audit will be of significant interest to health care providers using the current Cx Bladder test.

Further action requested. Please state how the results of the study are intended to be disseminated (National Ethics Standards para 11.54).

1. The Committee stated that plans for return of results to the participant and his/her doctor had not been addressed.

Further action requested: Please amend the protocol to address the return of results generated by the investigational methodology to the participant and health care provider. Ensure this information is included as part of informed consent. (National Ethics Standards para 7.1).

1. The Committee noted cultural issues for Māori surrounding the use of tissue and data.

Further action requested. Please undertake formal Māori consultation for this study.

1. The Committee noted that the evidence of peer review was copied from the information in the application form, and thus not a genuine peer review.

Further information requested: please provide evidence of independent scientific review. (*Standard Operating Procedures* para *11*)

1. In re-submitting this application, please address the ethical issues more directly in the application form and/or study protocol.

Decision

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

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| **2** | **Ethics ref:** | **20/STH/159** |
|  | Title: | ARISE |
|  | Principal Investigator: | Prof Lutz Beckert |
|  | Sponsor: | Insmed Incorporated |
|  | Clock Start Date: | 01 October 2020 |

Prof Lutz Beckert 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 intervention study evaluating a new medication for mycobacterium avium Complex (MAC) lung disease: amikacin liposome inhalation suspension. The formulation being trialled is a combination of amikacin liposome inhalation suspension [ALIS] + azithromycin [AZI] + ethambutol [ETH], and will be compared with empty liposome control [ELC] + AZI + ETH). 10 participants will be recruited in NZ (250 worldwide in 28 countries).
2. This study was discussed in conjunction with 20/STH/160 (ENCORE)

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 for future submissions that the answers given on the application form were in dense technical language, and should be made appropriate for lay readers. A number of incorrectly answered questions were also noted.
2. The Committee asked how the study site would manage any clinically actionable incidental findings. The Researcher explained that few incidental findings are expected, and would typically be communicated back to the participant’s GP.
3. It was clarified that data generated in the study would be made available for use in future unspecified research. There is an optional consent for further analysis of tissue samples after all study data is collected (for future specified research).
4. It was clarified that all samples and data used in the study will be de-identified after collection and stored in a de-identified form.
5. The Committee asked about the risk of hoarseness and loss of voice which may result from the study medication. The Sponsor explained that these effects have been seen commonly, but are typically manageable and usually not persistent.
6. The Committee asked if worsening CD is an important issue for this population. The Sponsor explained that some worsening was seen, but patients are normally managed well and the symptoms resolve.
7. The Committee suggested that the first approach to patients be made by a separate member of the study team to avoid any conflict of interest. The Researcher confirmed that this would be done by a separate person, and in a separate office.
8. The Committee asked if the patient populations will overlap ARISE and ENCORE studies. The Researcher explained that people will be approached and then asked which study they would most like to take part in, but will only take part in one study or the other. The differences in the studies is primarily the different set of questionnaires, to avoid overburdening participants with all the questionnaires from both studies.

The Committee requested the following changes to the Participant Information Sheet and Consent Form (PIS/CF):

1. Please proof-read both documents for accuracy and formatting.
2. Please give each PIS a lay-friendly study title.
3. Main PIS/consent form:
4. Please clarify the purpose(s) for which tissue will be stored in this study, and clarify the optional analyses of tissue which relate to the study.
5. Please add a statement in the information sheet about side-effects from the study medication, and state that resultant hoarseness typically resolves.
6. Please make clear that the control arm is the same as standard of care, and that the investigational arm is standard of care + the investigational product. Please state what the probability is of receiving each treatment.
7. Please change ‘cups’ of blood to ‘ml’.
8. Please state that the CT scan results will be added to the participants’ patient record.
9. Please change the ACC statement to the ‘commercial’ ACC wording from the HDEC template. Please also delete the first privacy/confidentiality section (there are two).…
10. Please remove the section of ‘institutional ethics committee and how it protects you’.
11. Please remove the section ‘Payment for injury related to the study’.
12. Pregnancy PIS/CF: note that if any infant data is intended to be collected on the infant, a separate PIS is needed.
13. Please proofread and correct any US-specific references, especially for the ENCORE PIS.
14. The ENCORE PIS has more appropriate information on pregnancy screening, please copy this over to the ARISE PIS.
15. **ARISE PIS:**
16. Please add page numbers and footers.
17. Page 2: check the number of participants
18. Page 4: description of PFT is better in ENCORE PIS
19. Page 6 para 2: check number of questionnaires.
20. Page 16: correct the statement that samples will be stored for 2 weeks to 2 years.
21. **ENCORE PIS**:
22. Page 5: please delete the last sentence.
23. Please correct the statement that samples stored for 2 weeks to 2 years.
24. For note: please keep a tracked-changes document.

