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| **Committee:** | Northern B Health and Disability Ethics Committee |
| **Meeting date:** | 03 August 2021 |
| **Meeting venue:** | Via Zoom Meeting ID: 965 0758 9841  <https://mohnz.zoom.us/j/96507589841> |

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| **Time** | **Item of business** |
| 12.00pm | Welcome |
| 12.15pm | Confirmation of minutes of meeting of 06 July 2021 |
| 12.30pm | New applications |
| 12.30-12.55pm  12.55-1.20pm  1.20-1.45pm  1.45-2.05pm  2.05-2.30pm  2.30-2.55pm  2.55-3.20pm  3.20-3.40pm  3.40-4.05pm  4.05-4.30pm  4.30-4.55pm | 21/NTB/182 Kate/Stephanie  21/NTB/183 John/Leesa  21/NTB/189 Susan/Stephanie  Break (20 minutes)  21/NTB/188 Kate/Leesa  21/NTB/187 John/Stephanie  21/NTB/190 Susan/Leesa  Break (20 minutes)  21/NTB/191 Kate/Stephanie  21/NTB/193 John/Leesa  21/NTB/194 Susan/Stephanie |
| 4.55pm | Meeting ends |

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| **Member Name** | **Member Category** | **Appointed** | **Term Expires** | **Apologies?** |  |
| Mrs Stephanie Pollard | Non-lay (intervention studies) | 01/07/2015 | 01/07/2018 | Present |  |
| Mrs Kate O'Connor | Lay (ethical/moral reasoning) | 14/12/2015 | 14/12/2018 | Present |  |
| Mrs Leesa Russell | Non-lay (intervention studies), Non-lay (observational studies) | 14/12/2015 | 14/12/2018 | Present |  |
| Mr John Hancock | Lay (the law) | 14/12/2015 | 14/12/2018 | Present |  |
| Ms Susan Sherrard | Lay (consumer/community perspectives) | 19/03/2019 | 19/03/2022 | Present |  |

## Welcome

The Chair opened the meeting at 12pm and welcomed Committee members.

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 06 July 2021 were confirmed.

## New applications

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| **1** | **Ethics ref:** | **21/NTB/182** |  |
|  | Title: | Alcohol-Related ED Presentations 2021 |  |
|  | Principal Investigator: | Dr Laura Joyce |  |
|  | Sponsor: |  |  |
|  | Clock Start Date: | 22 July 2021 |  |

Dr Laura Joyce 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 primary aim of the proposed study is to assess the change in the proportion of emergency department (ED) presentations that are alcohol-related, compared to 2013 and 2017. The participants will be patients presenting to the Christchurch Hospital ED with alcohol-related injuries or medical conditions.
2. Patients will be screened with two triage questions: (1) whether alcohol is related to their presentation and (2) whether they have consumed any alcohol in the last four hours. Patients will be eligible for the study if they had positive answers to either or both questions. Collaboration with ED staff will allow for identification of further patients who may have had alcohol relevant to their presentation. Consent will be obtained from the patient directly or from a parent or guardian if the patient is under the age of 16-years-old.
3. Various data is collected from participants as to the nature of the consumption, location of purchase (observational). There is an interview. Participants may be impaired due to their alcohol consumption and some are under 16-years-old.

Summary of resolved ethical issues

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

1. The Committee noted that this is the third time that the study will be run. The study will assess trends and suspicions that the world has changed in the past few years in that more people are buying alcohol off-licence and drinking in their own homes. It is suspected that during the COVID-19 pandemic, this will have increased. Further, people are likely to drink more when at home because it is cheaper. As off-licence alcohol consumption becomes more common, people can drink more. Recently, people can now order alcohol to be delivered to their homes. The researcher also wants to look at whether underaged people are purchasing alcohol for consumption at home and whether this changes the ED environment.
2. The Committee noted that there is funding for two summer students who will be collecting the data. However, the researcher is wanting 24 hours per day seven days per week coverage. The Committee asked how this would work with two staff on eight-hour shifts. The researcher advised that it would be over 42 shifts. There is a timetable for students based over that time. Students will do seven shifts on and four off, from 15 November to 10 December. The longest shift for students will be the 10-hour night shifts.
3. The Committee asked how consent is obtained and how the student will stay safe, noting the various reasons behind alcohol-related patient presentation in ED. The researcher advised that the ED team will protect student safety. Students will ask the patient’s nurse whether it is safe to approach patients. If it is safe, students can then approach the patient and obtain consent. Further, the students will be fourth and fifth years who will likely have worked in the ED before. They will know that they require permission from clinical staff too before approaching patients.
4. The Committee referred to the demographic form that contains some identifiable information on it such as National Health Index (NHI) numbers. The form asks whether consent has been obtained and reasons why/why not. The Committee asked at which point the student will have the patient identifiers of those they are screening. The researcher stated that the reason for identifiers are so patients are not approached twice. The data will be de-identified after the 42 shifts are complete.
5. The Committee enquired about the consent process if patients are under 16-years-old. The researcher stated that they have combined consent/assent. There is a different consent form for parents to sign but they also encourage that if the parent and patient agree that the patient also signs an assent. The Committee asked what the process is if the patient presents without any whānau/family support. The researcher stated that if the patient is under 16-years-old they would contact their whānau/family anyway for ongoing care. If no whānau/family support is available, the patient cannot be included in the study.
6. The Committee noted that adults who are too intoxicated will be excluded from the study. A tool will be used to measure this. The Committee asked who will establish whether a patient is too intoxicated. The researcher referred to Appendix C of the Protocol which details the tool, which is a subjective measure. The assessment will be done by the students in conjunction with clinical staff.
7. The Committee acknowledged that there may be potential for institutional racism and unintentional bias when clinical staff advise whether a patient has consumed alcohol and whether they can be approached by the researchers. The researcher also acknowledged this. The Committee did not request a solution to this matter but asked that the researcher take this into consideration when undertaking the study to avoid potential stigmatisation.

