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| **Committee:** | Extra HDEC Committee |
| **Meeting date:** | 24 September 2021 |

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| **Time Review****Reference** | **Project Title** | **Coordinating Lead****Investigator Reviewers** |
| 11:30- 21/CEN/23811:55am | (duplicate) Feasibility of implementing Ballistic StrengthTraining to improve mobility outcomes in inpatients with Traumatic Brain Injury | Mrs IzelGilfillan | Devonie / Leonie |
| 11:55- 21/CEN/24312:20pm | A Study to Investigate the Clinical Effectiveness andSafety of AK120 in Adults with Moderate-to-Severe Atopic Dermatitis | Prof. MariusRademaker | Tony/Leesa |
| 12:20- 21/CEN/24512:45pm | GENIUS | Dr Michelle Wilson | Leonie/ Barry |
| 12:45- 21/CEN/2471:10pm | Establishment of colorectal cancer organoids for therapeutic screening | Dr Rachel Purcell | Tony/ Barry |
| 1:30- 21/CEN/2421:55pm | Understanding apathy in Huntington's disease | DrCampbell/CJLe Heron | Leonie /Leesa |
| 2:20- 21/CEN/2462:45pm | Identification of the effects of methamphetamine using MRI scans | AP Miriam Scadeng | Devonie / Leonie |
| 1:55- 21/CEN/2392:20pm | Understanding Child Abuse Victims, their Caregivers and Clinicians Treatment Experience of TraumaFocused Cognitive Behavioural Therapy (TF-CBT). | MISSAUDREYKUSASIRA | Tony/ Barry |
| 2:45- 21/CEN/2403:10pm | Prevention of diabetes in Chinese, Caucasian, Māori & Pacific urban phenotypes resident in New Zealand | Dr Jennifer Miles-Chan | Tony /Leesa |

## Welcome

The Chair opened the meeting at 11:00am with a karakia.

Kia hora te marino

Kia whakapapa pounamu te moana

Hei huarahi mā tātou i te rangi nei

Aroha atu

Aroha mai

Tātou i ā tātou katoa

Hui ē!

Tāiki ē!

The Chair welcomed Committee members, noting that apologies had been received from Mr Barry Taylor.

The Chair noted that it would be necessary to co-opt members of other HDECs in accordance with the Standard Operating Procedures. Dr Patries Herst confirmed her eligibility and was co-opted by the Chair as a member 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

The Committee agreed that applications heard at the meeting would be transferred to the Southern Health and Disability Ethics Committee for long term governance.

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| **1**   | **Ethics ref:**   | 21/CEN/238 |
|   | Title:  | (duplicate) Feasibility of implementing Ballistic Strength Training to improve mobility outcomes in inpatients with Traumatic Brain Injury |
|   | Coordinating Investigator:  | Mrs Izel Gilfillan |
|   | Sponsor:  |  |
|   | Clock Start Date:  | 19 August 2021 |

Mrs Izel Gilfillian was present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. The study is a single arm feasibility study assessing ballistic strength training on mobility post moderate to severe TBI.

Summary of outstanding ethical issues

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

**SPONSOR:**

1. Please identify a sponsor for the study (e.g. the rehabilitation institution the study will occur at). In this context the sponsor is not the funder of the study but rather the organisation responsible for its management.

**DISSEMINATION OF RESULTS**

1. Please ensure all participants are provided with the option of receiving a lay summary of study results from the researcher, once these are available (p.2.8). A yes/no option in the consent form can be used to indicate preference.

**DATA MANAGEMENT**

1. Please provide a data management plan to satisfy Standard 12.15a of the NEAC Standards (2019); some elements are not covered in the PISCF. An exemplar is [available on the HDEC website](https://ethics.health.govt.nz/guides-templates-and-forms/data-and-tissue-management-plan-templates/) and may be useful.

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

**MAIN PISCF**

1. Amend results section to give participants the option of receiving a lay summary of study results.
2. Please undertake a general revision of formatting and headers.
3. Please update the sheet to name the Sponsor of the study.

**APHASIA PISCF**

1. Please include more information in the aphasia sheet on what is happening to participant data i.e. state it is being sent to South Africa and include the risk of privacy / confidentiality breach. Please include information on the risk of a privacy / confidentiality breach of participant data.
2. State that information already collected will be retained if the participant withdraws.
3. Provide participants with the option of receiving a lay summary of study results.
4. Please undertake a general revision of formatting and headers.
5. Provide all contact numbers (direct dial if possible).