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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| **3** | **Ethics ref:** | **20/STH/160** |
|  | Title: | ENCORE |
|  | Principal Investigator: | Prof Lutz Beckert |
|  | Sponsor: | Insmed Incorporated |
|  | Clock Start Date: | 01 October 2020 |

Prof Lutz Beckert 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 intervention study evaluating the efficacy and safety of a new medication for mycobacterium avium Complex (MAC) lung disease: amikacin liposome inhalation suspension. The formulation being trialled is a combination of amikacin liposome inhalation suspension [ALIS] + azithromycin [AZI] + ethambutol [ETH], and will be compared with empty liposome control [ELC] + AZI + ETH). 10 participants will be recruited in NZ (250 worldwide in 28 countries).
2. This study was discussed in conjunction with 20/STH/159 (ARISE)

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 for future submissions that the answers given on the application form were in dense technical language, and should be made appropriate for lay readers. A number of incorrectly answered questions were also noted.
2. The Committee asked how the study site would manage any clinically actionable incidental findings. The Researcher explained that few incidental findings are expected, and would typically be communicated back to the participant’s GP.
3. It was clarified that data generated in the study would be made available for use in future unspecified research. There is an optional consent for further analysis of tissue samples after all study data is collected (for future specified research).
4. It was clarified that all samples and data used in the study will be de-identified after collection and stored in a de-identified form.
5. The Committee asked about the risk of hoarseness and loss of voice which may result from the study medication. The Sponsor explained that these effects have been seen commonly, but are typically manageable and usually not persistent.
6. The Committee asked if worsening CD is an important issue for this population. The Sponsor explained that some worsening was seen, but patients are normally managed well and the symptoms resolve.
7. The Committee suggested that the first approach to patients be made by a separate member of the study team to avoid any conflict of interest. The Researcher confirmed that this would be done by a separate person, and in a separate office.
8. The Committee asked if the patient populations will overlap ARISE and ENCORE studies. The Researcher explained that people will be approached and then asked which study they would most like to take part in, but will only take part in one study or the other. The differences in the studies is primarily the different set of questionnaires, to avoid overburdening participants with all the questionnaires from both studies.

The Committee requested the following changes to the Participant Information Sheet and Consent Form (PIS/CF):

1. Please proof-read both documents for accuracy and formatting.
2. Please give each PIS a lay-friendly study title.
3. Main PIS/consent form:
4. Please clarify the purpose(s) for which tissue will be stored in this study, and clarify the optional analyses of tissue which relate to the study.
5. Please add a statement in the information sheet about side-effects from the study medication, and state that resultant hoarseness typically resolves.
6. Please make clear that the control arm is the same as standard of care, and that the investigational arm is standard of care + the investigational product. Please state what the probability is of receiving each treatment.
7. Please change ‘cups’ of blood to ‘ml’.
8. Please state that the CT scan results will be added to the participants’ patient record.
9. Please change the ACC statement to the ‘commercial’ ACC wording from the HDEC template. Please also delete the first privacy/confidentiality section (there are two).…
10. Please remove the section of ‘institutional ethics committee and how it protects you’.
11. Please remove the section ‘Payment for injury related to the study’.
12. Pregnancy PIS/CF: note that if any infant data is intended to be collected on the infant, a separate PIS is needed.
13. Please proofread and correct any US-specific references, especially for the ENCORE PIS.
14. The ENCORE PIS has more appropriate information on pregnancy screening, please copy this over to the ARISE PIS.
15. ARISE PIS:
    * Please add page numbers and footers.
    * Page 2: check the number of participants
    * Page 4: description of PFT is better in ENCORE PIS
    * Page 6 para 2: check number of questionnaires.
    * Page 16: correct the statement that samples will be stored for 2 weeks to 2 years.
16. ENCORE PIS:
    * Page 5: please delete the last sentence.
    * Please correct the statement that samples stored for 2 weeks to 2 years.
17. For note: please keep a tracked-changes document.

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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| **4** | **Ethics ref:** | **20/STH/161** |
|  | Title: | The relationship between cognition and swallowing in neurological disease |
|  | Principal Investigator: | Dr Sarah Perry |
|  | Sponsor: |  |
|  | Clock Start Date: | 01 October 2020 |

Dr Sarah Perry 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 a cross-sectional observational study involving participants with Parkinson's disease (PD), seeking to determine the relationship between swallowing disorder and cognition.
2. Participants will be recruited from another ongoing longitudinal study at the NZ Brain Institute (and will involve data collected in that study for those who choose to also participate in the present study, i.e. PD severity, attention, executive function, visuospatial function, learning/memory, language). Participants will be grouped based on cognitive impairment: 'normal' cognition (n=30), mild cognitive impairment (n=30), or dementia (n=20).
3. The objectives include to determine the prevalence of swallowing disorder in the 3 groups, predictors of swallowing disorder in the 3 groups, and the consistency in objective and self-reported measures of swallowing disorder in the 3 groups.
4. The main ethical issue is the vulnerability of some participants (reduced cognition/capacity for informed consent); informed assent from EPOA/spouse/family member may also be sought in addition to participants’ informed consent.

