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| **Committee:** | Southern Health and Disability Ethics Committee |
| **Meeting date:** | 11 September 2018 |
| **Meeting venue:** | Sudima Hotel, Christchurch Airport, 550 Memorial Drive, Christchurch |

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| **Time** | **Item of business** |
| 11:30am | Welcome |
| 11:35am | Confirmation of minutes of meeting of 14 August 2018 |
| 11:45am | New applications (see over for details) |
|  | i 18/STH/170  ii 18/STH/176  iii 18/STH/177 **(CLOSED)**  iv 18/STH/178  v 18/STH/180  vi 18/STH/181  vii 18/STH/183 |
| 2:40pm | General business:   * Noting section of agenda |
| 2:55pm | Meeting ends |

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| **Member Name** | **Member Category** | **Appointed** | **Term Expires** | **Apologies?** |
| Ms Raewyn Idoine | Lay (consumer/community perspectives) | 27/10/2015 | 27/10/2018 | Apologies |
| Dr Sarah Gunningham | Non-lay (intervention studies) | 27/10/2015 | 27/10/2018 | Present |
| Dr Nicola Swain | Non-lay (observational studies) | 27/10/2015 | 27/10/2018 | Apologies |
| Dr Devonie Waaka | Non-lay (intervention studies) | 13/05/2016 | 13/05/2019 | Present |
| Mrs Kate O'Connor | Lay (ethical/moral reasoning) | 14/12/2015 | 14/12/2018 | Present |
| Assc Prof Mira Harrison-Woolrych | Non-lay (intervention studies) | 27/10/2015 | 27/10/2018 | Present |
| Dr Cordelia Thomas | Lay (The Law) | 20/05/2017 | 20/05/2020 | Present |
| Ms Rochelle Style | Lay (ethical/moral reasoning) | 14/06/2017 | 14/06/2020 | Present |

## Welcome

The Committee elected Mrs Kate O’Connor as Chairperson for the meeting.

The Chair opened the meeting at 11:30 and welcomed Committee members, noting that apologies had been received from Ms Raewyn Idoine and Dr Nicola Swain.

The Chair noted that it would be necessary to co-opt members of other HDECs in accordance with the Standard Operating Procedures. Dr Cordelia Thomas and Ms Rochelle Style confirmed their eligibility, and were co-opted by the Chair as members of the Committee for the duration of the meeting.

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 14 August 2018 were confirmed.

## New applications

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| **1** | **Ethics ref:** | **18/STH/181** |
|  | Title: | Co-Designing Health in Cerebral Palsy |
|  | Principal Investigator: | Mrs Melinda E Silva |
|  | Sponsor: |  |
|  | Clock Start Date: | 30 August 2018 |

Dr Fiona Graham was present in person for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. The study investigates the process of co-designing an eHealth intervention with, and for, parents of children with cerebral palsy for the purpose of supporting therapy exercise programmes that parents are implementing at home as part of their child's usual care.
2. It will also involve partnering with parents to co-design a future clinical trial to evaluate the effectiveness of the co-designed eHealth intervention and the feasibility of using a body-worn accelerometer (ActivPAL) at home with their child to monitor physical activity.

Summary of ethical issues (resolved)

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

1. The Committee noted that there was some confusion about the project being intervention or observational in nature and asked that this be clarified by the Researchers. The Researcher explained that there will be a separate application for an intervention study once this study has completed.
2. The Committee noted there is only one PIS for all children and young people under the age of 16 and suggested the Researchers refer to the HDEC templates which have assent templates for 7-11 year olds and 12-15 year olds. The Researchers could also refer to assent forms used by Starship Hospital.