**Decision**

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

1. Please address all outstanding ethical issues, providing the information requested by the Committee.
2. Please update the participant information sheet and consent form, taking into account feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17).*
3. Please update the study protocol, taking into account the feedback provided by the Committee. (National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.7).

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

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| **2** | **Ethics ref:**   | 21/CEN/ |
|   | Title:  | A Study to Investigate the Clinical Effectiveness and Safety of AK120 in Adults with Moderate-to-Severe Atopic Dermatitis |
|   | Coordinating Investigator:  | Dr Marius Rademaker |
|   | Sponsor:  | IQVIA |
|   | Clock Start Date:  | 19 August 2021 |

Dr Marius Rademaker was not 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 2 study of AK120, a humanized immunoglobin antibody drug seeking to test this in patients with moderate to severe atopic dermatitis. Design is RCT with three arms, control, a stable dose, and an arm with a bolus dose and then a lower stable dose ongoing. Control arm is cross over, receiving study drug after 12 weeks of placebo, in week 16. participants also get study supplied emollient cream. Seeking 105 participants worldwide and 3 in NZ. Study procedures require 18 visits over 43 weeks, but the first 30 get 26 visits for intensive blood sampling. Assessments include blood sampling, ECG and a study diary. Rescue therapies with systemic therapies result in withdrawal from study, but non systemic therapies are available.

Summary of outstanding ethical issues

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

**GENERAL**

1. Please outline the recruitment and screening strategy for the study as this was not clear from the application.
2. Please supply any advertisements that may be used to promote the study.

**EARLY TERMINATION OF STUDY**

1. Should the study be terminated early for ‘efficacy’ (r.1.6), it would be expected that participants receiving active treatment, and who are judged to be receiving clinical benefit, should be permitted to completed the scheduled duration of treatment. Please clarify whether this has been discussed with the Sponsor.
2. The Committee noted 3.1.3 in the protocol allows the Sponsor to terminate at its discretion. This is not permissible in New Zealand and a clinical trial should not be halted for commercial reasons. Please amend the protocol to address this.

**CULTURAL ISSUES**

1. For future submissions, adherence to the Tiriti is not a suitable response to question p.4.1.
2. Please confirm the process for planned Māori consultation and at what stage this is at.

**EDIARY**

1. Clarify whether participants are required to enter identifying information in order to access the eDiary.

**DTMP**

1. Remove references to an imaging vendor; no imaging is undertaken in the study.
2. For section 9.1 please provide a maximum documentation retention period, not a minimum.

**MAIN PISCF**

1. Please undertake a general revision to the tone of the information sheet so it is more neutral and does not over-promise potential benefits.
2. Please clarify whether non-access to a data enabled mobile phone or tablet is an exclusionary criteria.
3. Please include a lay friendly explanation of cell depleting agents on page 8.
4. p4. Remove the time windows from assessments / visits; no context is given and it reduces readability.
5. p4. State whether participants can elect not to take part in the intensive sampling.
6. p5. Add a table for the intensive visits.
7. p8. Delete advice regarding pregnancy and contraception; this is covered thoroughly on p11.
8. p9. Delete ‘teaspoons’ from the blood volumes.
9. p9. The application form states initials will be included on safety / screening samples; reconcile.
10. p10. Delete ‘close medical monitoring’ as a benefit of study participation.
11. p10. Explain the adverse events listed in simple lay language.
12. p14. please remove 'reasonable' in terms of expense reimbursement, as this is not an objective measure. You could use 'standard expenses' instead.
13. p15. The ‘What are my rights’ section is repetitive and overly complex. Review and simplify; in particular, delete information provided more clearly on p16.
14. p15. Explain what ‘If you choose to provide your consent to participate in this study, the collection of your information is not time limited (that is will not expire), without your expressed decision to do so’ means.
15. p16. Access to identifiable information as described is far too broad. The Sponsor should not be accessing identifiable data for analysis, for example.
16. p17. please specify a time after which records will be destroyed. A minimum period of non-destruction does not assure participants that their identifying information will be destroyed after a certain time period.

**OPTIONAL PISCF**

1. p2. Delete information about reimbursement for the main study – it is irrelevant.
2. p2. Clearly state that research will include genetic research, and what genes are in lay language.
3. Saying “their people” on page 2 is a poor choice of words. Please revise.
4. Macrons are used in main PISCF but not here for Māori and whānau. Please amend this as while it is grammatically correct to substitute to double vowel this is poorly understood by the general public.
5. As this blood is stored out of New Zealand this PIS needs a statement that suggests that "as the tissue samples will be stored and used outside New Zealand’s jurisdiction future use will no longer be subject to New Zealand laws and regulations and may not be reviewed by a NZ ethics committee".