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 long it will have been since the time of the participants’ cognitive testing that they are approached and invited onto the study. The Researcher explained that it will have been no longer than 3 months. Furthermore, support persons/caregivers will be invited to be present. The Committee asked if anyone would be present who would be able to make an assessment at the time that patients are invited to participate. The Researcher explained that research nurses would be present at the time. Please state in the protocol that some assessment of competence will be made at the time of consent.
2. The Committee asked about the risk of choking in conducting the swallowing test. The Researcher explained that the risk is low, and that there would always be other clinical staff around who could assist in any incident of this kind.
3. The Committee asked why data is being stored for future unspecified research. The Researcher explained that this is to increase the utility of the data, and would only involve de-identified data.

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 about the Researcher’s data management plans. The Researcher explained that video recordings will be collected along with other information, and the Committee suggested for the videos to be recorded at below-eye level so as to reduce the identifiability.  
   Action requested: please update the protocol accordingly.
2. The Committee asked about the justification for not informing participants’ GPs of any incidental findings, which the Researcher explained was based on respecting the participants’ wishes.   
   Action requested: due to the potential clinical findings in the study, the Committee asked for this to be made compulsory and explained in the PIS.
3. Action requested: please ensure that ethnicity data is collected based on the NZ census categories.
4. Action requested: please develop a formal data management plan. You can see the HDEC template here: <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 (PIS/CF):

1. Please refer to ‘thinking’ instead of ‘cognition’.
2. Please state that participants *will* be given a copy of the PIS/CF to take away with them.
3. Please amend “you may ask for your data to be deleted when you withdraw”, to state that the researchers will ask participants this when they withdraw.

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 Mrs Helen Walker.

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| **6** | **Ethics ref:** | **20/STH/164** |
|  | Title: | Investigation into the efficacy and safety of a micronutrient formula compared with placebo on mood in teenagers |
|  | Principal Investigator: | Prof Julia Rucklidge |
|  | Sponsor: |  |
|  | Clock Start Date: | 01 October 2020 |

Prof Julia Rucklidge 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 a double blind RCT of a micronutrient product versus placebo. The study will involve 150 NZ teenagers of 12 to 17 years old with 'dysregulated emotions'.
2. Participants will self-refer (via their parents) or be referred by GPs or counsellors who will have access to the inclusion and exclusion criteria. Participants will take the micronutrient product (up to 12 capsules a day) or placebo in the first 8 weeks (blinded treatment period) followed by a further 8 weeks of micronutrients in the open-label part of the study. The teenagers will complete online questionnaires/psychometric testing at baseline and throughout the study.

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 emotional dysregulation is a diagnosable mental illness in the DSM. The Researchers explained that it is not in the DSM and is not a diagnosis specifically, but is transdiagnostic. The Committee expressed concern about participants self-diagnosing and self-referring via their parents, and the potential stigma associated with that. The Researchers stated that ED would be described as a symptom, rather than a diagnosis. The Researchers further explained that ED is a group of emotions, and identifying it can help those experiencing it to manage those emotions. The Researchers explained that an *impairing* level of ED would be an inclusion criterion, as determined through the use of internationally approved questionnaires.
2. The Committee discussed whether seeking online consent is appropriate, given the vulnerable population being invited onto the study. The Researchers explained that a prolonged consent process would be used, with a video meeting of both child and parent, and a video meeting of each separately. The PIS/CF would be mailed to participants, signed and a photo would then be sent back to the Researchers.
3. The Committee asked about the purpose of the ‘extra questions’ at the end of the protocol, which the Researchers clarified were study-relevant questions not attached to any formal questionnaire.
4. It was confirmed that the study is receiving scientific peer review from SCOTT.

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 suggested that it might not be appropriate for the individuals in the target age range to be consented by their parents. They suggested that competent adolescents could be asked to consent, and others would require parental consent. The Researchers noted that the study does involve some complexity, and confirmed that they would like to seek parental consent or informed consent from the adolescents where appropriate.  
   Action requested: please update the Participant Information Sheet and Consent Forms and study protocol.
2. The Committee asked how children would be consented to the study. The Researchers explained that both parents and children would be asked to participate in the study, with the parents completing questionnaires to provide their own perspective about the emotional regulation of the child. They would like to first have a joint meeting with the parent and child, followed by an individual meeting to explain the study to the child. The Committee stated that consent would also need to be sought from the parent(s), and this dual participation would need to be made very clear in the participant information sheets, including that the parents will be asked to provide information *about* the children.
3. Action requested: please update the Participant Information Sheet and Consent Forms and study protocol as appropriate.
4. Further information requested: please develop a formal data management plan. You can see the HDEC template here: <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(PIS/CF):

1. Please add a separate information sheet and consent form to cover the *parent’s* participation specifically.
2. Please proof-read for technical language and check formatting to improve readability.
3. Assent form: please state that participants will be asked to re-consent when they turn 16, and upload a form for that re-consent.
4. Please refer to the study investigators as researchers, rather than clinicians.
5. Please ensure that the frequency of adverse reactions aligns with the CIOMS guidance.
6. Under ‘what if my symptoms get worse’, please add a number they can call.
7. Page 3 of the PIS: “we encourage you to include your parents in this meeting as we would also like their perspective on how you are doing in the study”. Please state instead that your parents will be included.
8. Please correct the page numbering in the PIS.
9. Add a section stating confidentiality and how data will be managed, stored and used (differentiating between identifiable, de-identified and anonymous data – see the new HDEC PIS/CF template for guidance).