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 referred to the Data Management Plan and requested that the researcher use the [HDECs template](https://ethics.health.govt.nz/assets/Uploads/HDEC/templates/data-only-management-template-oct2020.docx) to articulate management of the data through the life cycle and to harmonise data protocols across staff.
2. The Committee asked about the researcher’s intention to retrospectively determine participant eligibility using notes and staff consultation, and retrospectively track without consent of anyone who cannot be seen in person. The researcher stated they want to know details about patients who did not consent to take part, to know that if the people who did take part are representative of the population. They have routinely collected administrative data in the ED that they audit regularly from a clinical perspective. The information about who declined to participate (or who were too incapacitated to participate) would be de-identified to the patient’s age and gender in order to see if these were different to the ones who did take part. The Committee asked that this comparison be made clear in the Data Management Plan because the researcher is using personal health information (the NHI) without consent. Further, as this would be a waiver of consent this requires HDEC approval. Please refer to Chapter 12 of the [NEAC Standards](https://neac.health.govt.nz/national-ethical-standards/) when updating the Data Management Plan and when responding to the Committee in order to justify the wavier of consent.
3. The Committee requested a Participant Information Sheet and Consent Form directly for parents, and a separate assent form for the child (which can be simplified and made more age appropriate). Please also provide a younger age assent form (for 10–15-year-olds).
4. The Committee referred to families giving their assent as per p.3.2.1 of the application. The Committee asked for clarification. The researcher stated that often patients will present with a family member or support person. It is important to involve whānau/family as they would have an idea as to what their relative patient might agree to if sober. Please document and be clear in the Protocol that you are not requesting assent from the whānau/family. Instead, they are supporting an individual in giving the most informed consent they can. The supported decision making approach is also more in line with   
   Right 7.3 of the [Code of Health and Disability Services Consumers' Rights](https://www.hdc.org.nz/your-rights/about-the-code/code-of-health-and-disability-services-consumers-rights/#:~:text=The%20Code%20of%20Health%20and,Health%20and%20Disability%20Commissioner%20Act).
5. The Committee noted that the Participant Information Sheet is missing information around the storage, destruction, access, and use of participants’ data. Please provide this information and refer to the [HDECs template](https://ethics.health.govt.nz/assets/Uploads/HDEC/templates/participant-information-sheet-consent-form-template-sep20.doc) for guidance.
6. The Committee noted that under 16-year-olds will be asked how they accessed alcohol. The Committee asked if these patients will be asked to disclose criminal activities. The researcher stated that the names of people who provided the patients with alcohol will not be requested. Due to patient confidentiality, the researcher would not be obliged to provide information to police in this situation. Please clarify in the Participant Information Sheet that you are just collecting generic information from the patient about how they were supplied alcohol.

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

1. Please remove the witness signature box. Please refer to wording from the [HDECs template](https://ethics.health.govt.nz/assets/Uploads/HDEC/templates/participant-information-sheet-consent-form-template-sep20.doc) which provides standard wording for declaration by investigators (rather than by witness).

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 the suggestions made by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement 2019, 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 Mrs Kate O’Connor and Mrs Leesa Russell.

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| **2** | **Ethics ref:** | **21/NTB/183** |  |
|  | Title: | Cerebral Palsy Respiratory Project |  |
|  | Principal Investigator: | Professor Susan N Stott |  |
|  | Sponsor: | Auckland District Health Board |  |
|  | Clock Start Date: | 22 July 2021 |  |

Professor Susan Stott, Cass Byrnes, and Alexandra Sorhage were present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. The study is an observational study to survey respiratory issues in cerebral palsy in children and young adults, with a 12-month follow-up.
2. One hundred and fifty participants with cerebral palsy will be recruited to observe their respiratory health and outcomes. Participants will be aged 0 to 26-years-old. Some participants will have diminished capacity and have their parent/legal guardian consent on their behalf.
3. Data linking is involved as part of the 12-month follow up via the Ministry of Health.

Summary of resolved ethical issues

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

1. The Committee asked why the follow-up aspect of the study is not mandatory. The researchers stated that it is just providing the option to participants not to have their data linked to the Ministry of Health data. The Committee asked how long the data is linked and the researchers said it is for 12 months.

Summary of outstanding ethical issues

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

1. The Committee asked the researchers to confirm what data will be obtained from the Ministry of Health. The researchers stated it is hospital admissions over the one- year period for respiratory related illness only. Also, mortality, and pharmaceutical dispensing i.e. antibiotic use for respiratory illness. Please be specific in the protocol about what data will be collected.
2. The Committee asked the researchers to describe the consent process. The researchers stated that the consent checklist will be done online with the consent and assent forms embedded at the beginning of the survey plus an option of receiving a paper copy. There is also a paper only option that includes the consent and assent forms. The Committee asked about the difficulty that children with cerebral palsy might have in terms of giving consent. The researchers stated that a number of these children, as well as those over 16-years-old, will have cognitive impairment. The Committee asked how much difficulty there may be in using an online consent form. The researchers stated that parents/guardians of under 16-year-olds would consent on their behalf. This will be the same for those over 16-years-old when appropriate. The researchers stated they have tried to make it as accessible as possible, and they will help as much as possible with completing the consent forms and surveys. For example, if participants have physical difficulty completing the documents, research assistants are available to do so on their behalf. The Committee advised that assent needs to be tailored to the age range of the children. Please provide two forms, one for ages seven to 11 and one for 12 to 15-year-olds. *(National Ethical Standards for Health and Disability Research and Quality Improvement 2019, Chapter 6).*
3. The Committee advised that parental consent is appropriate for children under 16-years-old. However, for ages 16 and above, they should be able to provide consent for themselves. Alternatively, it is possible to use a supported decision-making consent process, which is where adult participants are encouraged to make the decision themselves but have someone with them who can help with this. *(National Ethical Standards for Health and Disability Research and Quality Improvement 2019, Chapter 6).*
4. The Committee noted the difficulty of electronic consent is that it can be challenging to ensure that a supported decision-making process is fair and appropriate. The researchers stated that when motor ability is graded, it is also associated with neurological ability. The children are graded in severity on a scale of one to five. Children who are graded four and five will likely have difficulty in consenting/assenting themselves. The proportion of those who would be in that category would be approximately 40 percent. The Committee reinforced that it requires a separate assent form for participants aged seven to 11-years-old and 12 to 15-year-olds. There also needs to be a parental Participant Information Sheet and Consent Form (PIS/CF) and a PIS/CF for adults. Please also provide information about the supported consent process for adults (this process would ideally be undertaken in person or verified by the research team e.g. via Zoom) to ensure it is not one adult consenting on behalf of another, as this is not currently permitted under New Zealand law. It would be beneficial to have the survey completed via Zoom as well, however, please be mindful that there must be time between participants receiving the information and making their decision to consent. Please also provide information about the process to those who would be providing the supported consent. *(National Ethical Standards for Health and Disability Research and Quality Improvement 2019, Chapters 6 and 7).*
5. The Committee asked if there will be any adults in the study who cannot consent for themselves at all. The researchers said there is potential for this. The Committee requested a Participant Information Sheet and Consent Form for the whānau/family of the person who cannot consent for themselves (as non-consenting adults). This form must explain to the whānau/family what the study is going to do, and why participation is requested, and ask what the whānau/family thinks the person would want to do if they could consent. Please refer to Chapter 7 of the [NEAC Standards](https://neac.health.govt.nz/national-ethical-standards/part-two/7-informed-consent/) for guidance on how to manage and provide detail on this process. In addition to providing a separate form, in the Protocol, please detail the process of how you will ascertain wishes of those who cannot consent for themselves and how this process will be managed. *(National Ethical Standards for Health and Disability Research and Quality Improvement 2019, Chapter 7).*
6. The Committee noted that the researchers could submit an application for waiver of consent instead. Consultation with and a letter of support from a New Zealand Cerebral Palsy society or advocates group could support this. *(National Ethical Standards for Health and Disability Research and Quality Improvement 2019, Chapter 7).*
7. The Committee requested that for future applications, the researchers provide the details of the sponsor. At a.5.2 and b.1.1, only a surname is provided.
8. Please include in your response to the Committee, the response from your Māori consultation and how it has been implemented into the study. There is also currently no Māori data sovereignty governance structure. *(National Ethical Standards for Health and Disability Research and Quality Improvement 2019, Chapter 3).*
9. Please remove the New Zealand Cerebral Palsy Register data set linking sentence from your protocol as you are not linking to it during your study.
10. Please include more information about how you plan to recruit participants and analyse the data.
11. Please remove the tracked changes from the Data Management Plan and upload a clean copy.
12. Please consider the new laws under the Privacy Act 2020 in regards to sharing data overseas. Participants must be notified if their data will be shared outside of New Zealand in that the data may not be protected by the same controls under New Zealand law.
13. In the advertisement and checklist, please mention the data linking activity.
14. For the checklist, please refer to the NZ Stats guidelines in regards to collecting level two ethnicity and gender. Please also add a free text box asking for any suggested improvements. Please also remove the comments boxes in the document.
15. Please provide independent peer review using the [HDECs template](https://ethics.health.govt.nz/assets/Uploads/HDEC/hdec-peer-review-template-june-2021.docx).