**Decision**

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

1. Please address all outstanding ethical issues, providing the information requested by the Committee.
2. Please update the participant information sheet and consent form, taking into account feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17).*
3. Please update the study protocol, taking into account the feedback provided by the Committee. (National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.7).

After receipt of the information requested by the Committee, a final decision on the application will be made by Mr Anthony Fallon and Mrs Leesa Russell.

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| **3** | **Ethics ref:**   | 21/CEN/245 |
|   | Title:  | GENIUS |
|   | Coordinating Investigator:  | Dr Michelle Wilson |
|   | Sponsor:  | Auckland City Hospital |
|   | Clock Start Date:  | 20 August 2021 |

Dr Michelle Wilson 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.

Mrs Leesa Russell declared a potential conflict of interest, recused herself from the discussion and relinquished voting rights. The Committee maintained quorum throughout discussion of the application.

Summary of Study

1. Feasibility study assessing creation of genomic test result databank in New Zealanders with cancer. Linkage of genomic results with retrospectively +/- prospectively collected health data. Intended database use is to assess NZ-specific genomic profiles; identify inequities in access to testing; identify treatment options available to participants on and off trial; and use in future research. n=400, NZ only.

**Summary of resolved issues**

1. The Committee noted the application read as if the study would approach anyone who had a genetic test and queried how the study would know who had one performed. The Researcher stated it is clinician referred and there is no way to search for all records.

Summary of outstanding ethical issues

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

1. The Committee noted the application form references on and off trial treatment opportunities whereas the protocol reference clinical trial referrals only. Please clarify what is intended by treatment opportunities.

*(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.7).*

1. The Committee queried the recruitment process and requested the trial documentation be revised so it is clear that investigators with a trial will contact the study and the study does not have a centralised list of every clinical trial.
2. Please ensure that someone who is not the participant’s usual clinician discusses the study at some point in the recruitment process, so potential participants may decline participation to someone who is not a member of their clinical team.

**Data Management Plan**

1. Please provide a justification for using data for future unrelated research, including research that is not medical or scientific in nature. This is very broad and increases the risk of data harm for participants.

*(National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15).*

1. Section 8.1 does not appear to apply to the current study. Review and delete if appropriate.

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

*(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17).*

1. The Committee noted the Participant Information Sheet and Consent Form (PISCF) had a low Fleisch score (55) and may be difficult to comprehend. The Committee acknowledged the research is in a technical area but stated it is important for people to understand what they are consenting to.
2. The Committee noted the section that states “Rarely, it may be necessary for the Investigator to share identifiable data with people or groups not listed above – for example, in the event of a serious threat to public health or safety, or to the life or health of the participant or another person; or if the data is required for certain legal situations”. Please add additional detail on when a study investigator may need to share identifiable information, what information would be shared, who it would be shared with and why it would be shared.
3. Move the final two sentences from page 1 to the section detailing information access and use.
4. Amend ‘The chance of this database linking you to a new treatment is small’ in the context of study withdrawal. Suggest moving to the benefits / risks section.
5. Separate out the components of the study more clearly into subsections: a) mandatory information being collected and b) optional components (referral for on / off trial Rx; prospective collection of health data). Participants should be able to easily understand what the mandatory and optional components of the study are.
6. Clearly state what information would be collected about a participant in the study and what it would be used for.
7. State who has access to the key linking identifiers with coded data.
8. State whether coded data may be shared with overseas researchers and/or added to other genomic databases, including commercial databases.
9. The DMP states that data may be used for future unrelated research that is not medical or scientific in nature. Make this very clear in the PIS or amend the DMP; most patients reading the document will assume any future research will be related to genomics and cancer.

**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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| **4** | **Ethics ref:**   | 21/CEN/247 |
|   | Title:  | Establishment of colorectal cancer organoids for therapeutic screening |
|   | Coordinating Investigator:  | Dr Rachel Purcell |
|   | Sponsor:  | University of Otago |
|   | Clock Start Date:  | 20 August 2021 |

Dr Rachel Purcell 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, recused herself from the discussion and relinquished voting rights. The Committee maintained quorum throughout discussion of the application..

Summary of Study

1. The study intends to grow organoids to provide a resource for the current study and for future studies of colorectal cancer (CR).
2. Organoids will be banked in three organoid biobanks (as part of existing biobanks) for future unspecified research (FUR) to characterise the organoids for gene expression and proof-of-concept therapeutic screens such as non-coding RNAs9 and the microbiome. It will include matched clinical data. There is a separate optional PIS for this part of the study.