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.
* Please attach the SCOTT review for the study if it has been received.

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

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| **5** | **Ethics ref:** | **20/STH/162** |
|  | Title: | Residential care staff use of relational and supportive interventions for residents living with dementia who like to walk |
|  | Principal Investigator: | Mrs Christianah Adesina |
|  | Sponsor: |  |
|  | Clock Start Date: | 01 October 2020 |

Mrs Christianah Adesina 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 using critical ethnography (i.e. it involves observation of residents/staff in public areas of the residential facility, and interviews with same people) in order to explore how residential care staff use relational and supportive interventions with residents living with dementia who like to walk.
2. Participants are residents with dementia, who like to walk, their family carers/whanau, and residential care staff. Participants will be recruited from several aged care facilities; the facility manager will provide consent on behalf of the facility.

Summary of resolved ethical issues

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

1. The Committee noted the vulnerability of the participants, by virtue of some having reduced cognition and a restricted ability to make independent decisions due to having dementia. The Researcher explained that previous experience has shown that this population, despite their vulnerability, wish to participate in research. In order to respect that, while acknowledging their vulnerability, a continuous consent process will be used, with simple and concise information presented to participants at each visit.
2. It was confirmed that the CI for the study would be assessing individuals’ capacity to consent. The researcher confirmed the CI was appropriately trained and experienced to make the determination of capacity to consent. The Researcher explained that she would be running the study as a researcher, and would not be practicing as a registered nurse during the study period.
3. The Committee asked how participants will be involved if certain staff members do not wish to participate. The Researcher explained that staff who do not wish to participate will not be observed, and instead it will simply be noted that the participant interacted with ‘a staff member’. Families who participate will only be included if the whole family consents.
4. The Committee asked if Māori consultation is being sought, which the Researcher confirmed has already been completed.
5. The Committee asked for clarification about what types of data will be collected. The Researcher clarified that the main information being collected is the documents the residential facility has about walking and their policies regarding residents walking with dementia, and the observations recorded in written form. One-on-one interviews will also be recorded in written notes.

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 how potential participants will be identified. The Researcher explained that facilities will be approached and asked to identify those residents with dementia who like to walk, and in doing so will be accessing health information about those individuals. The Committee asked for a justification to be given for the use of this information.

Further information requested: please explain how the nature, degree and likelihood of possible benefits in accessing this information outweigh the nature, degree and likelihood of possible harms.   
Please also provide evidence showing that there are scientific, practical, or ethical reasons why consent cannot be obtained before accessing this information; that appropriate data governance plans are in place; and that you have identified whether consultation is required, and if required have undertaken appropriate consultation with cultural or other relevant groups, and those consulted support the proposed use.

1. Further information requested: please add a formal data management plan for all data used in the study. A template for this plan is available on the HDEC website: <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 (PIS/CF):

1. **PIS/CF residents**:
2. Consider whether the bullet points assist readability in each section.
3. There is some repetition (e.g. having a say) and that makes the PIS longer than necessary. Please check if any could be removed.
4. On the first page you say you will ‘have a chat’ with residents. However, just as important is that you plan to observe them, but this is not mentioned until the second page. Further you do not make it clear who you are looking at and what for and where you will be and how often they will be observed. It’s important for your participants to have a chance to consider if they will find this intrusive or not.
5. Please review for simplicity of the language, e.g. replace ‘it is voluntary to participate’ with ‘taking part in the study is your choice’.
6. Please proof-read for typos.
7. Consider amending the title to "how staff care for you when you want to walk"
8. Benefits section: the benefits are stated too strongly – please make clear that this study is very unlikely to have any benefits for participants.
9. Please simplify the language (and length of sentences) in most of the consent form clauses.
10. Please simplify the PIS further, removing any information/words which are not essential for the individuals, e.g. ‘your institution’, or bullet point 3 under ‘why am I being asked to participate’ on page 2.
11. Under ‘what are the risks involved in the study’, please describe what risks there may be.
12. For all forms: please remove the yes/no tick boxes from the consent form for all statements that aren’t truly optional.
13. **Staff PIS**: please describe the safeguards that are in place, in case the observations are critical of the residential facility. Please also describe this as a potential risk.
14. **Facility PIS:** please add that you have an obligation to inform the facility if any of the practices observed pose any risk to participants, and to report it if serious.
15. **Staff and family/carers PIS:** please state where interviews will take place, how long they will last for and who will be transcribing them.
16. **Family/carers PIS:** please make clear how the researcher found out who the reader is and why they’re being asked to take part in this study. Please also state whether the reader is being asked to support the decision making of their family member, or consent to take part themselves, or both.
17. **Staff PISCF:** Please amend to ensure the meaning of the language used is clear. Some of the language is confusing, e.g. "participants will have been looking after residents with dementia who walk for a minimum of three months" and "researcher will carry out one-on-on interview with the staff or with their support person culturally if they wish to do so".
18. **Staff and family/carers PIS**: Please add greater information about data collection and data management (refer to the HDEC template if unsure https://ethics.health.govt.nz/system/files/documents/pages/participant-information-sheet-consent-form-template-sep20.doc).