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

1. Please use the [HDECs template](https://ethics.health.govt.nz/assets/Uploads/HDEC/templates/participant-information-sheet-consent-form-template-sep20.doc) when filling out the PIS/CF forms to ensure that these comply with the *National Ethical Standards for Health and Disability Research and Quality Improvement 2019, paras 7.15 – 7.17.*
2. Please remove “by completing this questionnaire” as it is confusing.
3. Please move the relevant parts of the purpose section to the procedures section.
4. Please address the PIS/CF to the person it is intended for/addressed to. Please also be clear about the PIS/CF for parents/guardian or child and their respective roles and use appropriate language to address them accordingly (e.g. ‘your child’ versus ‘you’).
5. Please use macrons on Māori words.
6. Please ensure each section answers the question in the title and ensure the additional information is provided in that section only if it is not able to be provided elsewhere.
7. Please amend the “who can take part” section in the adult PIS. Please amend the suggestion that parents should be 0 – 26-years-old when it should be the child. The adult PIS also suggests that the child can complete it, please amend and arrange for someone to proofread the documentation.
8. Please correct the reference to young person’s age to 16 – 26 not 17 – 26-years-old.
9. Please include more information about your study in the ‘Who can participate’ section, by adding that this is a research study, there is a questionnaire, and there will be follow-up using data linking.
10. Please add the risks of your study. For example, risks of data confidentiality.
11. Please remove the paragraph under the ‘What if I have concerns about my child’ section of the adult PIS. Please review this whole section.
12. As participants will be provided information about their risk factors, please make this clear.
13. For storage of data, please state that this will be kept for 10 years after participants turn 16-years-old. (*National Ethical Standards for Health and Disability Research and Quality Improvement, para 6.28)*.
14. Please amend the ‘What will happen to my information’ section. As the information might be used after 10 years, please state that you may use the participants’ study information after 10 years for future studies. Please also describe what these future studies may be about. Please also put this information in the Protocol and Data Management Plan.
15. Please add “if you withdraw after the data is used, the data will still be included in the usage” in the access information and withdrawing criteria section.
16. In the CF there is separate consent for participation in part one and part two but only one tick box is available. Please review.
17. For the parental PIS/CF, the footer states ages seven to 11-years-old. Please review.
18. Please mention that the survey looks at oral health as well as respiratory.
19. Please make clearer what is a questionnaire and what is a survey.
20. Please clearly state that you will be undertaking future research using the data collected.
21. Please outline how you are planning to talk to whānau/family of the participants.
22. Please use Qualtrix, not Microsoft Excel, for data management and collection. Please also remove all references to Microsoft Excel.
23. Please mention predictive risk and use of predictive risk, particularly in relation to the data linking.

Decision

This application was *declined* by consensus, as the Committee did not consider that the study would meet the ethical standards referenced above. The Committee encouraged resubmission to the Northern B HDEC.

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| **3** | **Ethics ref:** | **21/NTB/189** |  |
|  | Title: | BGB-11417-105 in Combination With Dexamethasone and Carfilzomib/Dexamethasone in Patients With Relapsed/Refractory Multiple Myeloma |  |
|  | Principal Investigator: | Dr Rajeev Rajagopal |  |
|  | Sponsor: | BeiGene NZ, Limited |  |
|  | Clock Start Date: | 22 July 2021 |  |

Dr Rajeev Rajagopal, Rocco Crescenzo, Jeny Koshy, and Parag Patel were present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. This is a global multi-centre, open-label, dose-finding study of BGB-11417 in combination with either dexamethasone or dexamethasone and carfilzumib in patients with relapsed/refractory multiple myeloma with t(11,14) translocation.
2. It consists of two parts. Part 1 (dose escalation) will be used to find the most appropriate dose of BGB-11417 - firstly in combination with dexamethasone. This dose will then be given to another cohort of patients in combination with both dexamethasone and carfilzomib. If the dose of BGB-11417 is not tolerated in this cohort, a lower dose will be considered. Part 2 (cohort expansion) will investigate the final determined dose/s of BGB-11417 from Part 1 in larger cohorts of patients.

Summary of resolved ethical issues

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

1. The Committee noted that in the Participant Information Sheet, the researchers referred to earlier trials from February 2021. The Committee asked if there is any possibility that patients enrolled into this study could receive more updated/current information. The researchers explained that there has been no change in the safety reported between the dates. Further, when more data is available the researchers are open to sharing it. The Committee noted that this will necessitate an update to the Participant Information Sheet and potentially the Investigator’s Brochure, in terms of additional safety information.
2. The Committee referred to the optional bone marrow biopsy and asked for clarification on when this is optional (noting that one is mandatory for screening diagnosis). The researchers stated that as part of the trial, there will be a baseline bone marrow biopsy. The trial will look at biomarkers and other information that might be helpful for future treatment of patients. The additional bone marrow biopsy is optional for patients only if they wish to provide a sample.
3. The Committee queried whether Māori consultation has been undertaken. The researchers advised that this is always part of their process, but they were waiting for ethics approval first. The Committee clarified that researchers do not need to obtain ethics approval prior to undertaking Māori consultation. The Committee was satisfied that this would be done appropriately through the District Health Board.

