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| **Committee:** | Northern B Health and Disability Ethics Committee |
| **Meeting date:** | 02 May 2023 |
| **Zoom details:** | <https://mohnz.zoom.us/j/9738756003> |

| **Time** | **Review Reference** | **Project Title** | **Coordinating Investigator** | **Lead Reviewers** |
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| 11:30am - 12:00pm | 2023 FULL 15504 | A RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED, MULTICENTER STUDY TO ASSESS THE EFFICACY AND SAFETY OF RIFAXIMIN SOLUBLE SOLID DISPERSION (SSD) TABLETS FOR THE DELAY OF ENCEPHALOPATHY DECOMPENSATION | Dr Hannah Giles | Ms Kate O'Connor and Dr Andrea Forde |
| 12:00 - 12:30pm | 2023 FULL 13714 | Needs of transgender adults, youth and parents of transgender children within primary healthcare services | Dr. Katie McMenamin | Ms Alice McCarthy and Mr Barry Taylor |
| 12:30 - 1:00pm | 2023 FULL 15542 | Newborn genomics - Te Ira oo Te Arai | Professor Justin O'Sullivan | Mr Ewe Leong Lim and Dr Amber Parry Strong |
| 1:00 - 1:30pm | 2023 FULL 15291 | A Study of the Safety and Tolerability of HM43239 in Patients with Acute Myeloid Leukemia | Dr Lauren Child | Ms Maakere Marr and Mrs Leesa Russell |
|  | BREAK (20 mins) |  |  |  |
| 1:50 - 2:20pm | 2023 FULL 15382 | Evaluation of VX-121/Tezacaftor/Deutivacaftor in Children with Cystic Fibrosis Age 1 Through 11 Years (VX21-121-105) | Professor Catherine Byrnes | Ms Alice McCarthy and Dr Andrea Forde |
| 2:20 - 2:50pm | 2023 FULL 14044 | Optimising meningioma prognostication. | Dr Clinton Turner | Mr Ewe Leong Lim and Mr Barry Taylor |
| 2:50 - 3:20pm | 2023 FULL 16681 | COMPASS feasibility study | Senior Lecturer in Health Psychology Anna Serlachius | Ms Maakere Marr and Dr Andrea Forde |
| 3:20 - 3:50pm | 2023 FULL 15311 | Monitoring oxidative stress with gastrointestinal surgery | Mr Wal Baraza | Ms Maakere Marr and Dr Amber Parry Strong |
|  | BREAK (10 mins) |  |  |  |
| 4:00 - 4:30pm | 2023 FULL 16721 | Speech Therapy Delivered by Assistants: Outcomes and Effectiveness | Dr Toby Macrae | Mr Ewe Leong Lim and Mr Barry Taylor |
| 4:30 - 5:00pm | 2023 FULL 16668 | IMC-F106C-101: Phase 1/2 Study of IMC-F106C in Advanced PRAME-Positive Cancers | Doctor Catherine Han | Ms Alice McCarthy and Dr Amber Parry Strong |
| 5:00 - 5:30pm | 2023 FULL 15396 | GS-US-200-5717: A Study to Evaluate Subcutaneously and Intramuscularly Administered Lenacapavir in Healthy Participants | Dr Christian Schwabe | Ms Kate O'Connor and Mrs Leesa Russell |
| 5:30 - 6:00pm | 2023 FULL 15407 | GS-US-200-5710: A Study to Evaluate Subcutaneous and Intramuscularly Administered Lenacapavir in Healthy Participants. | Dr Christian Schwabe | Ms Kate O'Connor and Mrs Leesa Russell |