Summary of ethical issues (outstanding)

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

1. The Committee asked how recruitment for the study would work. The Researcher explained they will obtain names from the Cerebral Palsy Register and also advise community groups. Interested parents will then self-refer. The Researchers will send out an information sheet which includes contact details for the Researchers together with a form which includes “questions for consent and participation demographics” and also a consent form which includes eligibility questions. The Committee was not satisfied with this process as it required potential participants to provide data prior to formally consenting. The Committee stated that the informed consent process should be done first and then screening for eligibility. This should be reflected in the protocol and information sheet for parents/caregivers, including when the GMFCS questionnaires for 4-6 year olds and 6-12 year olds will be asked. . (*Ethical Guidelines for Intervention Studies* *para 5.41 & 6.22*)
2. Please amend the parent/caregiver information sheet and consent form, taking into account the suggestions made by the Committee (*Ethical Guidelines for Intervention Studies* *para 6.22*).
3. The Committee had concerns that children’s views on participation may be marginalized by the recruitment process. The Committee asked that the protocol be updated to describe how children’s views will be heard and respected. *(Ethical Guidelines for Intervention Studies Appendix 2)*
4. The Committee stated that all children’s records must be held for ten years after the child turns 16. *(Ethical Guidelines for Intervention Studies Appendix 2)*

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

1. Add pictures and descriptions of study activities to help families understand what will be asked of them.
2. Please use lay terms to explain the project in simple English.
3. Clarify that the ActivPAL will be being tested for comfort and usability.
4. Explain if the ActivPAL will be collecting data and if so where it will go and who will see it.
5. Please amend the title of the forms for minors to reflect that they will be assenting and not consenting to be in research.
6. Please check that there are no unexplained acronyms in the information documents or questionnaires (eg, do not use the abbreviation “GMFCS” without explanation).
7. Please include that all children’s data is stored for ten years after the child turns 16.
8. Explain that whichever parent agrees to participate must participate throughout and that they cannot switch.Note that the make-up of the focus groups is likely to change depending on participant availability.
9. Explain that parents will not have to pay if the device is broken.
10. Explain that there is no guarantee that participants will benefit.
11. Explain that participants will have ongoing free access to the programme once it is developed.
12. Provide a better explanation of the different phases of the study including that the first stage is a feasibility study
13. Please include risks of using the device itself (eg, skin irritation)
14. Please remove the eligibility questions from the parents’/caregivers’ consent form (ie, questions 9-11). The collection of demographic and socioeconomic data should not be part of the consent form. The ladder question is potentially confronting; please emphasise there is no right or wrong answer.
15. Please add Māori cultural support, the Health and Disability Commissioner’s Advocacy service, and HDEC’s contact details to the end of the information sheets.
16. The Committee requested the compensation wording is updated for accuracy, they suggested the following statement: *“If your child were injured in this study, which is unlikely, you would be eligible* ***to apply*** *for compensation from ACC just as you would be if your child were injured in an accident at work or at home. This does not mean that your claim will automatically be accepted. You will have to lodge a claim with ACC, which may take some time to assess. If your claim is accepted, you will receive funding to assist in your recovery. If you have private health or life insurance, you may wish to check with your insurer that taking part in this study won’t affect your cover.”*

Decision

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

* Please amend the information sheet and consent form, taking into account the suggestions made by the Committee (*Ethical Guidelines for Intervention Studies* *para 6.22*).
* Please address how children’s views will be heard and how their records will be stored. (*Ethical Guidelines for Intervention Studies Appendix 2*).
* Please amend the study protocol taking into account the suggestions made by the Committee. (*Ethical Guidelines for Intervention Studies* *para 5.41*)

This following information will be reviewed, and a final decision made on the application, by Mrs Kate O’Connor and Dr Devonie Waaka.

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| **2** | **Ethics ref:** | **18/STH/176** |
|  | Title: | The SORE Study |
|  | Principal Investigator: | Dr Marinus Stowers |
|  | Sponsor: |  |
|  | Clock Start Date: | 30 August 2018 |

Dr Marinus Stowers was not present for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. The study evaluates the safety and efficacy of ropivacaine for regional anaesthesia in lower limb surgery.
2. Ropivacaine, a local anaesthetic, will be given intraosseously (into the bone). The study will assess the safety and efficacy of two different doses in reducing pain during and after surgery.