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 Prof Jean Hay-Smith and Mrs Helen Walker.

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| **7** | **Ethics ref:** | **20/STH/165** |
|  | Title: | Persica 002, Phase 1B PP353 vs Placebo in the treatment of chronic low back pain |
|  | Principal Investigator: | Dr Nigel Gilchrist |
|  | Sponsor: | Persica Pharmaceuticals Limited |
|  | Clock Start Date: | 01 October 2020 |

Deidre Thompson and team 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 a phase 1 first in human study of a new combination product (containing the antibiotic linezolid) which is to be injected into a single spinal disc for the treatment of chronic low back pain (CLBP).
2. The study will take place in 5 countries: it will recruit 40 participants with CLBP; 20 in NZ.
3. The study is in two parts:   
   Part A: Safety and tolerability in 6 patients (1 injection of product)   
   Part B: RCT versus placebo in 34 participants (up to 3 injections)

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 whether part A will also be conducted in other countries, which the Researchers confirmed. They explained that NZ is included due to the stable situation regarding COVID-19 in this country.
2. It was confirmed that the study has received approval from MHRA and is further receiving scientific peer review from SCOTT.
3. The Committee asked if the MODIC 1 changes could also be consistent with etiologies other than disc infection. The Researchers explained that it is possible, but currently MODIC 1 changes are thought to be most likely secondary to low-grade infection.
4. The Committee asked for information about the recruitment process and how conflicts of interest would be avoided. The Researchers explained that patients would be referred via their spinal surgeons, and would then be formally invited onto the study by the CI. Those patients would then be followed up by other research staff.
5. For future reference, the Committee stated that the questions in the application form about Māori should be answered more thoroughly.

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: please develop a formal data management plan, including details about use and storage of images and if/how they will be de-identified. You can see the HDEC data management plan template here: <https://ethics.health.govt.nz/system/files/documents/pages/data-only-management-template-oct2020.docx>
2. For the e-diary, please send out study email addresses to participants, rather than asking them to use their own email address.

The Committee requested the following changes to the Participant Information Sheet and Consent Form (PIS/CF):

1. It was clarified that the antibiotic has been administered in humans using this method or in this formulation. Please state in a clear box at the top of the PIS that this medication has not been given in this formulation or in this method of administration before.
2. Please review the formatting, using wider margins, bullet points, and a more reader-friendly layout.
3. Please use a lay-friendly title for each PIS.
4. Please state that there may be no benefit from participating in this study, and the risk that chronic lower back pain might get worse.
5. Please explain in the risks section what the potential consequences of the stated risks are (for example, if the dose is injected in the wrong place).
6. Please list all potential adverse reactions, preferably with frequencies.
7. Please include a NZ-relevant contraception statement (see the HDEC reproductive risk template) as some of the methods listed are not available in NZ.
8. Please state which tests are notifiable to the Medical Officer of Health.
9. Please explain that PK samples will be sent overseas and include an appropriate cultural statement.
10. Please state how long participants will be required to lie flat for study procedures.
11. Please state that the participants’ GP will be informed of their participation in the study.’
12. Image-training PIS: please add greater information about how data will be managed (what will be done with the images, if they will be identifiable and shared in any form). Please refer to the HDEC PISCF template data collection and use section for guidance on what should be included (https://ethics.health.govt.nz/system/files/documents/pages/participant-information-sheet-consent-form-template-sep20.doc)

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 Assc Prof Mira Harrison-Woolrych.

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| **8** | **Ethics ref:** | **20/STH/166** |
|  | Title: | (duplicate) MINOCA-BAT |
|  | Principal Investigator: | Dr Jithendra Somaratne |
|  | Sponsor: |  |
|  | Clock Start Date: | 01 October 2020 |

No member of the research team 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. Patients who have an acute Myocardial Infarction (AMI) but are showing no evidence of coronary artery disease after an angiogram (i.e. no coronary artery stenosis ≥ 50%), and who have met the inclusion and no exclusion criteria, will be randomized to one of four arms of secondary prevention treatment.