Summary of outstanding ethical issues

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

1. The Committee referred to the Future Unspecified Research (FUR) Participant Information Sheet and Consent Form (PIS/CF). The Committee asked how the researchers envision consent working in terms of delivering the main PIS/CF and FUR PIS/CF. The researchers stated that they will ask patients to consent to both the main study and the FUR upfront at the beginning of the study. Patients may withdraw consent at any time. The researchers felt comfortable that all information can be understood at the time of obtaining consent.

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

1. Please soften the wording around ‘survival follow up’ to something such as ‘long term follow up after disease progression’.
2. In the ‘What do I have to do’ section, please add the restriction around limiting sun exposure and using sunscreen.
3. Please reference effective contraception measures by using the [HDECs template](https://ethics.health.govt.nz/assets/Uploads/HDEC/templates/participant-information-sheet-consent-form-template-reproductive-risks-apr20.docx) under the contraception section for New Zealand participants.
4. Please refer to the correct HDEC i.e. ‘Northern B HDEC’ not the Northern A HDEC.

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 the suggestions made by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement 2019, para 7.15 – 7.17).*

After receipt of the information requested by the Committee, a final decision on the application will be made by Ms Susan Sherrard and Mrs Stephanie Pollard.

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| **4** | **Ethics ref:** | **21/NTB/188** |  |
|  | Title: | A self-compassion chatbot for adolescents with T1D |  |
|  | Principal Investigator: | Dr Anna Serlachius |  |
|  | Sponsor: |  |  |
|  | Clock Start Date: | 22 July 2021 |  |

Dr Anna Serlachius and Anna Boggiss 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. Adolescents with type 1 diabetes experience high rates of distress, depression, anxiety, and disordered eating behaviours, compared to their healthy peers. Using a pilot randomised controlled trial, the researchers would like to examine any possible improvements in self-compassion, diabetes-related distress, stress, disordered eating behaviour, diabetes self-care behaviours, and glycaemic control from using a self-compassion chatbot app, compared to those using a diabetes self-management education app.
2. A target of 74 adolescents (aged 12 to 16) will be recruited from the Starship paediatric diabetes outpatient clinics and online. Once participants have consented/assented to participate they will complete baseline questionnaires, and either be given access to the self-compassion chatbot app or a diabetes self-management education app. The self-compassion chatbot will ask participants how they have been lately and how their diabetes self-management is going before starting conversational lessons on self-compassion and mindfulness tools.
3. After three weeks, participants will complete questionnaires and then again at three months after the intervention. The researchers will also collect participants’ routine glycaemic control (HbA1c) from their clinical records at baseline, three and six-months. Those who live outside of Auckland will be asked to self-report their glycaemic control (HbA1c) at these timepoints.

Summary of resolved ethical issues

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

1. The Committee asked how recruitment will work. The researchers stated that there are two branches. The first is to recruit in-clinic and this is currently undergoing locality approval. The second is online recruitment that allows for assent in circumstances where participants are under 16-years-old. A flyer will be sent to Diabetes New Zealand and flyers will be uploaded on their website. There will also be several managed support groups on Facebook that the researchers will obtain permission to post in. Participants will have seen the Participant Information Sheet because they sign up to the HABITS portal.

Summary of outstanding ethical issues

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

1. The Committee asked the researchers to confirm that this is not the first time the self-compassion chatbot has been run but, it is the first time being used for adolescents with type 1 diabetes. The researchers confirmed this, and they will be comparing the chat-bot with a Starship Hospital diabetes app on Medsafe that collates all self-management information needed for type 1 diabetes. Please provide more information in the Protocol around the app as a comparator in the study. For example, detail what it is, how it is accessed, what it looks like, how it is different? etc. Please also provide information on the security around it and if it collects any information (including metadata about usage and the user).
2. The Committee asked how the risk escalation process works and the advice that if there is serious risk for the user, the user should dial 111. The researchers stated that they will monitor the chatbot and there is the option of referring participants to the diabetes team’s psychologist. The researchers noted that under the HABITS studies, no participant has given an indication of intention to self-harm etc. The Committee asked about the timeliness for risk escalation. The researchers stated that the message about dialling 111 would happen automatically and the researchers would be notified by automated email, then a referral would be made immediately. However, the Committee noted that the chatbot is provided 24 hours per day and a notification to the research team may happen outside of work hours. The Committee stated that the researchers have a duty of care to participants and an obligation to intervene if participants report harm to themselves or others. The Committee requested a formal plan for risk management in the case of participant mental health distress. The Committee suggested that the researchers have a way for a potential notification to be routed to the Crisis team if possible. Please clarify the formal process in the study documentation to clearly articulate what the process is for risk escalation in a manner that is proportionate to the level of risk. Inclusion of a flow chart may be helpful to illustrate how this process will work.
3. The Committee also noted that the researchers may refer participants to their family. This may not be appropriate in all familial situations. The Committee suggested the possibility of notifying the participant’s general practitioner.
4. The Committee also noted that it may be distressing if participants are locked out of the app if they are directed to dial 111.
5. The Committee requested a detailed Data Management Plan. This can either be in the Protocol or as a separate document. This will need to include advice on what metadata will be collected and whether this involves location/GPS. Please refer to the [HDECs template](https://ethics.health.govt.nz/assets/Uploads/HDEC/templates/data-only-management-template-oct2020.docx) for guidance on what a Data Management Plan should include. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15a).*
6. The Committee referred to the app developer’s website that states that they integrate the app into the HABITS analytics platform, and this will track participants’ health records, including mental health, for several years. As part of the Data Management Plan, please address this statement and clarify to participants that this will not happen for their data.
7. The Committee referred to r.1.5 and r.1.6 of the application. The Committee noted that the researchers stated they will not do any safety analysis, are not creating any stopping rules, and not collecting any adverse events. The Committee recommended that the researchers consider these, particularly adverse event collection. This is because participants may report that they are distressed. It may be useful to have outcome information about action taken on adverse events and to improve the app. This would support a mechanism to ensure the escalation process is safe and secure for participants. Examples of adverse events could include self-harm and hyperglycaemic episodes.
8. The Committee noted that Māori partnership is discussed in the app and interviews. The Committee commended this. The Committee asked if additional koha will be provided for the additional interviews for Māori participants. The researchers confirmed this. There is no information about the interviews in the Participant Information Sheet so please include this.
9. The Committee requested copies of the survey questions and asked how people will be recruited for that. Please include information about the survey in the Participant Information Sheet and Protocol. Please include information in the Data Management Plan about what will be collected and analysed in the surveys, and how this information will be stored.
10. The Committee referred to the use of the word ‘benefits’ in the Participant Information Sheet. Please rephrase this and state that the app ‘might improve your wellbeing’ as it is not certain whether the app will work in this study population.
11. Please include information in the Participant Information Sheet about possible withdrawal from the study. Please include information about what happens if someone withdraws from the study, what will happen to their data, and whether there will be a point where their information will no longer be used.
12. In the Participant Information Sheet, there is a statement that there is no risk in the study but then a statement that participants ‘might be distressed’ and there is reference to the crisis support services. Please consider rephrasing this and include advice/a description of what participants will be advised to do if they experience mental health distress during the study. Please also note that ‘distress’ is a risk, so it is incorrect to state that there are ‘no risks’.
13. The Committee advised that data retention is required for 10 years after the participant’s 16th birthday. The Committee also recommended that participants should be reconsented after turning 16-years-old.
14. The Committee referred to p.4.2 of the application and advised the researchers that Māori consultation is required. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 3.7)*.
15. The Committee noted that for the electronic consent process, parental consent is requested after the child. Please provide some information to reassure the Committee that the child will not click both boxes and confirm parental consent for themselves. It may be useful to put writing in bold to emphasise to the child that they must not tick the boxes about parental consent.