Summary of ethical issues (outstanding)

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

1. The Committee stated that it was unclear what treatment the three study groups would receive in their respective arms. Particularly in the standard care/control arm of the study. Will the anaesthesia in this arm be standardised given differing practices, how will anaesthesia be administered to ensure the study blind is maintained, and how data will be managed and stored? Please explain these issues more thoroughly in the protocol and information sheet (*Ethical Guidelines for Intervention Studies* *paras 6.22 & 5.41*)
2. Please amend the information sheet and consent form, taking into account the suggestions made by the Committee (*Ethical Guidelines for Intervention Studies* *para 6.22*).
3. The Committee noted that arterial cannulation would be performed on all participants and that it was not apparent what justification there was for the risks associated with this procedure versus the benefits., particularly to control-arm participants. (*Ethical Guidelines for Intervention Studies* *paras 5.18 – 5.21*).
4. Please clarify if there is a placebo in the study as this is mentioned in the application form but not the study protocol or the information sheet. (*Ethical Guidelines for Intervention Studies* *paras 5.22*).
5. Please respond to the peer review comments by acceptance or rebuttal of the issues raised. (Ethical Guidelines for Intervention Studies Appendix 1)
6. Please justify why the study will not be collecting ethnicity data in NZ-led study. Please use Statistics New Zealand's ethnicity classifications when collecting ethnicity data to ensure the options available are suitable for New Zealand participants. These classifications are: *New Zealand European, Maori, Samoan, Cook Islands Maori, Tongan, Niuean, Chinese, Indian, Other (such as Dutch, Japanese, Tokelauan) please state. (Ethical Guidelines for Intervention Studies para 5.41)*

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

1. The PIS begins by stating the purpose of the study is to ‘test a different way of giving local anaesthetic during ACL reconstruction surgery” but it is more than that because, as described in the researcher’s application, it also involves an approved medicine being used for a new indication or through a new mode of administration
2. Please explain technical terms in lay language in the PIS (eg, cannula)
3. Please make it clear in the PIS that this is a pilot study
4. Describe the frequency of the side effects associated with the study drug, and also describe the risks (and frequency of side effects) of the standard care anaesthetic for comparison.
5. Please also outline in the PIS the potential benefits of using ropivacaine
6. Please produce a flow diagram to help participants understand the study process from consent to completion and how the arms of the study differ.
7. Explain how participants will be monitored during the study.
8. The PIS does not include a reference participant’s rights of access to data and correction under the Privacy Act.
9. Please explain why participants may need to be contacted in the future if required (app r.2.4). If this is necessary, participants must consent.
10. If incidental findings/abnormal results may be found through this research, please include a plan to manage them and refer to them in the PIS. Abnormal findings are mentioned in the consent form but not in the PIS (matters should not be raised in the consent form for the first time)
11. Are individual results able to be returned to participants (at their option). If so, please include in the PIS and the consent form. The consent form should only include tick boxes where the statements are truly optional.
12. Please amend the PIS and consent form to consent to informing GPs of study participation.

Decision

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

* Important information such as study process and on risks is missing from the information sheet. (*Ethical Guidelines for Intervention Studies* *para 6.22*).
* The protocol lacks key information about the use of placebos or how the blind will be maintained. (*Ethical Guidelines for Intervention Studies* *paras 5.22 & 5.41*)
* That scientific issues associated with standard care being variable have not been addressed. *Ethical Guidelines for Intervention Studies para 3.5)*

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| **3** | **Ethics ref:** | **18/STH/183** |
|  | Title: | MyeChild 01 |
|  | Principal Investigator: | Dr Siobhan Cross |
|  | Sponsor: | ANZCHOG |
|  | Clock Start Date: | 30 August 2018 |

Dr Siobhan Cross was present by teleconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. MyeChild 01 is an international phase III clinical trial in children with acute myeloid leukaemia (AML). Trial questions are aimed at improving patient outcomes and limiting treatment related toxicity.

Summary of ethical issues (outstanding)

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

1. The Committee stated that the information sheet was very long and the amount of information included could impact on understanding. The Committee asked that, where possible, the PIS be simplified without excluding information. *(Ethical Guidelines for Intervention Studies* *para 6.22*).
2. Please amend the information sheet and consent form, taking into account the suggestions made by the Committee (*Ethical Guidelines for Intervention Studies* *para 6.22*).
3. The Committee had concerns about what information is being sent to Pfizer and the identifiability of it (currently proposed to include DoB, initials and gender). Please clarify this and include this in the protocol and information sheets, noting the committee’s preference that only YoB be used. (*Ethical Guidelines for Intervention Studies* *paras 5.41 & 6.22*).
4. The Committee asked the researchers to clarify if there are any future unspecified research studies in addition to the four optional future studies referred to in the PIS. If not, please remove the PIS and consent form entitled “Optional Future Unspecified Use of Tissue Consent Form’ because it is confusing. (*Ethical Guidelines for Intervention Studies* *para 5.41*)
5. The re-consent forms for 16+ should separately identify, and align with, the 4 optional future research studies which are referred to in the PISC for the Randomization 1 and 2 parts of the study.