1. Beta blocker or ACEI/ARB

2. Beta blocker alone

3. ACEI/ARB alone

4. No beta blocker or ACEI/ARB

1. Patients will receive a follow-up phone call from a research nurse every 6 months for the duration of the study, to assess compliance and endpoints. Patients will be notified when the study ends and will be advised to continue treatment until their next ordinary visit to their physician.

Summary of outstanding ethical issues

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

Actions required:

1. Peer Review: please state whether clear exclusions for MINORCA enrolments have been addressed in protocol.
2. Recruitment: please confirm that participants will be given the opportunity to speak with a research-only member of team during recruitment process (after the initial approach by a member of the participant’s clinical team), to minimise any conflict of interest for investigator-clinicians.
3. Please develop a brief data management plan. You can see the HDEC data management plan template here: <https://ethics.health.govt.nz/system/files/documents/pages/data-only-management-template-oct2020.docx>

Further information requested:

1. Please confirm that there will be no potential for future (un)related research using this study’s dataset, as stated in the application form.

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

1. Please add a short statement outlining the reproductive risks of the study medications, and asking participants to take all appropriate measures to avoid a pregnancy.
2. The GP should be informed of study participation.
3. Please add a statement that study data will not be made available to other researchers or used for future research (as per the application form).
4. State that data will be sent and stored overseas.
5. Please add a brief data risks statement (covering that you are sending data overseas, and what would be done in the event of a confidentiality breach).

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 Mrs Helen Walker.

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| **9** | **Ethics ref:** | **20/STH/168** |
|  | Title: | Effectiveness of Multistrain Probiotics as an adjuvant treatment in Major Depressive Disorder - a pilot study |
|  | Principal Investigator: | Dr. Venkat Naga |
|  | Sponsor: | Oakley Mental Health Research Foundation |
|  | Clock Start Date: | 01 October 2020 |

Dr. Venkat Naga 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 a pilot study of probiotics versus placebo in patients on medication for Major Depressive Disorder. It will be conducted in NZ only, and will involve recruiting from general practice.
2. The study design is a RCT with 20 patients (10 in each group) taking probiotics or placebo sachets for 8 weeks. Endpoints include interleukin biomarkers, completion of depression scales and food & exercise diaries.

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 the reasons for conducting this study. The Researcher explained that previous studies have not covered the eating aspect of MDD, or individuals with MDD in the community setting. Some of those previous studies have enrolled patients in in-patient units who will often be taking other medications.
2. The Committee asked how the Researcher would ensure that any safety information that becomes available during the course of the study would be communicated to participants. The Researcher explained that this would be done by contacting participants either by phone or email, and would be done promptly.
3. It was clarified that participants would be recruited from general practice centres, but screening and other study processes would happen at the University of Auckland.

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 about the aims of the study, and it was clarified that this is a feasibility study.

Action requested: Please amend the wording in the PIS about the purpose of the study, and make clear that this study is looking at the feasibility of conducting a larger randomised controlled study in New Zealand in the future.  
Please also amend the protocol to reflect this.

1. The Committee noted that the study design was not appropriate to achieve efficacy outcomes as stated in the PIS. The Researcher clarified that this is a feasibility study, which may lead on to an efficacy study.

Action requested: please amend the protocol and PIS to make clear that this study is looking at feasibility, and other aims are exploratory only.

1. Further information requested: please explain in the study protocol the processes that would be carried out in the event of a data breach.

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

1. The Committee asked about the risk of the probiotic disseminating in the air. The Researcher explained that, once opened, the bacteria can escape from the probiotic, creating a minor chance of contamination. This could pose a risk to immunocompromised people in the area.   
   Please amend the wording around this risk, stating simply that you should keep the probiotic sealed because there is a small risk to someone who is immune-compromised. Please also use a lay term in place of ‘disseminated’.
2. Risks/benefits section: please firstly state that there may be no benefit to participating in the study.
3. The Committee asked if there is any risk of the probiotic interfering with participants’ antidepressant medication. The Researcher explained that there is no known risk of this, however there is some risk in asking participants to not change their medication throughout the study. The Committee asked for a statement to be added, along the lines of “if you experience worsening symptoms, here’s what to do”.
4. Please make it clear that only anonymous or coded information will be shared with the study sponsor.
5. Please state that the participant’s GP will be informed of their enrolment in the study.
6. Please explain the basic eligibility criteria more clearly, in lay terms.
7. Please use a PIS title appropriate for lay readers.
8. Please simplify all uses of the term ‘adjuvant’.
9. Please proofread for grammar and readability, i.e. checking for appropriate uses of bold text.

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 Mrs Helen Walker.

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| **10** | **Ethics ref:** | **20/STH/169** |
|  | Title: | ZN-c5-006: A study assessing the effect of food on ZN-c5, in healthy post-menopausal women. |
|  | Principal Investigator: | Dr Chris Wynne |
|  | Sponsor: | Novotech NZ Ltd |
|  | Clock Start Date: | 01 October 2020 |

Dr Chris Wynne 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.