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| **Member Name**   | **Member Category**   | **Appointed**   | **Term Expires**   | **Apologies?**   |
| Ms Kate O’Connor  | Lay (Ethical/Moral reasoning) (Chair) | 13/08/2021 | 16/08/2024 | Present |
| Mrs Leesa Russell | Non-Lay (Intervention/Observational Studies) | 13/08/2021 | 16/08/2024 | Present  |
| Mr Barry Taylor | Non-Lay (Intervention/Observational Studies) | 13/08/2021 | 16/08/2024 | Present |
| Ms Alice McCarthy | Lay (the Law) | 22/12/2021 | 22/12/2024 | Present |
| Ms Joan Pettit | Non-Lay (Intervention Studies) | 08/07/2022 | 08/07/2025 | Apologies |
| Dr Amber Parry-Strong | Non-Lay (Health/Disability service provision) | 08/07/2022 | 08/07/2025 | Present |
| Mr Ewe Leong Lim | Lay (Consumer/Community perspectives) | 08/07/2022 | 08/07/2025 | Present |
| Ms Maakere Marr | Lay (Consumer/Community perspectives) | 08/07/2022 | 08/07/2025 | Present |
| Dr Andrea Forde | Non-lay (Intervention studies) | 22/12/2021 | 22/12/2024 | Present |

## Welcome

The Chair opened the meeting at 11:00am and welcomed Committee members, noting that apologies had been received from Ms Joan Pettit.

The Chair noted that it would be necessary to co-opt members of other HDECs in accordance with the Standard Operating Procedures. Dr Andrea Forde of the Northern A HDEC 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.

## Confirmation of previous minutes

The minutes of the meeting of 04 April 2023 were confirmed.

## New applications

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| **1**   | **Ethics ref:**   | **2023 FULL 15504** |
|   | Title:  | A RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED, MULTICENTER STUDY TO ASSESS THE EFFICACY AND SAFETY OF RIFAXIMIN SOLUBLE SOLID DISPERSION (SSD) TABLETS FOR THE DELAY OF ENCEPHALOPATHY DECOMPENSATION INCIRRHOSIS (RED-C) |
|   | Principal Investigator:  | Dr Hannah Giles |
|   | Sponsor:  | Salix Pharmaceuticals, Inc.  |
|   | Clock Start Date:  | 06 April 2023.  |

Dr Hannah Giles 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 resolved ethical issues

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

1. The Committee queried how a placebo design is ethical. The Researcher stated New Zealand does not have any prevention treatment available so participants in the placebo group would not otherwise be receiving treatment to prevent or delay onset of encephalopathy. The Researcher clarified the drug is intended as a quality-of-life treatment and not an extension of life treatment. The Researcher stated if the study is successful they would hope participants in the placebo group would be offered a cross-over or extension but this would depend on the data analysis.
2. The Committee queried the risk of C. Diff infection by participating. The Researcher stated it is seen very rarely and as these patients have limited life expectancy it is unlikely they will take the drug long enough to be at risk.
3. The Committee requested the Researcher encourage the Sponsor to apply for licensure for a lower dose if the study is successful.
4. The Committee queried whether the study would have advertisements as this was indicated on the form, but none were supplied. The Researcher confirmed advertisements would not be used as participants would be recruited in-clinic.
5. The Committee queried contraceptive requirements. The Researcher confirmed both partners would require conception and a mixture of hormonal and barrier methods are acceptable.

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 whether the quality-of-life scoring system is a validated measure. The Researcher believed it was and agreed to confirm this.
2. The Committee requested an update to the data management plan to include the name of the coordinating investigator and ensure it only contains information relevant to this study.
3. The Committee requested the Researcher revise the answer to C1 in the application form to include any available statistics on prevalence in Māori.
4. The Committee noted the answer to E3.2 in the application contained information on how the study would respond to adverse events but not acute psychological distress. The Committee requested the Researcher revise the answer describe how this will be managed if it occurs.

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

**Main PIS:**

1. Please include the Sponsor's name and address on the first page header.
2. Please state the approval/supply status in New Zealand and remove the reference to "in your country".
3. Please undertake a general revision for lay-friendly language and define all acronyms the first time they are used (e.g. BID).
4. Please clearly distinguish between mandatory samples required for participation in the main study and optional samples for the sub-studies.
5. Please revise the sentence advising that participation may potentially limit trials of "other future study drugs" to be more specific.
6. Please remove the reference to NuvaRing as this is no longer available in New Zealand.
7. Please remove the reference to Greenphire if this will not be used.
8. Please change 'Medsafe' to 'Health Research Council' when discussing SCOTT on page 16.
9. Please remove the panel on the consent form agreeing to a home nurse visit as this is not offered in New Zealand.
10. Please include pregnancy safety data on humans, as this is an old medicine, and remove side effects observed in animals.