Summary of outstanding ethical issues

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

1. Please revise the PIS to make it clear the study wants to use samples to create organoids and what experiments will be done on them and that participants have the option to donate their samples to the biobank.
2. Please revise the protocol so the consenting progress is done by a researcher and not a member of the participant’s clinical team.
3. The Committee advised the DTMP needed more protection for Māori data.
4. The Committee advised that strict governance of the tissue bank is required to dictate when specimens may or may not be released to other researchers.
5. The Committee recommended the Researcher adapt the [data and tissue management plan template available on the HDEC website.](https://ethics.health.govt.nz/guides-templates-and-forms/data-and-tissue-management-plan-templates/)

*(National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15).*

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

(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17).

1. Please state how long you don’t know how viable organoids so the potential for long term storage is not known.
2. Page 2 – should this refer to the sample being taken ‘during’ surgery, not after: “When

you have surgery for colorectal cancer we will take some more samples of colorectal tissue,

but this is done after the surgery and won’t involve any additional procedures for you.”

1. Page 2 – please substantively and significantly improve the description of organoids
2. Page 2 - please substantively and significantly improve the description of the genetic testing and ensure all the Genetic and Genomic NEAC Standards are met.
3. Page 2 – the risks are much greater than the risks for surgery – this section needs to be significantly amended and must refer to the risks with the organoids and the risks with the genetic testing and the risks of loss of confidentiality.
4. Page 2 – the privacy section needs significant amendment – please refer to the HDEC template and refer to identifiable data, de-identified data, anonymised data in addition to the possibility that third party researchers may be able to access study data. Note also the greater identification risks with genetic data. Advise of rights of access, correction, what happens on withdrawal etc etc
5. Page 3 – there is insufficient information for Māori – refer to the comments made by the Māori adviser
6. Please include discussion of potential IP rights and commercialisation.

**Main Consent Form**

1. Use tick boxes only where optional (e.g. the participant can answer ‘NO’ and still participate in the study).
2. Amend all sections as appropriate based on previous comments, especially whether the organoid part of the research is optional.
3. Please don’t mention issues for the first time in the CF – they must be addressed in the body of the PIS – eg, withdrawal, abnormal findings and contacting GP, commercial use.

**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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| **5** | **Ethics ref:**   | 21/CEN/242 |
|   | Title:  | Understanding apathy in Huntington’s disease |
|   | Coordinating Investigator:  | Miss Lee-Anne Morris |
|   | Sponsor:  | New Zealand Brain Research Institute |
|   | Clock Start Date:  | 26 August 2021 |

Dr Campbell Le Heron and Miss Lee-Anne Morris were present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. The aim of the research is to
* determine if apathy in HD is driven by hypersensitivity to effort and/or insensitivity to rewards, using an effort-based decision making framework;
* determine which of these altered cognitive processes at baseline are most predictive of change in apathy at one year follow up;
* develop predictive cognitive markers of apathy in this disease.

Summary of resolved ethical issues

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

1. The Committee queried whether the study would only recruit adults that had the capacity to consent for themselves. The Researcher confirmed it would and part of the inclusion criteria is the full capacity for consent.
2. The Committee queried where the study was at with its Māori consultation. The Researcher stated it was in progress but they were facing an issue of whether it should occur via the DHB or University.

Summary of outstanding ethical issues

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

1. The Committee requested detail on the incentives model of the intervention. The Researcher stated it was more a behavioural task participants and participants choose the level of effort they want to exert. The study will then model how participants make decisions of effort vs reward and the processes driving those decisions.
2. The Committee requested additional information be given to participants about this and to make sure they understand the money they receive is not them being paid for work but rather for the study.
3. The Committee noted some participants would be more successful than others and receive more ‘incentives’. The Committee queried if there was a form of koha available for all participants to avoid the feeling of being unsuccessful in their endeavours. The Researcher confirmed there is a koha available and in previous studies has been half of what they could potentially earn overall e.g. if the maximum possible was $20 the koha would begin at $10.
4. The Committee suggested a formal consultation process with Huntington’s disease groups may be beneficial to the study.
5. Please adapt the [HDEC data management plan template](https://ethics.health.govt.nz/assets/HDEC-data-only-management-template-Oct-2021.docx) and provide a data management plan that contains more detail on how data will be managed.
6. The Committee noted some questionnaires were described as deidentified but would contain identifiers such as name, date of birth and addresses. Please remove these identifiers to protect the information.
7. The Committee queried the process for if a concerning response was discovered on any of the questionnaires with mental health questions. The Committee requested a process to manage participants experiencing distress or mental health concerns be devised and details explaining what will be done added to the PIS.