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

1. Please clearly explain what is standard care and what is additional as part of research. The Committee suggested a flow chart as part of this to help explain the study processes and allocation.
2. Please move the side effects section to be before the optional substudies sections.
3. Please include that the supplier of the study drug, Pfizer, will being sent data about patients including any adverse events etc. Please list what information will be sent to Pfizer.
4. The Committee requested an amendment to the study title because it was concerned about the potential conflation between ‘my child’ as a descriptor of a parent’s relationship to his or her child and ‘mye child’ being a study about research into AML with the possible connotation that parents may feel they should consent to the participation of their child in the study to be caring parents .
5. Please include data risks in the section about the Optional Studies because they are particularly relevant to them, especially the studies which involve genetic research (eg, of re-identification and protection of confidential information outside New Zealand may be different and offer less protection). Please also note in the optional study of tumour banking for future research that the decisions about whether or not future studies will be undertaken will be determined by ethics committees outside New Zealand which may apply different criteria to those applied by New Zealand ethics committees).
6. The Committee requested the compensation wording is updated for accuracy, they suggested the following statement: *“If you were injured in this study, which is unlikely, you would be eligible* ***to apply*** *for compensation from ACC just as you would be if you were injured in an accident at work or at home. This does not mean that your claim will automatically be accepted. You will have to lodge a claim with ACC, which may take some time to assess. If your claim is accepted, you will receive funding to assist in your recovery. If you have private health or life insurance, you may wish to check with your insurer that taking part in this study won’t affect your cover.”*
7. Please clarify whether there is a 5th optional study which should be clearly explained in the PIS and consented for, namely, remaining samples of blood and bone marrow taken for MRD testing – currently the PIS for R1&R2 refers to this (page 7)

Decision

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

* Please amend the information sheet and consent form, taking into account the suggestions made by the Committee (*Ethical Guidelines for Intervention Studies* *para 6.22*).
* Please amend the study protocol taking into account the suggestions made by the Committee. (*Ethical Guidelines for Intervention Studies* *para 5.41*)

This following information will be reviewed, and a final decision made on the application, by Mrs Kate O’Connor and Mrs Sarah Gunningham.

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| **4** | **Ethics ref:** | **18/STH/178** |
|  | Title: | (duplicate) DBT at Korowai Manaaki: A Process Evaluation |
|  | Principal Investigator: | Dr Clare-Ann Fortune |
|  | Sponsor: | Victoria University of Wellington |
|  | Clock Start Date: | 30 August 2018 |

Ms Molly Weenik was present by teleconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. The study evaluates the use of Dialectical Behavioural Therapy at Korowai Manaaki through quantitative and qualitative methods to get a clear idea as to how the programme is being implemented and allow feedback to flow back through to the programme itself.

Summary of ethical issues (resolved)

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

1. The Committee noted that some of the reasons for the application being previously declined had not been addressed. The Committee noted the efforts made by Ms Weenik, one of the Co-investigators who is doing this research as part of her Masters’ degree. The Committee expressed disappointment that the supervising CI had not appeared before the Committee and had also not appeared before the Central HDEC when this research was declined.