**Substudy PIS (all):**

1. Please use a white on blue colour scheme for the headings.
2. Please include information on the sub-study sheets advising that extra samples for the bacteria study will be taken during regular study visits.
3. Please include a statement on the PK study sheet advising that it requires an additional 12 hours to the regular visit.
4. Please ensure consistency around the wording of information on data as it differs between the consent form and information sheet. The consent form uses 'personal information' and the main PIS describes 'identifiable' and 'coded' information.

**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 data management plan to contain information relevant to this study only *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15).*

After receipt of the information requested by the Committee, a final decision on the application will be made by Ms Kate O'Connor and Dr Andrea Forde.

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| **2** | **Ethics ref:**   | **2023 FULL 13714** |
|   | Title:  | A sector analysis of the needs of transgender adults, youth and parents of transgender children within primary healthcare services |
|   | Principal Investigator:  | Dr Katie McMenamin |
|   | Sponsor:  |  |
|   | Clock Start Date:  | 21 April 2023 |

Dr Katie McMenamin 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 resolved ethical issues

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

1. The Committee advised that as this was a not an intervention study and no procedure would be performed, participants under 16 years with sufficient capacity to provide their own informed consent may do so without parental consent. The Researcher queried how to respond if a parent contacted them unhappy that their child participated without their consent. The Committee stated the Researcher can inform them the study has ethics approval from the HDEC and participants with sufficient capacity under 16 may participate in qualitative research without parental consent.
2. The Committee recommended becoming familiar with the [National Ethical Standards on children and young people (para 6.19 - 6.30](https://neac.health.govt.nz/national-ethical-standards/part-two/6-ethical-management-of-vulnerability/)) and advised as long as the study was consistent with the standards children under 12 would be eligible to participate.
3. The Committee noted the peer reviewer commented on the inclusion of transfeminine, transmasculine and nonbinary participants and queried who would be eligible to participate. The Researcher stated anyone who is transgender would be welcome to participate including nonbinary people.

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 recommended revising the inclusion criteria in the protocol to allow children under 12 to participate and to embed a process for participants 12-16 to provide their own consent. The Committee recommended creating the following information sheets to manage this:
	1. A young person’s information sheet and assent form for participants under 12.
	2. A slightly more complex information sheet for participants aged 12-16 who lack maturity and do require parental consent.
	3. An information sheet for participants 16 and above and those under 16 with sufficient capacity to consent.
	4. An information sheet for parents
2. The Committee requested the Researcher add a process for determining capacity to consent in the protocol.
3. The Committee queried whether the questionnaire is appropriate to capture the different experiences of youth and older people who may encounter different challenges. The Researcher stated they have been working with a trans advisory group to create specific questions to address this and would supply it to the Committee.
4. The Committee requested the inclusion of a detailed safety plan in the protocol on how to manage distress or suicidal ideation in participants. Information explaining this process should be added to the information sheets.

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

1. The Committee requested inclusion of a short statement on the study's objective(s) and what it is trying to achieve.
2. The Committee requested information on possible risks (e.g. participation may be upsetting) and how the researchers will respond. The Committee recommended adapting the section from the [HDEC template.](https://ethics.health.govt.nz/assets/Uploads/HDEC/templates/participant-information-sheet-consent-form-template-v5.0april2023.doc)
3. The Committee recommended including visual imagery in the information sheets as this may assist neurodiverse participants.

**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 Ms Alice McCarthy and Mr Barry Taylor.

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| **3** | **Ethics ref:**   | **2023 FULL 15542** |
|   | Title:  | Newborn genomics - Te Ira oo Te Arai  |
|   | Principal Investigator:  | Prof Justin O'Sullivan  |
|   | Sponsor:  | The University of Auckland  |
|   | Clock Start Date:  | 07 April 2023  |

Professor Justin O'Sullivan 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 resolved ethical issues