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

1. Please review the ‘What’s in it for me?’ section. This section is not included in the [HDECs template](https://ethics.health.govt.nz/assets/Uploads/HDEC/templates/participant-information-sheet-consent-form-template-sep20.doc). Please review this and follow the template approach for guidance.
2. Please remove koha from the ‘benefits’ section and instead refer to it later in the document. Koha is not a benefit. It is a gift given in reciprocity. The benefit is that participants will contribute to knowledge about this area of study and is an opportunity to try something new, which may or may not work. Please also do not emphasise koha in the recruitment strategy.
3. Please do not collect patient information in the Participant Information Sheet.
4. Please remove contact details from the first paragraph and instead put these at the end of the form.
5. Please remove the box referring to this being a first in human study. Instead, please state that you do not know yet whether the chatbot will work for the study population of type 1 diabetics.
6. Please include pictures of the chatbot – especially for parents as they will not be using the chatbot themselves.

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 the suggestions made by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement 2019, 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 Mrs Kate O’Connor and Mrs Leesa Russell.

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| **5** | **Ethics ref:** | **21/NTB/187** |  |
|  | Title: | A validation of placental pathology reports in New Zealand. |  |
|  | Principal Investigator: | Miss Esti de Graaff |  |
|  | Sponsor: |  |  |
|  | Clock Start Date: | 22 July 2021 |  |

Esti de Graaff, Dr Ngaire Anderson, and Dr Kate Bartlett 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 study looks at ethnic inequity around still birth rates and will investigate whether features of placental pathology differ between perinatal deaths of Indian women and women of other ethnic groups. The study will analyse pathology reports of deaths that occurred between 2008 and 2017.
2. The researchers have identified several types of possible bias associated with these reports. Considering the important implications of the findings, the researchers propose a blinded audit-type review of the original histological slides by an experienced perinatal pathologist, from a representative sample of the cohort.
3. While the focus of this study is specifically to investigate outcomes among Indian women, the researchers acknowledge that Māori women are also at increased risk for some of the primary outcomes and therefore will be investigated as a comparison group. Additionally, women of New Zealand European ethnicity will be included in this study, representing a group with lower risk of perinatal mortality.

Summary of resolved ethical issues

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

1. The Committee asked what the nature of consent is when women consent for placental pathology to be undertaken, and what their understanding might be in regards to use, storage, and access. The researchers stated that the histology forms usually just request a form signed by the technician and not the woman. When placenta comes to the laboratory, it is usually for diagnostic reasons about the outcome of pregnancy or any future pregnancy planning. As for tissue storage, patients can request to have their tissue returned to them and this is a common request. From there, sections are taken from the tissue and put onto glass slides and stored for 20 years in the department. The purpose for this long storage is for historical and clinical reasons. For example, in cancer patients, if a patient re-presents their slides will be retrieved to investigate whether the tumour looks same as a previous one.

Summary of outstanding ethical issues

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

1. The Committee noted that there has been good consultation undertaken with Māori and the procedures have been adjusted around recommendations made through the consultation process. The Committee noted that feedback obtained from Indian members of the advisory group stated that placenta is not of particular cultural/spiritual significance to Indian women. The Committee noted that there is immense diversity across ethnicities and religions in India and asked whether there is an Indian women’s group the researchers could consult with beyond the two Indian women in the advisory group. The Committee requested that the researchers expand their consultation process, given the potential stigma that may arise from publishing the study results, and in terms of significance of placental tissue.
2. The Committee noted that Pasifika women are currently excluded from the study due to heterogeneity across Pacific peoples. However, this exists among Indian women too. The researchers acknowledged this and stated that the way ethnicity data is recorded in New Zealand, women from Pacific backgrounds can be distinguished, but not Indian women. The Committee asked if the potential for stigma is increased by the comparator being Māori women. The Committee suggested that if the researchers have the time and resources, they should continue with the Indian sub-groups and Māori, but also include Europeans, to then provide a non-Māori/non-European other group. The current omission of Pasifika women implies that Māori and Indian are being compared, when actually the study is trying to answer questions about Indian women. An additional comparator group should be included to minimise the risk of stigmatisation. The Committee suggested that the researchers re-consult with Dr Helen Wihongi about this matter and in terms of how to report facts without stigmatising populations. It may also be helpful to consult with a Māori stillbirth association or New Zealand pregnancy loss group.
3. In terms of equity, it is stigmatising not to include Pasifika women in the study, noting that they have one of the highest perinatal death rates in New Zealand. Please bear in mind the possible inclusion of Pasifika women when considering discussion of other categorisations of women for the study.
4. The Committee referred to the application for waiver of consent. The Committee asked why consent cannot be obtained from the mothers. The researchers stated that a main reason is because the perinatal deaths occurred between 2008 and 2017. It would be difficult to find some women considering they may have moved homes/changed contact details. The researchers advised that if they did have contact details available, they would consider asking the women for consent. However, they also noted that the discussion would be about a traumatic past event and there would be a risk of causing harm to these women/whānau through sudden contact.
5. The Committee asked if the researchers know what the women would be likely to consent to or not agree to. The researchers stated that women often are offered with the option of having their placenta/histological slides returned to them after investigation. If they were unlikely to consent, they would likely have already had their slides returned to them at the time of investigation. Further, the researchers will not destroy or alter the tissue. The Committee noted that the further consultation across populations would also provide further information on this point.
6. The Committee requested a Data and Tissue Management Plan. Please use the [Data and Tissue Management Plan template](https://ethics.health.govt.nz/assets/Uploads/HDEC/templates/hdec-data-tissue-management-template-oct2020.docx) available on the HDECs website.
7. The Committee noted that when the researchers review the placental histology, they may find major or minor errors of clinicians. The Committee asked what the researchers would do if a major error were to be found. The researchers advised that for women with perinatal loss, their management and any subsequent pregnancy involves increased surveillance. The women will likely have already been followed up appropriately. The researchers would forward any major discrepancy found to the lab in order for the respective clinician to be informed. The researchers do not expect any actual findings. Placental pathology rarely affects the mother so it would be unlikely to find conditions in the mother.
8. The Committee asked if there is a monitoring committee and governance structure in place as part of the study that could investigate any cases of major or repeated minor errors. The researchers advised these are not currently in place. The Committee suggested including in the protocol, explanation around what were to happen in the unlikely event that they find an actionable incidental finding. This should include detailed steps about the approach to address this situation. For example, including what the approach is if it were found that one pathologist in particular was consistently making similar errors.
9. The Committee noted that the researchers did not identify a sponsor. The Committee suggested that the appropriate contact would be the University of Auckland but that the researchers should check with their research office.