Summary of ethical issues (outstanding)

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

1. Please amend the information sheets as well as the assent and consent forms, taking into account the suggestions made by the Committee (*Ethical Guidelines for Intervention Studies* *para 6.22*).
2. Please clarify what the process is for determining who will provide consent for the young person to take part in the study e.g. parent, or legal guardian. (*Ethical Guidelines for Intervention Studies* *para 5.41*)
3. The Committee had concerns about how disclosures of abuse or other sensitive issues will be managed. Likewise the how issues disclosed by staff such as stress or burnout also need a management plan. Please explain how in the protocol and information sheets. (*Ethical Guidelines for Intervention Studies* *para 5.41 & 6.22*)
4. Please provide evidence of peer review that shows that the pre and post testing sample size is powered or amend the protocol to not assess this. (*Ethical Guidelines for Intervention Studies* Appendix 1)
5. Please provide a facilitator information sheet and consent forms. (*Ethical Guidelines for Intervention Studies* section *6*).
6. The protocol does not address potential risks to participants. Considering the protocol allows researchers to meet youth offenders and whānau in their homes, this should be explicitly referred to in the protocol. In addition, please clarify whether the researchers are trained in home-based interviewing. (Ethical *Guidelines for Intervention Studies* *para 5.41*)

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

1. Please tailor all PISs to the relevant audience. Currently, the PISs for the under 16s, the staff, the family/whānau and the over 16s are not tailored sufficiently to those participants involvement in the research. Similarly with the consent forms.
2. Please include separate PISs and assent forms for appropriate age brackets for the under 16s. The templates on the HDEC website will provide assistance. Please include pictures on the 14 to 15 year old forms to help ensure participants with literacy issues can still understand what they are being asked. Please explain to participants what Dialectic Behaviour Therapy is.
3. Please directly address participants e.g. “You will be asked to…”
4. Please amend the statement “make the program the best that is can be” on page two as it could be considered unduly influential..
5. Please remove the statement about a copy of the thesis being given to all organisations.
6. Please simplify the statement “young people’s file data..” and explain what this actually involves in simple terms.
7. Please remove the ACC statement as ACC do not cover mental injury.
8. Please state that participants will not specifically benefit from participation in this study but the research may help young people in the future who attend Korowai and undertake DBT.
9. Please explain that once the tape is turned off participants will not be able to change anything or remove data. Please note the committee’s preference that a longer ‘cooling off’ period be offered;
10. Please consider adding a 24 hour contact number as the current one is an office hours landline.
11. Please add a sentence to the staff sheet about them not having to give a reason to refuse and that it will not affect the care of any of the young people participating in the research..
12. Please consider whether the identifiability of staff may also have implications for their employment. Is so, it should be discussed as a risk. Please also consider other risks for staff and identify them.
13. If staff are present during the interviews (for safety reasons) the young people should be told in the PISs.
14. Please clarify what you be asking staff about. Currently, the PIS for staff states the interview will be covering topics such as "what young people find helpful and what involvement whanau have"; but there is no mention of staff perspective.
15. Please explain how disclosures will be managed from all participants.
16. Please remove the withdrawal statement from the whānau consent form.
17. Please amend the commencement date wherever it is given.
18. Please explain that facilitators are the people who have been working with the young people.
19. Mention that the researcher will be observing the unit in all information sheets, whether they will be sitting in on DBT sessions and what information will be recorded.
20. Explain what information will be presented to the Auckland DHB and Oranga Tamarki Regional Youth Forensic Services. It is not sufficient to state that information will be presented to those organisations ‘in a way that suits them”. The young people should be very clear about who will have access to the answers they have given - will the staff have access? Parents/caregivers? Care must be taken to ensure that participants are not identifiable from the publication of the study results
21. Please address rights of access to study information and correction (where relevant) in all PISs, including whether transcripts may be reviewed and corrected.
22. Please clarify what ‘anonymous’ information will be kept in the study database and what future research it may be used for. The data does not appear to be anonymous because pseudonyms are being given.
23. Access to the ‘file data’ of young people to obtain information about their charges, sentences, risk assessment information such as pre-and post-psychometric measures (eg the Difficulties in Emotion Regulation Scale) must either be consented or a waiver of consent must be justified to the committee in terms of guideline 6.43 of the NEAC Observational Guidelines.
24. Study data must be retained for 10 years after a young person has turned 16.
25. Please include a data management section in the protocol.
26. Please reconsider the koha of three pieces of chocolate for young people who participate in the study and who are in the residence (compared to $15 for those who were previously in the residence)
27. Please make it clear that the research is being undertaken as part of a Masters’ thesis.