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

1. Please clarify whether submission of data to the NZBRI Data-bank is mandatory.
2. Notification of the participant’s GP in the event of a significant abnormal result should be a mandatory component of study participation. Please remove the optional tick-box from the consent form.
3. Please include a section consenting to submission of study data to the Databank
4. Please include information on what will happen if a concerning response is indicated on the questionnaires (e.g. “If X we will do Y”) so participants understand the process if they disclose such information.
5. Please remove ‘motivational disorder’ from documentation and replace it with ‘apathy’.
6. Reconsider the deficit-focused language and could consider using ‘symptoms’ or ‘changes’ in the participants life rather than focusing on ‘problems’ of living with Huntington’s.

**Decision**

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

1. Please address all outstanding ethical issues, providing the information requested by the Committee.
2. Please update the participant information sheet and consent form, taking into account feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17).*
3. Please update the study protocol, taking into account the feedback provided by the Committee. (National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.7).

After receipt of the information requested by the Committee, a final decision on the application will be made by Mr Anthony Fallon and Dr Leonie Walker.

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| **6** | **Ethics ref:**   | 21/CEN/239 |
|   | Title:  | Understanding Child Abuse Victims, their Caregivers and Clinicians Treatment Experience of Trauma Focused Cognitive Behavioural Therapy (TF-CBT). |
|   | Coordinating Investigator:  | Ms Audrey Kusasira |
|   | Sponsor:  | AUT |
|   | Clock Start Date:  | 21 August 2021 |

Ms Audrey Kusasira and Prof Jane Koziol-McLain 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 PhD research seeks to explore the experience of young people aged between 8 - 17, caregivers and clinicians of Trauma Focused Cognitive Behavioural Therapy (TF-CBT) to gain the young peoples’ perspectives of the therapy.

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 advised that 16 and 17 year olds in New Zealand are legal adults that may provide their own consent. The Committee advised there may also be 15 year olds with the capacity to provide informed consent. The Committee noted there would need to be a consent form for these participants to enter the study on as well as age appropriate assent forms for younger children of all abilities.
2. The Committee noted if a participant turns 16 during the study they would need to be reconsented on the main information sheet and consent form.
3. The Committee advised that clinicians would be considered participants in the study and so would need their own specific information sheet and consent form.
4. The Committee noted it was not clear from the protocol whether the youth, caregiver and clinician must all agree to take part of if there are combinations that may or may not (e.g. two say yes and one says no). Please formalise this so all scenarios are covered.
5. The Committee advised that the statement about keeping information private is not best practice for a study of this nature and participants will need to know what sort of information would trigger a response (i.e. you are required to tell someone). Please revise this on the youth information sheets and make it clear what the threshold is.
6. The Committee advised the study protocol does not comply with the [National Ethical Standards](https://neac.health.govt.nz/national-ethical-standards/) for various reasons and requested the Researcher become familiar with the Standards, specifically standard 9.8 which the study will need to meet.

*(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.7-9.8).*

1. Please ensure all participants understand access rights to transcripts and if the child/parent will have access to joint or separate transcripts.
2. The Committee noted that $25 reimbursement for parking/travelling would not go far and if it is truly reimbursement there will need to be an adequate amount to cover these expenses. The Committee advised it is important for participants to not be financially disadvantaged by their participation and reimbursement of expenses is separate to a koha.

Other issues identified by the Committee include the following.

**DATA MANAGEMENT**

1. A DMP is required to fulfil requirements of Standard 12.15a of the NEAC Standards. The Committee recommended the Researcher adapt the data management plan template available on the HDEC website.

*(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.7-9.8).*

1. Inconsistent responses to data management are noted across study documentation. Consent forms, contact lists, and potentially raw audio tapes are identifiable, contrary to r.2.4.
2. Health information should be retained for at least 10 years after the participant turns 16 (r.2.5)

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

(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17).

**PISCF CAREGIVERS**

1. Make it clear what the population under study is. Abuse is mentioned in the title only.
2. State that there are no benefits to participants arising from this study.
3. State whether the caregiver can participate without the youth (and vice versa).
4. State that clinicians will also be interviewed for the study.
5. Better describe the ‘activity’ for Step 1; it is an interview and will be audio-recorded, and that the recording is optional (as indicated on the assent consent page).
6. State where interviews will be conducted.
7. State whether the Step 2 interviews are conducted separately or together.
8. State whether a support person can be present.
9. State whether direct quotes may be used in publications / reports.
10. State whether participants will be reimbursed for out-of-pocked expenses.
11. State how identifiable data will be managed.
12. State what happens to the recordings re transcription, redaction of potentially identifying information and retention.
13. State whether the participant can access and correct the transcription.
14. State whether the caregiver will have access to the youth’s responses (and vice versa).
15. State that there is a risk of confidentiality / privacy breach.
16. Provide information about rights of access and correction.