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

1. The Committee noted the exclusion criteria included a previously diagnosed genetic disorder and queried the possibility of multiple genetic disorders. The Researcher explained the study would involve acutely unwell babies and if an established diagnosis would explain the presenting situation the resource would not be used to find a similar diagnosis but if the presentation cannot be explained by an existing diagnosis the baby would be eligible and the study would investigate the cause.
2. The Committee noted the application stated genetic testing would occur if a parent refused a post-mortem investigation and expressed concern. The Researcher clarified that some parents refuse any post-mortem investigation or autopsies and they would be invited to participate in the study to potentially determine if a genetic cause contributed. The Researcher confirmed they would be given the option and would not do testing without consent.
3. The Committee requested additional information on the AI component of the study. The Researcher explained it is an AI developed by a commercial company and uses an algorithm to assess known clinical variants against its literature database. The AI results can then be verified manually by a specialist.
4. The Committee noted adult-onset conditions would not be disclosed. The Researcher stated the objective of the study is to investigate a diagnosis for an acutely unwell child and it is common practice in genetics to not disclose information that is not required to be known at this point in time. The Researcher explained any adult-onset diseases or recessive conditions can be disclosed during the reconsenting process when participants turn 16, if they choose to accept this information.

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 whether disability perspectives were included in study consultation. The Researcher stated they had discussion with Rare Disorders NZ in the early stages but not recently. The Committee noted genetic conditions can have a significant impact on ability and encouraged the Researcher to do further disability consultation.
2. The Committee queried how the study would manage a situation involving one parent giving consent and the other refusing. The Researcher stated genetic counsellors operating through the hospital are experienced in these situations and there are established protocols to manage them. The Committee requested this be incorporated into the study protocol.
3. The Committee queried whether samples collected in the study would be used in the future. The Researcher stated technology is advancing rapidly and if a diagnosis cannot be determined now the samples may be analysed again depending on future developments. The Committee requested information explaining this be added to the participant information sheet and specifying that repeat sampling may be done for genetic causes of disease only and not broader research.
4. The Committee noted that infant participants would require a re-consenting process at 16 years old. The Committee advised this can be submitted as an amendment in the future. The Committee requested a statement explaining this be added to the PIS.

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

1. The Committee requested the information on benefit to Māori and Māori cultural issues in the application be incorporated into the PIS to give it a stronger Māori lens.
2. The Committee noted Auckland City Hospital has a preferred cultural statement and suggested the Researcher confirm they are using the correct one.
3. The Committee requested a general revision to incorporate lay language as some people may not understand the difference between DNA samples and DNA sequence data or what 'misattributed parentage' means.

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

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| **4** | **Ethics ref:**   | **2023 FULL 15291** |
|   | Title:  | A Phase 1/2, Open-label, Multicenter, Dose Escalation and Expansion Study of the Safety, Tolerability, Pharmacokinetics, andPharmacodynamics of HM43239 in Patients with Relapsed or Refractory Acute Myeloid Leukemia (AML) |
|   | Principal Investigator:  | Dr Lauren Child |
|   | Sponsor:  | Aptose BioSciences, Inc. and Labcorp New Zealand Ltd |
|   | Clock Start Date:  | 21 April 2023.  |

Dr Lauren Child 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 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 statement on future research of samples was broad and non-specific. The Committee requested the Researcher either refine it to 'research related to this disease' or supply a [Future Unspecified Research (FUR) information sheet and consent form](https://ethics.health.govt.nz/assets/Uploads/HDEC/templates/future-unspecified-use-tissue-piscf-template-v4.0april2023.doc).
2. The Committee noted a ~15% response rate to the drug was low and the protocol did not include discussion on why this is acceptable. The Committee queried whether the response rate was reflective of a low subclinical dose or not. The Researcher stated they will clarify with the Sponsor.
3. The Committee recommended the Researcher encourage Sponsor to submit the drug for licensure in New Zealand if the study is successful.

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

1. The Committee noted a statement indicating the Sponsor can stop the study for any time for any reason. In New Zealand an intervention study in which participants are potentially receiving benefit must not be stopped for primarily commercial reasons. Please amend the statement to reflect this.
2. Please revise the contraceptive section to be gender neutral ('If you are capable of becoming pregnant').
3. Please undertake a general revision to simplify the risks (e.g. 'Fewer than 10 in 100').
4. Please remove side effects from lab animal tests and only include side effects observed in humans.
5. Please remove the 'in combination with' referring to other drug side effects.
6. Please include the name and address of the Sponsor on the heading.

**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).*

After receipt of the information requested by the Committee, a final decision on the application will be made by Ms Alice McCarthy and Dr Andrea Forde.