Decision

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

* Important information was missing from the information sheets and consent forms. An information sheet and consent form for facilitators was missing. *(Ethical Guidelines for Intervention Studies Section 6)*
* The study protocol lacks a plan for how disclosures from the young people and staff will be managed with confidentiality and how these will be referred and escalated. (*Ethical Guidelines for Intervention Studies* *para 5.41*)
* It was unclear if the study sample size is sufficiently powered to draw some of its’ proposed conclusions. (*Ethical Guidelines for Intervention Studies* Appendix 1)

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| **5** | **Ethics ref:** | **18/STH/180** |
|  | Title: | Improving Nutrition in Youth Offenders: Barriers and Solutions |
|  | Principal Investigator: | Dr Hermione Roy |
|  | Sponsor: |  |
|  | Clock Start Date: | 30 August 2018 |

Dr Hermione Roy was present by teleconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. The study investigates perceived barriers to young people at Korowai Manaaki eating a healthy diet as well as potentially taking micronutrients (multi-vitamins and minerals).
2. The results will be used to inform an intervention package to help improve young people's diets.

Summary of ethical issues (resolved)

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

1. The Committee queried if the Researcher will be making claims about the efficacy of the nutritional supplement. The Researcher confirmed she will not be making claims about any nutritional supplements’ efficacy and would amend the study documentation accordingly.

Summary of ethical issues (outstanding)

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

1. Please amend the information sheet and consent forms, taking into account the suggestions made by the committee *(Ethical Guidelines for Observational Studies para 6.10)*
2. The Committee noted that while study participants could be considered vulnerable due to their age or situation they are only being asked to complete a food preference survey. The Committee felt that young people in general will be competent to complete a survey asking them about their food preferences and that the participants should therefore provide their own consent wherever possible. (*Ethical Guidelines for Observational Studies para 6.10)*

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

1. Make it clear that, if vitamins or micronutrients are prescribed in the unit, participants may have to source and pay for them if they wish to continue taking them after leaving the unit.Amend the title of the young person’s assent form to reflect that young people can consent to a survey about their food preference.
2. Please explain that food may not improve during their time at Korowai Manaaki but that it may be better for young people in the future.
3. Please use Statistics New Zealand's ethnicity classifications when collecting ethnicity data to ensure the options available are suitable for New Zealand participants. These classifications are: *New Zealand European, Maori, Samoan, Cook Islands Maori, Tongan, Niuean, Chinese, Indian, Other (such as Dutch, Japanese, Tokelauan) please state.*
4. Please remove promotional statements such as “Vitamins and minerals help people stay healthy”
5. Please give all participants (including the young people) the option of receiving a lay-friendly summary of results.
6. Please state that there will be healthy food provided at the meetings.
7. Please use the consent form template for the consent form for staff participants, using tick boxes, where the issue is truly optional.
8. Please review the PIS for young people to ensure it makes sense. For example, the first section talks about ‘these groups’ but the focus groups haven’t been mentioned at that point (they are not mentioned until the second section).
9. The PIS for young people mentions that members of the groups will be asked not to share what is discussed in the group. Please add in words to the following effect: “And you must not share with other people what was said in the group because we want everyone’s privacy respected”.
10. The young people should also know about their right to withdraw from the research – this right is not mentioned in the PIS.
11. All participants (including the young people) should know that they have rights to access their data and to correct it if there are mistakes.
12. The staff PIS mentions that anonymised notes will be entered into an electronic file and stored on the principal investigator’s password protected computer indefinitely.  Please note that the notes are de-identified, not anonymised and amend the PIS accordingly.
13. Please improve the safety and confidentiality section of the protocol by providing more detail about data management and security. For example: please include information pertaining to the assignment of unique study numbers to all participants, how and where the key-code to unlock the de-identified data will be stored, justify the indefinite retention of study data and explain why the audio tapes need to be kept once transcribed, improve the storage of study data – it is not sufficient to keep it on the PI’s computer, notwithstanding it is password protected; include information about how many people may access the data
14. Please consider whether there is a risk for the staff participants that their comments will be readily identifiable by their managers and whether that presents a risk for their general employment. The staff PIS mentions only that their participation in the research will not impact on their relationship with Korowai.