**ASSENT FORMS**

1. The font is difficult to read.
2. Most of the requests for the caregiver PISCF should be covered.
3. Make it clear that the youth can say ‘no’ even if the caregiver says ‘yes’
4. Make it clear that the decision will not impact therapy.

**PISCF – Young People**

1. The recording of the interviews via audio taping should be included in the body of the PIS as new info should appear in the CF.
2. Age groups are too broad to have 1 single PISCF – please consider the NEAC standards and the varying degrees of comprehension of the target population, and produce more. HDEC templates and website guidance can assist here.
3. Please clarify who will be in the room for the interviews
4. Please amend step 2 to include the need to participate in the 4 sessions for this research

**PISCF – Caregivers**

1. The recording of the interviews via audio taping should be included in the body of the PIS as new info should appear in the CF.
2. Please review for some syntax errors such as missing words.
3. “How will my child’s privacy be protected?” – While some of the required information is included here, please review to include more detail as per HDEC PISCF template.
4. Step 2 – Please amend to clarify caregiver isn’t getting CBT
5. Step 2 – Please clarify the activity to be undertaken.
6. Step 2 – Page 2 It says that it will include 3-4 30-60 minutes of your child’s time but form and elsewhere states 4. Please make consistent.

**PISCF – Clinicians**

1. No PISCF submitted; this is required.

**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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| **7** | **Ethics ref:**   | 21/CEN/246 |
|   | Title:  | Identification of the effects of methamphetamine using MRI scans |
|   | Coordinating Investigator:  | AP Miriam Scadeng |
|   | Sponsor:  |  |
|   | Clock Start Date:  | 21 August 2021 |

AP Miriam Scadeng 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 research studies the impact meth has on the brain and the potential for a multi-modal MRI approach to comprise an assistive diagnostic tool to identify and monitor changes both in the brain and in the heart. In combination with tests of decision making, the researchers seek to evaluate the changes and to determine if abstaining from methamphetamine exposure allows recovery in the brain and heart.

Summary of resolved ethical issues

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

1. The Committee queried if the babies would need to be sedated to be placed in the MRI machine. The Researcher stated if a baby is fed and kept warm they are very likely to stay asleep in the scanner and though it won’t work for everyone there is evidence that it’s a successful method so sedation by drugs will not be necessary.
2. The Committee queried if school age children would be pulled out of class for the MRI scan. The Researcher confirmed they would not as it would be done afterhours when convenient for the family.

Summary of outstanding ethical issues

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

1. The Committee queried how potential participants would be identified. The Researcher stated an investigator who works as a GP is contacted by Police in situations of family violence and drug use. The Researcher clarified a child would not be referred solely due to ‘drug exposure’ but because it was identified that they needed additional support from a GP. The Committee requested it be made clear in the protocol that Dr Hughes is not soliciting referrals from the Police but if in his normal clinical duties becomes aware of a potential participant he may approach them.
2. The Committee queried how participation in the study above standard care may benefit participants. The Researcher stated it would make medical resources available to them they may not otherwise receive. The Committee requested information be added to the PIS so participants understand that their participation in the research in no way impacts any other care they may receive from the GP.
3. The Committee noted the informed consent process was not captured well in the documentation and requested information outlining the referral and identification pathways be added to the protocol.
4. The Committee advised that some 15-year-olds may be competent to provide consent themselves.
5. The Committee advised that assent forms for 7–15-year-olds would need to be written. The Committee advised that comprehension between the children may vary significantly so simple forms and more detailed forms appropriate to the comprehension level of different participants will be needed.
6. While Dr Hughes may initially approach his patients to gauge interest in study participation, please ensure another member of the research team conducts the remainder of the recruitment process (r.5.4.1).

Other issues identified by the Committee include the following.