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 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 John Hancock and Mrs Stephanie Pollard.

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| **6** | **Ethics ref:** | **21/NTB/190** |  |
|  | Title: | (duplicate) Non-Invasive Ventilation Mask Assessment |  |
|  | Principal Investigator: | Dr Robert Martynoga |  |
|  | Sponsor: | Fisher & Paykel Healthcare |  |
|  | Clock Start Date: | 22 July 2021 |  |

Jessica Fogarin 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. An assessment of usability, perceived comfort, and performance of the investigational Non-Invasive Ventilation (NIV) mask in the hospital environment. Up to 50 patients admitted for NIV therapy at Waikato Hospital will have the study mask which fits under the nose and over the mouth.
2. Participants will be asked to complete a questionnaire on the usability, performance, and perceived comfort of the mask.

Summary of resolved ethical issues

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

1. The Committee noted that this was a resubmission of an application declined by a different HDEC. The Committee thanked the researcher for the work undertaken to address the matters raised by the other HDEC.
2. The Committee asked how much information clinical staff will provide and whether they will be study participants. The researcher stated that their feedback will only be collected using a smiley face scale. Given this is minimal data collection and no identifiable information being obtained, the Committee was satisfied that a separate Participant Information Sheet and Consent Form is not required for clinical staff. The Committee suggested just providing clinical staff with a pamphlet or brochure.

Summary of outstanding ethical issues

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

1. The Committee noted that the researcher has identified that there are two issues with the mask. First, placement of the mask on female Muslim patients wearing head coverings. Secondly, for Māori patients the head is tapu. The Committee advised that information is now required about what the researcher will do for these patients. For example, please make clear in the Participant Information Sheet that you will ask for permission before touching the head, and ask participants if there is anything else they would like you to do before touching their head.
2. The Committee referred to the post-participation form. Please include information about what will happen to the data collected if participants withdraw from the study.
3. In the advertisement, please remove the statement that there are ‘no risks’. The Committee suggested stating that there are ‘no serious risks’ instead.
4. Please remove reference to the Medicines New Zealand Guidelines for compensation as these guidelines apply to medicines, not devices.

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

1. Please ensure that formatting is consistent across all Participant Information Sheets and Consent Forms. Please refer to the [HDECs template](https://ethics.health.govt.nz/assets/Uploads/HDEC/templates/participant-information-sheet-consent-form-template-sep20.doc) for guidance.
2. Please use the same picture for all Participant Information Sheets and Consent Forms.
3. For the non-consenting form, please include a warning box that this study is first in human and there are no proven benefits yet.
4. Please include the social media clause in the whānau/family Participant Information Sheet (currently it is only in the post-participation form).

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. *(National Ethical Standards for Health and Disability Research and Quality Improvement 2019, para 7.15 – 7.17).*

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| **7** | **Ethics ref:** | **21/NTB/191** |  |
|  | Title: | Stand Strong, Walk Tall - Pilot |  |
|  | Principal Investigator: | Dr Sarah Christofferson |  |
|  | Sponsor: |  |  |
|  | Clock Start Date: | 22 July 2021 |  |

Dr Sarah Christofferson 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 Phase Two of ‘Stand Strong, Walk Tall’ (SSWT), a community-based intervention for people who self-identify as having a sexual interest in children.
2. In this phase, the researchers seek to:
3. conduct a pilot of the SSWT programme using a sample of self-referred clients in New Zealand.
4. as part of the pilot, initiate a research database that can be built on (with broader implementation of the SSWT service) to facilitate future projects aiming to enhance understanding of people who have a sexual interest in children, their treatment needs, and treatment responses.
5. evaluate the impact of the SSWT programme on pilot clients (i.e. participants), including on child wellbeing as well as factors related to risk of future offending.
6. Twenty participants in the pilot phase of the intervention itself. It is flexible and based on the individuals’ treatment needs.

Summary of resolved ethical issues

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

1. The Committee asked if the researcher will be the main therapist or will there be some therapists contracted as well. The researcher stated that she and a co-researcher will be the primary pilot clinicians. They are open to the possibility of external clinicians being involved. These people would be working in services that the funder, the Ministry of Social Development, has contracts in place in the harmful sexual behaviour community treatment area. These clinicians would receive training, oversight, and support if they do take clients in the study.
2. The Committee asked if participants will be able to attend therapy sessions in person without being identified. The researcher stated that they use the clinic for other reasons in addition to the study. Participant attendance would not flag any particular reason for presentation.