Decision

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

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

This following information will be reviewed, and a final decision made on the application, by Mrs Rochelle Style and Mrs Sarah Gunningham.

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| **6** | **Ethics ref:** | **18/STH/170** |
|  | Title: | Ketamine and Neuromodulation in Anorexia Nervosa |
|  | Principal Investigator: | Professor Paul Glue |
|  | Sponsor: |  |
|  | Clock Start Date: | 30 August 2018 |

Professor Paul Glue was present by teleconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. The study investigates the effects of ketamine alone, neuromodulation alone, and ketamine plus neuromodulation, on mood, obsessionality, and eating disorder symptoms in patients with enduring anorexia nervosa.

Summary of ethical issues (outstanding)

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

1. The Committee noted that patients with a body mass index of 13 could be considered acutely unwell and that the ethical guidelines state that intervention studies should always be conducted in the least vulnerable members of a vulnerable group. The committee stated that they did not feel sufficient justification had been made for including these participants. *(Ethical Guidelines for Intervention Studies para 5.30)*
2. The Committee stated that key information was missing from the protocol and requested that the following be added:
   * How patients would be recruited and if this would be through their GPs or a community mental health team.
   * The justification for recruiting patients at the lowest end of the BMIs considered as inclusion;
   * That inpatients would not be recruited and that research nurses will make the initial recruitment approach.
   * That a support person for dosed participants once they return home is a requirement and not an option.
   * How the risk of the dose size, given the metabolic effects of anorexia, will be managed.
   * The scientific rationale for the selected dose, particularly with regards potential toxicity in this population, as the current dose is based on studies in depression and anxiety, not anorexia.
3. Please provide criteria for study termination as the current ones do not align with the tests being performed in the study. E.g. there is no electrolyte testing in the study. (*Ethical Guidelines for Intervention Studies* *para 6.64*).
4. Please provide a more in depth explanation for how safety will be monitored and assessed in the study including if there will be any independent persons on the data safety monitoring committee. *(Ethical Guidelines for Intervention Studies para 6.50).*
5. Please amend the information sheet and consent form, taking into account the suggestions made by the Committee (*Ethical Guidelines for Intervention Studies* *para 6.22*).
6. The Committee felt that the peer review document did not provide sufficient assurance that the study design was robust. Please provide further evidence of favourable independent peer review of the study protocol (*Ethical Guidelines for Intervention Studies* Appendix 1)

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

1. Please use the HDEC reproductive risks wording which can be found on our website.
2. Please reword the risk section as it appears to refer to anxiety and not anorexia nervosa.
3. Please summarise what assessments will be performed in lay language.

Decision

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

* Please amend the information sheet and consent form, taking into account the suggestions made by the Committee (*Ethical Guidelines for Intervention Studies* *para 6.22*).
* Please provide evidence of favourable independent peer review of the study protocol (*Ethical Guidelines for Intervention Studies* Appendix 1)
* Please amend the study protocol taking into account the suggestions made by the Committee. (*Ethical Guidelines for Intervention Studies* *para 5.41*)
* Please provide details of the Data Safety Monitoring plans *(Ethical Guidelines for Intervention Studies para 6.50).*
* Please justify the inclusion of such a highly vulnerable group (BMI 13 patients with enduring anorexia nervosa) in the study. (*Ethical Guidelines for Intervention Studies* *para 6.64*).

|  |  |  |
| --- | --- | --- |
| **7** | **Ethics ref:** | **18/STH/177** **(CLOSED)** |
|  | Title: | BEDROC Study |
|  | Principal Investigator: | Prof Paul Glue |
|  | Sponsor: | Douglas Pharmaceuticals |
|  | Clock Start Date: | 30 August 2018 |

Prof Paul Glue was present by teleconference for discussion of this application.

Potential conflicts of interest

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

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

Decision

This application was *provisionally approved* by consensus.

## 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:

|  |  |
| --- | --- |
| **Meeting date:** | 09 October 2018, 11:45 AM |
| **Meeting venue:** | Sudima Hotel, Christchurch Airport, 550 Memorial Drive, Christchurch |

The following members tendered apologies for this meeting.

1. **Problem with Last Minutes**

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

The meeting closed at 2:45pm.