Dr Devonie Waaka declared a potential conflict of interest due to working in the same institution as the CI and did not take any part in the approval process.

Summary of Study

1. This is a phase 1 open-label pharmacokinetics study of the effect of food on an investigational medicine (ZN-c5-006) for breast cancer. This is a CCST study (NZ only) including 18 healthy post-menopausal women. 150mg of Zn-c5 will be given on two occasions (2 study visits, each with a 2 night stay) under fed and fasting conditions, six days apart.

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: please correct the insurance certificate to state that the study involves 18 participants.

Decision

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

* Please address all outstanding ethical issues raised by the Committee.

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| **11** | **Ethics ref:** | **20/STH/170** |
|  | Title: | A Phase 2 Study to Evaluate Efficacy and Safety of AL002 in Participants With Early Alzheimer's Disease |
|  | Principal Investigator: | Dr Nigel Gilchrist |
|  | Sponsor: | Alector Inc. |
|  | Clock Start Date: | 01 October 2020 |

Dr Nigel Gilchrist and Deidre Thompson 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 an intervention study of AL002, a new medicine to treat Early Alzheimer's Disease.
2. The study design is a two-part phase 2, randomised, double-blind, parallel-group, dose-ranging, placebo controlled 4 weekly IV administration for 96 weeks.
3. In part 1 40 participants will be randomised 1:1:1:1 to AL002 at 15, 40 or 60 mg/kg or placebo.
4. Part 2 will include 225 new participants, plus part 1 participants who wish to continue in the study. After an interim assessment of available data one dose level may be discontinued.
5. Approximately 15 participants are expected to be enrolled in New Zealand.

Summary of resolved ethical issues

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

1. For future applications, the Committee asked for answers to questions in the application form to summarise relevant information in lay language, rather than refer only to protocol page numbers or sections.
2. The Committee noted the significant amount of time required on the behalf of participants in the study, and asked why no compensation was being offered to participants. The Researchers explained that participants tend to find the assessments beneficial for themselves, and consequently participate happily.
3. The Committee asked if there was the possibility of any incidental findings arising in the study, which the Researchers confirmed. The researcher explained how incidental findings would be managed.
4. The Committee asked how capacity to consent would be ascertained. The Researchers explained that participants in the study would be in the early stages of memory loss, and will be referred to them by a specialist who will have assessed their capacity.
5. The Committee asked, if study visits were required to be done remotely, how those would be recorded. The Researchers explained that they would be recorded via handwritten questionnaires. It was further clarified that in the event of a lockdown due to COVID-19, participants would not be able to go to the clinic to receive a dose of the study medication.
6. The Committee noted the use of questionnaires designed to identify suicidal ideation or behaviour, and asked what steps would be taken if that was detected. The Researchers explained that reviews of those results are conducted regularly, and any concerning findings would be communicated to the CI and the sponsor, and either discussed with the participant or withdrawn from the study and referred onwards if appropriate.

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: Please confirm which other countries have ethically approved the study.
2. Further information requested: Please upload a formal data management plan. You can see the HDEC template here: <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 (PIS/CF). These refer to the main PIS unless otherwise specified:

1. The Committee stated that whole genomic analysis should not be a compulsory element of participation. Please amend the PIS/CF accordingly.
2. Please add a table of visits, tests and time required (a schedule of assessments) to make this clear to participants.
3. Please state on the first page that this drug has not been tested on people with Alzheimer’s disease before.
4. Page 2 paragraph 7: please state in addition that group 1 will include a placebo cohort.
5. Page 3: please explain biomarkers in lay terms.
6. Page 6: storing samples for 25 years seems excessive, please explain why this is so long or make it similar to other samples.
7. Page 7: ensure the reference to permitted Cannibidiol use is permissible per NZ law.
8. Pages 8 and 9: the references to individual blood draw quantities is particularly unhelpful when these is no guide as to the frequency of each test. Suggest providing only the total amount of blood required during the study.
9. Page 9: brief reference is made to what appears to be mandatory genomic testing. Justify the mandatory nature of this testing. Discuss what genomic assays are planned. Include adequate information in the PISCF about the testing that will be done, potential importance to blood relatives, return of results etc. per the National Ethical Standards.
10. Page 9: Include laboratory names and cities.
11. Page 10: Include the likelihood of discomfort associated with the lumber puncture procedure.
12. Page 11: Replace references to acetominophen with paracetamol.
13. Page 12: Sexually active participants are by definition not practicing complete sexual abstinence - move from this section.
14. Page 12: Additional consent must be gained to collect pregnancy information from study participants; please make this clear.
15. Page 13: Explain why other costs for long visits (meals etc) will not be included.
16. Page 13: The compensation statement has been altered from that required to be used. Please use the HDEC-approved text.
17. Page 14: Please remove references to legal representatives.
18. Page 15: please add greater information to the data section, referring to the HDEC PISCF template for guidance:
19. Discuss whether scans performed will be retained in the participant's clinical record.
20. Discuss future research.
21. Discuss risks of data harm.
22. Discuss data sharing with 3rd parties eg Winterlight and the 'Data Company' collecting questionnaire recordings. The link to a privacy statement is insufficient. Explain who has access to / who owns the data collected. State whether data collected by these third parties be shared with other third parties for related and/or unrelated use (e.g. commercial purposes?). Currently the information provided is extremely unclear.
23. Page 15 paragraph 2: please amend to reflect the fact that participants may not be able to access some study specific data until after the study has been completed and data has been analysed to protect the scientific integrity of the trial.
24. Please remove all yes/no tick boxes that are not truly optional (i.e. informing the GP of study participation, as this should be mandatory for this study).
25. **Future Unspecified Research (FUR):**
26. Please state whether broader genomic research may be performed on these samples and make it clear (in lay language) that whole genome analysis may be performed
27. Please make clear that samples may be stored and analysed in any country.
28. Please explain data use, as per the HDEC template.
29. **Pregnancy PIS**:
30. Note that most NZ women are not under the care of gynaecologists for their pregnancy. It is preferable to refer to ‘Lead Maternity Carer’.
31. Please include the risk of increasing distress / anxiety due to study participation.
32. Note that a separate consent would be required for information collected from the newborn. This PIS can only cover information about the pregnancy and child before it is born.
33. Please state that their data will be collected as if it were the main participants’ data.
34. Please add a table of visits and visit durations.
35. Please ensure the data section has all the information outlined in the HDEC PISCF template, and made specific to the pregnant partner (who will not be having MRI scans etc).