Summary of outstanding ethical issues

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

1. The Committee noted that the intervention has been described as a ‘new service’. However, it is not a new service yet. Describing it in this way may cause misunderstanding that it is a proven treatment. Further, given the nature of the study, potential participants will take a great risk by volunteering. Please reframe and state that this is a pilot study.
2. The Committee discussed with the researcher whether there is obligation to disclose information provided by participants (e.g. about offending) to the New Zealand Police. The researcher stated in the Participant Information Sheet that confidentiality will need to be breached around concerns about safety of the participant or anyone else. However, please include in the Participant Information Sheet, more information about possible legal consequences if the researcher is required to share this information. The Committee asked whether the Code of Ethics is prescriptive. The researcher confirmed this and stated that it is principle based and provides guidance as to when disclosure is required. Please also refer participants to the Code of Ethics via the Participant Information Sheet. Further, the Committee requested that the researcher provide information about the legal review of the study. *(National Ethical Standards for Health and Disability Research and Quality Improvement 2019, para 12.9).*
3. The Committee noted that IDI data linking would introduce significant and ongoing risk to participants that may not be justified in the context of a pilot study. The researcher agreed and advised that the IDI aspect could be deferred to a possible later study. However, the criminal history information of participants will remain for this study. The researcher agreed to remove the IDI aspect of this pilot study. Please also make clear in the Participant Information Sheet that you will be confirming participants’ criminal records via official criminal history information and that further information about this will be obtained at longer follow up periods.
4. The Committee requested that the researcher provide the framework for all modules and training.
5. The Committee noted that no study sponsor is listed, however, the study is funded by the Ministry of Social Development. The Committee suggested that the researcher confirm with the university that they are the appropriate sponsor that will take overall responsibility for the study. *(National Ethical Standards for Health and Disability Research and Quality Improvement 2019, Chapter 12 (para 12.38)).*
6. Please provide a Data Management Plan. The Committee suggests using the [HDECs template](https://ethics.health.govt.nz/assets/Uploads/HDEC/templates/data-only-management-template-oct2020.docx) for guidance. It is important to distinguish identifiable data from coded data, who has access to what data, how long it is stored for, whether it will be sent overseas, whether it will be access by other researchers in future etc. Please also include information in the Data Management Plan about institutional data governance policies as sponsorship is more about governance than it is about funding for the purposes of HDECs. *(National Ethical Standards for Health and Disability Research and Quality Improvement 2019, para 12.38).*
7. Please be clear in the Participant Information Sheet around withdrawal of consent for data use and point out if there are any limitations (this will be informed by content in the Data Management Plan). The Committee suggested including a statement that ‘we will use your data to the point of withdrawal from the study’. *(National Ethical Standards for Health and Disability Research and Quality Improvement 2019, para 12.44).*
8. The Committee noted that the researcher intended to use a Microsoft access database. This is no longer a standard for databases, please use Qualtrix instead as this can be provided by the university and is more secure. *(National Ethical Standards for Health and Disability Research and Quality Improvement 2019, para 12.11).*

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

1. Please add a Māori cultural support contact for participants. *(National Ethical Standards for Health and Disability Research and Quality Improvement 2019, para 3.7).*
2. Please distinguish future criminal record information from IDI study/data linking in the Consent Form. Please also remove reference to the IDI study as this will not be undertaken in this study.

Decision

This application was *declined* by consensus, as the Committee did not consider that the study would meet the ethical standards referenced above. The Committee encouraged resubmission to the Northern B HDEC.

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| **8** | **Ethics ref:** | **21/NTB/193** |  |
|  | Title: | Study of efficacy and safety of MIJ821 in addition to comprehensive standard of care on the rapid reduction of symptoms of Major Depressive Disorder in subjects who have suicidal ideation with intent |  |
|  | Principal Investigator: | Associate Professor SW Miles |  |
|  | Sponsor: | Novartis Pharmaceuticals Australia Pty Limited |  |
|  | Clock Start Date: | 22 July 2021 |  |

Associate Professor Wayne Miles and Deborah Campbell 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. A double-blind, placebo-controlled, randomised dose-ranging trial to investigate efficacy and safety of intravenous MIJ821 infusion in addition to comprehensive standard of care on the rapid reduction of symptoms of Major Depressive Disorder in patients who have suicidal ideation with intent. The study drug will be administered in addition to standard antidepressant medication.
2. The study will investigate seven different treatment groups to define the optimal dose and frequency of administration of MIJ821. There will be 195 participants in total across all sites.
3. Participants will have three infusions within a six-week period and if they respond, will be eligible for an extension study lasting 52 weeks with the ability to be re-treated if they have a relapse of depressive symptoms.

Summary of resolved ethical issues

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

1. The Committee noted that patients who weigh over 120kg will not be included in the study. The Committee asked if this will impact a large percentage of the Māori and Pacific population. The researchers advised that it probably will not cause impact and will not likely be a serious factor that precludes participation of Māori or Pasifika patients.
2. The Committee noted that some of the scales and forms are distressing to read and possibly stressful for participants. The Committee asked how the researchers will manage this. The researchers stated they do not consider that the scales and forms will make participants feel worse. The researchers acknowledged that it is important to be sensitive at all times when exploring the way someone is feeling. However, from experience in working with this group of patients, patients can feel accompanied in exploring the problem. It is often beneficial to patients and makes them feel heard and understood. Exploring these feelings will not be new to these patients.
3. The Committee asked about patients’ capacity to consent and whether patients who are imminently suicidal will have full capacity to consent to research participation. The researchers stated that patients who have absolutely reduced capacity would be those who have combined cognitive disability with suicidality and major depression. These patients will not be included in the study. The researchers considered that the patients who will be recruited will be able to fully understand the implications of depression that is difficult to treat and the reasons for the study. The Committee was satisfied that the researchers will not recruit patients who do not have full capacity to consent and that as mental health professionals, they will be engaged in the assessment process and with patients’ clinicians to appropriately identify patients who can and cannot consent.
4. The Committee asked about the possible dissociative reaction participants may have to the study drug. The researchers advised that there may be a degree of feeling detached from the world temporarily. However, the disassociations will not be large compared to extreme psychedelics. The study drug is a ketamine-like substance but is different to ketamine. In the animal and phase 1 studies, the effects appeared to be less than the typical dissociative effects of ketamine. Nevertheless, this is recognised as a risk and if something were to happen the researchers would monitor the participant closely and provide safe reassurance.
5. The Committee asked who will make the decision to bring participants back into the unit if they relapse and how relapse will be managed. The researchers advised that if they have a participant who meets the criteria for being responders or remitters, and they have a further return of the depressive phenomenology, they are entitled to ongoing treatment under the study, hence the 52-week extension period. The researchers will never be the primary care deliver for the participants. Participants will remain involved with their current treatment team during the study and the researchers will work closely with them. If participants require urgent services, the researchers will encourage that they receive care. For acute exacerbation that required rapid intervention, the researchers will ensure participants are cared for trough the Crisis team.