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| **5**  | **Ethics ref:**   | **2023 FULL 15382** |
|   | Title:  | A Phase 3 Study Evaluating the Pharmacokinetics, Safety, and Tolerability of VX‑121/Tezacaftor/Deutivacaftor Triple CombinationTherapy in Cystic Fibrosis Subjects 1 through 11 Years of Age (Protocol Number: VX21-121-105) |
|   | Principal Investigator:  | Professor Catherine Byrnes |
|   | Sponsor:  | Vertex Pharmaceuticals Australia Pty Ltd. and Adjutor Healthcare (NZ) Ltd |
|   | Clock Start Date:  | 07 April 2023 |

Professor Catherine Byrnes 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 resolved ethical issues

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

1. The Committee queried how the study drug differed from what is available in New Zealand. The Researcher stated it is a combination of three different drugs, two are the same but one has a slightly different configuration with a longer half-life requiring only one dose a day instead of the two required usually.
2. The Committee queried why someone who qualified for Pharmac-funded medicine would join the trial. The Researcher clarified funding is not available for younger children and participation in the study would allow for earlier access to treatment.
3. The Committee queried whether the study would use Greenphire to reimburse participants. The Researcher confirmed it would. The Committee stated this was acceptable as long as participants understand what information of theirs will be passed on to the third-party.

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 insurance policy had expired and cautioned it can only approve commercially sponsored research when it is assured ACC-equivalent insurance is available for participants. The Committee requested an updated policy certificate specifying New Zealand as a covered territory within a valid time period.

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

1. In the assent form please replace 'drug' with 'medicine' and 'poop' with 'poo'.

**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 Ms Alice McCarthy and Dr Andrea Forde.

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| **6**   | **Ethics ref:**   | **2023 FULL 14044** |
|   | Title:  | Optimising recurrence risk assessment for patients undergoing meningioma resection in Auckland. |
|   | Principal Investigator:  | Dr Clinton Turner |
|   | Sponsor:  |  |
|   | Clock Start Date:  | 11 April 2023 |

Dr Clinton Turner 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 resolved ethical issues

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

1. The Committee queried the likelihood of the study picking up any clinically actionable findings. The Researcher stated it was unlikely as to be eligible for inclusion a diagnosis of meningioma is required and the study will not test for any unknown mutations.
2. The Committee queried the identifiability of samples. The Researcher stated the patient's name would be on the paraffin tissue block but once the sample is cut and sent for methylation the lab workers would not see identified information.
3. The Committee noted the requirements for a waiver of consent for secondary re-use of tissue have been met and approved the application.

**Decision**

This application was *approved* by consensus

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| **7**  | **Ethics ref:**   | **2023 FULL 16681** |
|   | Title:  | A Self-compassion Chatbot to Improve the Wellbeing of Adolescents with Type 1 Diabetes (T1D): a Feasibility Study |
|   | Principal Investigator:  | Dr Anna Serlachius  |
|   | Sponsor:  | The University of Auckland  |
|   | Clock Start Date:  | 12 April 2023 |

Dr Anna Serlachius 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 resolved ethical issues

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

1. The Committee noted patients with Type 1 Diabetes are a commonly researched group and queried how the Researcher intended to not overburden this population. The Researcher stated they work closely with Starship Hospital which is protective of its patients and would only suggest their inclusion in a research project if they are not already involved in one.
2. The Committee queried how psychological distress in participants would be managed when using the chatbot. The Researcher stated the chatbot has a safety protocol embedded into it that reviews any free text sent by the user. If certain words are sent to the bot it will trigger the safety algorithm and advise the user to call 111 if they are in danger or unsafe. An automated email to the research team will be sent for follow up. The Researcher confirmed Starship hospital has a dedicated diabetes team psychologist who would respond.
3. The Committee queried the potential risk of misuse or phone addiction using the chatbot. The Researcher stated it has been developed with decision-tree logic and all responses have been written by the research team. The chatbot consists of 14 modules and once they are completed there is no further content. The Researcher confirmed there is no AI component and the chatbot cannot generate its own unique responses and does not connect with any social media applications.