**PROTOCOL**

1. Ensure the protocol includes version number, version date, and page numbers.
2. Clarify that the current research is in essence a feasibility study.
3. Adequately address the recruitment and informed consent process.
4. It is noted that use of other recreational drugs such as cannabis is not assessed (questionnaire). Confirm whether concurrent drug use could impact observed results.
5. Clarify how the study aim of assessing the impacts of abstinence from meth - noted as a study aim in the application form, but not referenced in the protocol - will be achieved; the questionnaire only asks for active use, not length of abstinence etc.
6. Clarify how abstinence will be assessed longitudinally; the demographic questionnaire captures use at the start of the study only.
7. Analysis of executive functioning is not described; nor is the proposed method to correlate executive function with MRI findings.
8. The data management plan does not fulfil the requirements of Standard 12.15a. Issues including confidentiality / privacy breaches and future use of data must be addressed.

*(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.7; 12.15).*

**INCIDENTAL FINDINGS / RETURN OF RESULTS**

1. Participants may not wish to be informed of abnormal results which are significant but not clinically actionable. Please ensure this is addressed in study documentation.
2. Explain how incidental findings of potential clinical significance will be managed, for example regarding GP notification. Informing the participant of the result is in itself insufficient (r.4.1).

**DEMOGRAPHIC QUESTIONNAIRE**

1. Remove identifying information (name, date of birth).
2. Confirm that the questionnaire will be completed only after informed consent is obtained.
3. Language switches between 2nd and 3rd person. Amend for consistency.
4. Ethnicity data should reflect NZ Census ethnic categories. Amend accordingly.
5. It is not appropriate to group meth with ‘other medications’ (Q8). Split into two questions.

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

*(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17).*

**PISCF ADULTS**

1. The title is inconsistent with the consent form and other study documentation (p1)
2. State that this is a feasibility study (p2).
3. State in lay language what an MRI scan is the first time it is referenced (p2).
4. Make it clear that eligibility criteria apply to the adult component of the study only. The text also reads as though the participant must be a current meth user (‘you have a desire to stop using meth’); this is not consistent with the protocol and requires reconciliation (p2).
5. Make it clear that the impact of abstinence from meth is also being assessed, and how ongoing abstinence will be determined (p2).
6. State that repeat MRI scans are required at 6-monthly intervals and how long study participation will last (p3). State also whether executive function tests will be repeated.
7. Re-write ‘non-invasive structural, functional, physiological and spectroscopic’ in simple lay language (p3).
8. Make it clear there are no benefits to participants (p3)
9. Risks of the study include risk of confidentiality / privacy breach; feelings of whakamā / shame; identification of incidental findings that are potentially serious but non-actionable…. Ensure these are addressed (p3).
10. Include an ACC statement in event of study-related injury (p4).
11. Address how the research team will arrange follow-up for incidental findings. Make it clear that is mandatory for the GP to be informed of significant findings, as stated in the protocol (p3).
12. Discuss options for return of significant, non-actionable results (p4).
13. The demographic questionnaire includes full name and date of birth – amend accordingly (p4).
14. Address risk of sending data overseas (p4).
15. Address rights of access to information held by the research team (p4)
16. Delete repeated statements regarding study withdrawal (referenced 3 times in the document).
17. It is stated that data will only be available to study researchers; this is inconsistent with statements in the PIS regarding sharing of data with other researchers (CF).
18. Provide options for the return of significant non-actionable results (CF).
19. Clarify that ‘a copy of the results’ is a copy of the overall study results’, not individual results (CF).
20. Amend to delete reference to ‘my child’s data’; the remainder of the document appears to be aimed at adult participants (CF).

**PISCF GUARDIAN**

1. Many of the issues raised for the adult PISCF apply; Review and amend accordingly.
2. The PISCF states that only children aged 0-9 months can participate; this is at odds with the study protocol.

**ASSENT FORMS**

1. None have been provided but are required. Ensure several forms are developed to cover different comprehension levels.

**Decision**

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

|  |  |  |
| --- | --- | --- |
| **8** | **Ethics ref:**   | 21/CEN/240 |
|   | Title:  | Prevention of diabetes in Chinese, Caucasian, Māori & Pacific urban phenotypes resident in New Zealand |
|   | Coordinating Investigator:  | Mr Wilson Yip |
|   | Sponsor:  |  |
|   | Clock Start Date:  | 21 August 2021 |

Mr Yip was not present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. The PiCUP study is a 12-month weight loss study (2 months weight loss + 10 months weight loss maintenance) investigating whether a combination of rapid weight loss plus foods hypothesised to help with blood glucose control can improve the risk of diabetes long-term.
2. The trial will be a 4 arm, parallel design, randomised controlled trial (RCT). The dietary intervention will span 12 months, consisting of an acute 2-month weight-loss Phase 1 followed by a longer-term 10-month weight loss maintenance Phase 2.