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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| **12** | **Ethics ref:** | **20/STH/173** |
|  | Title: | (duplicate) BIOPRO Study |
|  | Principal Investigator: | Doctor Meghan Hill |
|  | Sponsor: |  |
|  | Clock Start Date: | 01 October 2020 |

Doctor Meghan Hill 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 application is for two research projects investigating the physiologic pathways relating to labour signalling and timing of birth. Participants will also be asked if they are willing to consent for their samples to be used in future unspecified research. Tissue collected includes maternal blood, cord blood from placenta, and placental/umbilical cord tissue.
2. Currently, the PI has funding to support research relating to the physiology of labour (The University of Auckland) and research regarding the mechanisms of stillbirth (The Health Research Council). The work on physiology of labour is planned to include samples of placenta/cord tissue, cord blood and maternal blood. The work relating to stillbirth is planned to include samples from the placenta only.
3. Pregnancy specimens inclusive of cord blood, placental tissue and amniotic fluid are genetically distinct from the maternal patient. The researchers will be relying on maternal consent for the use of samples of foetal origin.

Summary of resolved ethical issues

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

1. The Committee discussed whether the placenta and cord blood belong to the mother or to the baby, and discussed whether a separate consent form was required for the mother to consent on behalf of the baby after it is born. The Researcher explained that it is standard practice to consider both placenta and cord blood as belonging to the mother.
2. The Committee asked if cells will be cultured, which the Researcher clarified will not be done.
3. The Committee asked how samples to be used in future unspecified research will be stored. The Researcher explained that they would be stored in a registered laboratory, and that there are no plans to establish a new tissue bank.
4. The Committee asked if it is possible for the mother to consent to just one type of blood/tissue. The Researcher clarified that, what tissue is used will depend on clinical factors, but they will be seeking consent in each case for all types.

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: Please upload a formal data management plan. You can see the HDEC template here: <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 (PIS/CF):

1. **Main PIS**
2. please add greater information on the risks of sharing data and tissue for future unspecified research, and refer to the HDEC PISCF template for guidance. Please also state whether the genetic analyses may produce any clinically actionable results to the participant or their family, and whether participants will be informed of any such results.
3. page 6: under ‘what happens after the study’, please describe how a participant may withdraw their tissue from the study and what would happen to their tissue.
4. page 2: “placenta after it is discarded” – please note that placenta won’t be discarded for all women.
5. Consent form: please remove the clause about informing the GP.
6. **FUR PIS:**
7. please remove the phrase “you have been chosen”.
8. please add greater information about what will happen to the tissue: what people may have access to them, whether they may be sent overseas

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 Professor Jean Hay-Smith.

## 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:** | 10 November 2020 |
| **Meeting venue:** | Via video conference |

The following members tendered apologies for this meeting.

* Professor Jean Hay-Smith

1. **Review of Last Minutes**

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

1. **Matters Arising**

The Committee discussed the timing of the meetings, and decided to start future meetings at 10am with a half hour lunch break.

The Committee discussed a progress report (HDEC reference: URB/07/12/058/AM07) for a long-running study, which has revealed several aspects of the study that do not appear to be in accordance with the new National Ethical Standards. The Committee agreed to suspend approval for the study. The Researchers for that study have subsequently been contacted, and have notified the Committee of their decision to conclude the study.

The meeting closed at 5:15pm.