Summary of outstanding ethical issues

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

1. Please include information advising that if a participant does not have access to a phone or mobile data this can be supplied for their participation.
2. Please specify what the voucher is for and when it will be given. The Committee noted the assent form states it would be given once the study is finished and the PIS stated after 12 weeks.

**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).*

After receipt of the information requested by the Committee, a final decision on the application will be made by Ms Maakere Marr and Dr Andrea Forde.

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| **8**   | **Ethics ref:**   | **2023 FULL 15311** |
|   | Title:  | Point of care mapping of oxidative stress in patients undergoing gastrointestinal surgery |
|   | Principal Investigator:  | Mr Wal Baraza |
|   | Sponsor:  | The University of Auckland |
|   | Clock Start Date:  | 13 April 2023 |

Wal Baraza 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 resolved ethical issues

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

1. The Committee noted the peer review commented on an inconvenient burden on participants and extra theatre time. The Researcher stated inserting a line would take an extra 30 - 40 minutes and has consulted with the hospital on this. The hospital agreed if the treating surgeon was on board with the study. The Researcher stated they would predominantly be choosing patients that would require a central line inserted for monitoring regardless of their participation in the study.
2. The Committee noted the study title was gastrointestinal surgery, but the peer review referred to colorectal surgery. The Researcher clarified the study would involve all gastrointestinal cases and would not be limited to colorectal surgery only.
3. The Committee queried the exclusion of participants with 'learning difficulties' as mentioned in the application form. The Researcher clarified it meant patients who would not have the capacity to understand or retain the information required to give informed consent.

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 pregnant women would be excluded from the study although pregnancy itself is not an exclusion for abdominal surgery. The Researcher stated elective gastrointestinal surgery is performed on pregnant women very rarely and they would need to take different hormonal and physiological changes into account in the study. The Committee noted the exclusion of pregnant women exacerbates the problem of not having enough study data in this population which sometimes does need abdominal surgery. The Committee requested a revision to the inclusion criteria to either include pregnant women or insert scientific rationale for their exclusion, so it does not appear to be a broad exclusion without basis.
2. The Committee encouraged the Researcher to investigate whether offering participants a koha for their participation is possible.

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

1. The Committee requested more information explaining the potential inconvenience of frequent sampling and a longer recovery be added to the information sheet as this may affect willingness to participate in the study.
2. The Committee noted the application stated tissue samples may be returned to participants if they request it but this is not mentioned on the information sheet. Please include a statement advising this and an option in the consent form for participants to request this.
3. Please include a statement advising that a karakia will not be available at the time of tissue destruction.

**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 inclusion criteria in the protocol to include pregnant women or provide a scientific justification for their exclusion.
3. 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).*

After receipt of the information requested by the Committee, a final decision on the application will be made by Ms Maakere Marr and Dr Amber Parry-Strong.

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| **9**  | **Ethics ref:**   | **2023 FULL 16721** |
|   | Title:  | Speech Therapy Delivered by Assistants: Outcomes and Effectiveness |
|   | Principal Investigator:  | Dr Toby Macrae |
|   | Sponsor:  | The University of Canterbury |
|   | Clock Start Date:  | 20 April 2023 |

Dr Toby Macrae 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 resolved ethical issues

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

1. The Committee queried how the study would ensure participants are not othered by their peers if they need to leave the classroom to participate. The Researcher stated most classrooms now have students shifting in and out with a lot of movement and one-on-one support. The Researcher stated they have not encountered difficulties with this previously.
2. The Committee queried whether children who had already received speech language therapy would be eligible to participate. The Researcher stated they would and the only exclusion would be children currently receiving speech therapy elsewhere.
3. The Committee queried how the therapy would be assessed. The Researcher stated at this time they were investigating whether assistant-delivered therapy is effective and if shown to be successful a later study would compare it against a qualified speech language therapist.

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 what training assistants would receive. The Researcher stated they had developed training material and training would be delivered before interaction with participants. The Committee requested the Researcher supply an overview of the training process so it can be assured there is a formalised training programme.
2. The Committee requested an update to the protocol to include information on how assent will be continuously assessed and the withdrawal process if a child shows resistance or dissent to the therapy.

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

1. The Committee requested a review of spacing on the consent form as some of the text is condensed.

**Decision**

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

1. Please supply documentation on the training process and what information assistants will receive.
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 to include a process on how dissent will be managed. (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 Ewe Leong Lim and Mr Barry Taylor.