Summary of outstanding ethical issues

The Committee discussed the following aspects of the application which need improvement upon resubmission.

**PROTOCOL**

*(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.7).*

1. The study population is inconsistent between the application form (AF), the protocol and the participant information sheet and consent form (PISCF). Māori and Pasifika are mentioned in the study title only. Please address this.
2. There is no split given in terms of enrolment by ethnicity.
3. It is unclear how matching will be achieved. Will the Asian cohort be recruited first to achieve age + BMI parity?
4. The sample size inconsistent (Section 2=425, AF and PISCF = 268).
5. The study arms are inconsistent between Section 3.1 and the application form.
6. F&B products are referred to throughout the protocol but are not identified; the rationale for the selection of each is not provided.
7. The selection / characteristics / size of the subgroups is not defined (MRI, calometry).
8. Smoking is an exclusion criteria but no mention is made of vaping. Is use of other nicotine products also excluded?
9. The focus group, survey and QOL questionnaires are not addressed.
10. Machine learning is not addressed sufficiently, though referenced briefly in the AF.

**DATA MANAGEMENT**

1. A data management plan is required to satisfy the requirements of [NEAC Standard 12.15a.](https://neac.health.govt.nz/national-ethical-standards/part-two/12-health-data/) Information provided in the protocol and PISCF is insufficient / inconsistent. The machine-learning component must be fully addressed.

**TISSUE MANAGEMENT**

1. Contradictory responses are provided regarding sending tissue overseas (b.4.5.2, b.5.4.3, r.3.8).
2. r.3.11 states a new tissue bank will be used to store samples. Provide details of the tissue bank, including evidence of HDEC approval.
3. It is stated that additional optional consent will be obtained for future use of tissue; no documentation has been provided for this.

**PARTICIPANT SAFETY**

1. Confirm that self-report of medical history and concomitant medications is sufficient to ensure the eligibility and safety of participants (r.1.2.1)
2. Study assessments may reveal potentially serious clinical abnormalities, which per best practice the primary health care provider should be informed of. Amend documentation to make GP notification of significant abnormal results a mandatory component of study participation (r.4.1.1).

**CULTURAL CONSULTATION**

1. Given the four desired urban phenotypes it appears that specific ethnicities would be targeted, however the response to p.4.5. states that this is not the case. Explain how the research team intends to recruit the desired number of participants from each of the four ethnicities described.
2. The population targeted is described as representative of the wider Auckland population (f.1.2) but does not include Indian Asians (Chinese Asians comprised 11% of the city’s population in 2018, Indian Asians comprised 10%).

**GROUP SESSIONS**

1. Per the PISCF, group counselling sessions involve collection of personal health information (medications, changes in health, body weight). This is not usually considered appropriate for a group setting. Discuss how this information will be collected given the group environment.

**PRE-SCREENING FORM**

1. Parts of the form go beyond general screening and would be best asked once informed consent is obtained (e.g. risk score).

**APPLICATION FORM - OTHER COMMENTS**

1. r.4.1.1 - Amend documentation to make GP notification of significant abnormal results a mandatory component of study participation
2. The validation cohort is not discussed in the application form (AF) but appears to be a separate 6 week sub-protocol with a 2-period crossover design. Ensure this is discussed in the AF on re-submission of the study.

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

**PISCF MAIN**

*(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17).*

1. Address what happens to samples where consent is not provided for future research (p14).
2. Access to and use of data is poorly explained. Amend using the HDEC PISCF template as a guide.
3. Amend the section regarding incidental findings (see above). It is inconsistent with the risk section and removes the responsibility from the researcher to arrange appropriate follow-up.
4. Amend the section regarding test results. Participants should have the right to access safety-related lab results during the study. The statement regarding insurance companies is inappropriate and should be deleted.
5. Provide contact details for cultural support.

**PISCF VALIDATION COHORT**

1. No PISCF submitted; this is required.

**PISCF FUTURE USE OF TISSUE**

1. No PISCF submitted; this is required.

**SURVEYS / QUESTIONNAIRES**

1. Referenced in the application but not submitted for review.

**PISCF FUR & VALIDATION COHORT**

1. No PISCF submitted; this is required.

**Decision**

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

## General business

The meeting closed at 3:10pm with a karakia:

Unuhia, unuhia
Unuhia ki te uru tapu nui
Kia wātea, kia māmā, te ngākau, te tinana, te wairua i te ara takatā
Koia rā e Rongo, whakairia ake ki runga
Kia tina! TINA! Hui e! TĀIKI E!