Summary of outstanding ethical issues

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

1. The Committee asked that when submitting documents for first consideration of new applications, the researchers do not provide duplicate documents and tracked changed versions. Tracked change versions are required for provisional approval instead.
2. The Committee discussed recruitment of participants with the researchers. If the Mental Health (Compulsory Assessment and Treatment) Act 1992 (MHA) is enacted during the study, this would be an adverse event. The Committee asked if the researchers would recruit patients in hospital who have been admitted under the MHA. The researchers confirmed they will not recruit patients admitted under the MHA. The Committee confirmed that the researchers do not need to provide an addendum to the study protocol confirming this. It is recorded that the researchers agreed not to recruit these patients into this study. It was noted, however, that the researchers may recruit these patients for a possible phase 3 study given that these patients may be treated with the study drug.
3. The Committee asked if the genomic sequencing is mandatory and the researchers confirmed this. The Committee advised that an additional consent is not required for the genomic sequencing given that it is in the main Participant Information Sheet and Consent Form. However, separate consent is required for Future Unspecified Research. Please use the [HDECs template](https://ethics.health.govt.nz/assets/Uploads/HDEC/templates/future-unspecified-use-tissue-piscf-template.doc) for guidance on how to complete this to the standard required and check for any inconsistencies with the District Health Board’s form.
4. The Committee asked how participants will cope with a long day (six to seven hours) with many surveys to complete. The researchers advised that there will be breaks. There are also smartphones available to complete cognitive assessments. Smartphones are available on the ward and for participants to take home. The Committee requested more information about how the data coming from the smartphones will be protected during transit between participants’ homes and the hospital.
5. The Committee requested a Data Management Plan. Please use the [HDECs template](https://ethics.health.govt.nz/assets/Uploads/HDEC/templates/data-only-management-template-oct2020.docx) for guidance.
6. The Committee noted that it is not clear in the Protocol or Participant Information Sheet and Consent Forms about how videos and recording will be used. Please clarify how they will be used, what you will be using, and whether this is optional (as currently stated on the Consent Form) etc.
7. The Committee asked if participants can be provided with taxi vouchers to cover travelling home after discharge. The researchers confirmed this. Please include this information in the Participant Information Sheet.
8. The Committee noted that the tablet forms appear to repeat questions twice. Please review and amend this.
9. Please review the language used in the slideset training for staff. This currently suggests that staff will tell participants that they will receive high quality care while in the trial. However, all mental health patients should receive high quality care regardless of whether they participate in the study.

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

1. Please ensure that content and formatting is consistent. Please refer to the [HDECs template](https://ethics.health.govt.nz/assets/Uploads/HDEC/templates/participant-information-sheet-consent-form-template-sep20.doc) for guidance.
2. Please include the warning box in regards to phase 1/2 trials (refer to the HDECs template as linked above).
3. Please ensure that the purpose of the study is clearly articulated.
4. Please remove the flipping a coin reference.
5. Please clearly state what is required in order to confirm that a participant is eligible for the study extension.
6. Please clearly state how participants will be monitored and explain the risks around this. Please also include information about the treatments that cannot be used during the study, particularly the mental health drugs.
7. Please provide the full address for laboratories.
8. Please remove reference to the Southern HDEC.
9. Please also review the content to ensure that the correct information is in the correct corresponding sections. For example, the section about who can take part in the study should answer the question about who is eligible to participate in the study. Currently, this section incorrectly discusses participant responsibilities and this information should be in the section about participation.
10. Please include the risks to liver, kidney, cardiac, cystitis, and respiratory side effects that are listed in the Protocol.

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 the suggestions made by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement 2019, 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 John Hancock and Mrs Leesa Russell.

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| **9** | **Ethics ref:** | **21/NTB/194** |  |
|  | Title: | PILOT STUDY OF KETAMINE IN PSYCHOGENIC NON-EPILEPTIC SEIZURES |  |
|  | Principal Investigator: | Dr Charlotte Mentzel |  |
|  | Sponsor: |  |  |
|  | Clock Start Date: | 22 July 2021 |  |

Dr Charlotte Mentzel present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. This study will investigate the effectiveness of ketamine in treating Psychogenic non-epileptic seizures (PNES). This is based on the idea that ketamine reduces the psychological trait of neuroticism and patients with PNES have been shown to have high levels of this.
2. There will be 10 participants for this open label, uncontrolled, safety and acceptability study with weekly ketamine titration over four weeks.
3. Medication is added to orange juice, weekly for dosing period with dose escalation. Prior to the dosing period, there is a recording period, a psychological intervention, recording of the medication, and additional recording. Participants will keep a seizure diary, undergo an electroencephalogram and various validated scales.

Summary of resolved ethical issues

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

1. The Committee asked if the experience of non-epileptic seizures looks similar to an epileptic seizure. The researcher stated that it is debilitating and impactful like a seizure but, patients cannot easily tell the difference.
2. The Committee asked if there is risk to the patient in experiencing disassociation. The researcher advised that there is some risk of potential disassociation, however, the feeling tends to be transient. Nevertheless, they would not discharge patients until the feeling disappears. They will also monitor any feeling of disassociation using a rating scale.
3. The Committee noted that recruitment is fairly ambitious given the low numbers people with the disorder in the respective community. The researcher stated that these patients tend to feel stuck and unheard. They often remain on neurology and psychiatric lists. Clinicians will advise patients that this study is available and ask for permission to have their contact details passed to the research team.
4. The Committee noted that there are no treatments available for this condition and asked if psychotherapy is an option. The researcher stated that there have been many studies on whether psychodynamic therapy or cognitive brain therapy (CBT) works. A CBT trial of 300 patients showed no improvement versus controlled intervention of supportive therapy. There is no clear evidence from randomised control trials that psychotherapy works.

Summary of outstanding ethical issues

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

1. The Committee noted that the researcher has referenced midazolam in some of the study documentation in error. Please ensure that these references are removed (for example in the protocol coversheet and on page 7 of the Participant Information Sheet and Consent Form).
2. The Committee noted that the peer review obtained was good. However, some of the responses to peer review have not been reflected in the protocol and Participant Information Sheet. Please ensure that all changes made as a result of peer review are implemented.
3. The Committee asked that taxi and petrol vouchers be made available to participants (for both travelling to and from the clinic). Please make clear in the Participant Information Sheet that these are available.
4. The Committee noted that the researcher has stated there is no sponsor. The Committee asked who would be taking overall responsibility for the study and whether this would be the university. The researcher stated that they understood the university would hold all the risks as is standard. The Committee suggested that the university be listed as the study sponsor for purposes of study governance. Please confirm this with the university.
5. Please ensure that the safety list regarding discharge of patients is uploaded with the study documentation if it has not already been uploaded.

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

1. Please check that the page numbers (and amount of page numbers in total) are correct.
2. Please simplify the descriptions in the table of assessments.
3. Please define ‘disassociation’ the first time that it appears.
4. Please include all pertinent side effects information (page 7). Participants should not need to ask their doctor to explain further information on side effects. This information should be made available to them in the study documentation.

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 the suggestions made by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement 2019, para 7.15 – 7.17).*

After receipt of the information requested by the Committee, a final decision on the application will be made by Ms Susan Sherrard and Mrs Stephanie Pollard.

## 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:

|  |  |
| --- | --- |
| **Meeting date:** | 07 September 2021 |
| **Meeting venue:** | Via Zoom |

1. **Review of Last Minutes**

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

1. **Matters Arising**
2. **Other business**

The Chair acknowledged the ongoing work of the Committee’s two non-lay members.

The Committee requested an update on information about flights and accommodation for the upcoming HDEC training day on 26 August 2021. The Secretariat will provide the Committee with this information.

1. **Other business for information**
2. **Any other business**

The meeting closed at 5.10pm