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| **10**   | **Ethics ref:**   | **2023 FULL 16668** |
|   | Title:  | A Phase 1/2 First-in-Human Study of the Safety and Efficacy of IMC-F106C as a Single Agent and in Combination with CheckpointInhibitors in HLA-A\*02:01-Positive Participants with Advanced PRAME-Positive Cancers |
|   | Principal Investigator:  | Dr Catherine Han |
|   | Sponsor:  | Immunocore, Ltd and IQVIA RDS Pty Ltd. |
|   | Clock Start Date:  | 14 April 2023 |

Dr Catherine Han 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 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 participants in healthy volunteer studies are paid for their time whereas participants in treatment studies involving extra and overnight visits are not. The Researcher stated studies looking at efficacy generally do not pay participants beyond reimbursements for costs incurred. The Researcher acknowledged this study involves visits extra to standard of care and for fairness could offer the standard payment of $100 per visit plus travel expenses. The Committee requested this be incorporated into the study across all sites. The Researcher confirmed this would be across the country as the lead site would distribute the PIS to additional sites which would contain the payment clause.
2. The Committee requested confirmation New Zealand was an applicable territory for the insurance certificate as it appeared to be a global policy.
3. The Committee queried whether the Sponsor intended to license the drug for use in New Zealand if the study is successful and encouraged the Researcher to follow this up.

**Decision**

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

* please update the participant information sheet to include a koha payment for visits in addition to standard of care.

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| **11**  | **Ethics ref:**   | **2023 FULL 15396** |
|   | Title:  | A Phase 1 Study in Healthy Participants to Evaluate the Safety, Tolerability, and Pharmacokinetics of Subcutaneous and Intramuscular Lenacapavir (GS-US-200-5717) |
|   | Principal Investigator:  | Dr Christian Schwabe |
|   | Sponsor:  | Giliead Sciences |
|   | Clock Start Date:  | 14 April 2023 |

Dr Christian Schwabe 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 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 has a short code-word title to distinguish it from the other study investigating the same drug. The Researcher confirmed this study's title was 'Calypso'.
2. The Committee queried whether the drug was intended for prevention or treatment. The Researcher confirmed it was intended for treatment and they would look at different indications in the future including treatment in conjunction with other agents.
3. The Committee noted the drug stays in the body or up to two years and is excreted through faeces. The Committee queried whether this had any implications for participants in the future and any procedures they may undergo such as colonoscopy. The Researcher stated they understood this would not be a risk.

**Decision**

This application was *approved* by consensus.

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| **12**   | **Ethics ref:**   | **2023 FULL 15407** |
|   | Title:  | A Phase 1 Study in Healthy Participants to Evaluate the Safety, Tolerability, and Pharmacokinetics of Subcutaneous and Intramuscular Lenacapavir (GS-US-200-5710) |
|   | Principal Investigator:  | Dr Christian Schwabe |
|   | Sponsor:  | Gilead Sciences |
|   | Clock Start Date:  | 14 April 2023 |

Dr Christian Schwabe 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 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 has a short code-word title to distinguish it from the other study investigating the same drug. The Researcher confirmed this study's title was 'Indigo'.
2. The Committee queried whether the drug was intended for prevention or treatment. The Researcher confirmed it was intended for treatment and they would look at different indications in the future including treatment in conjunction with other agents.
3. The Committee noted the drug stays in the body or up to two years and is excreted through faeces. The Committee queried whether this had any implications for participants in the future and any procedures they may undergo such as colonoscopy. The Researcher stated they understood this would not be a risk.

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 a discrepancy between remuneration values with the radio advertisement staying $13,000 and the PIS stating $10,000. The Researcher stated the correct value was $10,000. The Committee requested this be corrected.

**Decision**

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

* please correct the discrepancy in renumeration offered.

**General business**

1. The Chair reminded the Committee of the date and time of its next scheduled meeting:

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| --- | --- |
| **Meeting date:** | 06 June 2023 |
| **Zoom details:** | To be determined |

 The following members tendered apologies for this meeting.

* Leesa Russell
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**
3. **Other business for information**
4. **Any other business**

The meeting closed at 5:00pm.