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| **Committee:** | Central Health and Disability Ethics Committee |
| **Meeting date:** | 24 January 2023 |
| **Zoom details:** | 965 0758 9841 |

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| **Time** | **Review Reference** | **Project Title** | **Coordinating Investigator** | **Lead Reviewers** |
| 12:00-12:30pm | 2022 FULL 13703 | CLOCK trial: Preventing adverse events during paediatric cancer treatment: A multi-site hybrid randomised controlled trial of catheter lock solutions | Dr Andrew Wood | Mr Jonathan Darby and Mr Barry Taylor |
| 12:30-1:00pm | 2022 FULL 14009 | Evaluation of pain among the patients treated with different splintage devices for wrist fracture | Dr Pranesh Kumar | Dr Cordelia Thomas and Dr Patries Herst |
| 1:00-1:30pm | 2022 FULL 12763 | Online mental health support while waiting for therapy | Professor Richie Poulton | Mrs Helen Walker and Mrs Patricia Mitchell |
| 1.30-2.00pm | 2022 FULL 13947 | First in Human and Early Feasibility Clinical Study of the FloStent System | Professor Peter Gilling | Ms Jessie Lenagh-Glue and Mr Barry Taylor |
| 2:30-3:00pm | 2022 FULL 13434 | Partnering Early to Provide for Infants at Risk of Cerebral Palsy - The PĒPI ARC study | Dr Angelica Allermo Fletcher | Mr Jonathan Darby and Dr Patries Herst |
| 3.00-3.30pm | 2022 FULL 13929 | Platelet Rich Plasma injections for vocal fold atrophy and scarring | Dr Jacqueline Allen | Dr Cordelia Thomas and Mrs Patricia Mitchell |
| 3.30-4.00pm | 2022 FULL 13890 | BIO|MASTER.CSP | Dr Matthew O'Connor | Mrs Helen Walker and Mr Barry Taylor |
| 4.00-4.30pm | 2022 FULL 14050 | RAVEN: A Trial Treating Relapsed Acute Leukaemia with Venetoclax and Navitoclax | Dr Siobhan Cross | Ms Jessie Lenagh-Glue and Dr Patries Herst |
| 4.40-5.10pm | 2023 FULL 12707 | Management of musculoskeletal chest pain – a feasibility study | Dr Ewan Kennedy | Mr Jonathan Darby and Mrs Patricia Mitchell |
| 5.10-5.40pm | 2023 FULL 13689 | MK-6482-022: Study to compare the Efficacy and Safety of belzutifan plus pembrolizumab versus placebo plus pembrolizumab, in renal cancer patients after kidney surgery. | Dr Simon Fu | Dr Cordelia Thomas and Mr Barry Taylor |
| 5.40-6.10pm | 2023 FULL 13985 | Study of (Reduced Dose) Doravirine/Islatravir Taken Once Daily for the Treatment of HIV-1 Infection in Participants Who Previously Received DOR/ISL. | Dr Alan Pithie | Mrs Helen Walker and Dr Patries Herst |
| 6.10-6.40pm | 2023 FULL 15063 | A Study to Evaluate the Safety and Tolerability of AB-161 in Healthy Participants | Professor Edward Gane | Ms Jessie Lenagh-Glue and Mrs Patricia Mitchell |

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| **Member Name** | **Member Category** | **Appointed** | **Term Expires** | **Apologies?** |
| Mrs Helen Walker | Lay (Consumer/Community perspectives) (Chair) | 22/05/2018 | 22/05/2020 | Present |
| Mrs Sandy Gill | Lay (Consumer/Community perspectives) | 22/05/2020 | 22/05/2023 | Apology |
| Dr Patries Herst | Non-lay (Intervention studies) | 22/05/2020 | 22/05/2023 | Present |
| Dr Cordelia Thomas | Lay (the Law) | 20/05/2017 | 20/05/2020 | Present |
| Ms Patricia Mitchell | Non-lay (Health/Disability service provision) | 08/07/2022 | 08/07/2025 | Present |
| Ms Julie Jones | Non-lay (Intervention studies) | 22/05/2020 | 22/05/2022 | Apology |
| Mx Albany Lucas | Non-lay (Observational studies) | 22/12/2021 | 22/12/2024 | Apology |
| Ms Jessie Lenagh-Glue | Lay (Ethical/Moral reasoning) | 22/12/2021 | 22/12/2024 | Present |
| Mr Jonathan Darby | Lay (the Law/Ethical and Moral reasoning) | 13/08/2021 | 13/08/2024 | Present |
| Mr Barry Taylor | Non-Lay (Intervention/Observational Studies) | 13/08/2021 | 16/08/2024 | Present |

## Welcome

The Chair opened the meeting at 11.30am and welcomed Committee members, noting that apologies had been received from Ms Julie Jones, Ms Sandy Gill and Mx Albany Lucas  
  
The Chair noted that it would be necessary to co-opt members of other HDECs in accordance with the Standard Operating Procedures. Mr Barry Taylor and Mr Jonathan Darby confirmed their eligibility and were co-opted by the Chair as a members of the Committee for the duration of the meeting.

The Chair noted that the meeting was quorate.

The Committee noted and agreed the agenda for the meeting.

## Confirmation of previous minutes

The minutes of the meeting of 22 November 2022 were confirmed.

## New applications

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| **1** | **Ethics ref:** | **2022 FULL 13703** |
|  | Title: | Preventing adverse events during paediatric cancer treatment: A multi-site hybrid randomised controlled trial of catheter lock solutions (The CLOCK trial) |
|  | Principal Investigator: | Dr Andrew Wood |
|  | Sponsor: | University of Queensland |
|  | Clock Start Date: | 12 January 2023 |

Dr Andrew Wood, Dr Olga Ksionda and Professor Amanda Ullman 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 requested that the NEAC National Ethical Standards be listed with other ethical standards that have been considered in the protocol.

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

1. Please review all sheets for typos, readability and layout.

Assent Form (7-10):

1. Please include the use of images for improved understanding for children.
2. Please consider simplifying the document for younger children as this currently is too advanced for a 7–10-year-old age group. Please refer to the [HDEC template assent](https://ethics.health.govt.nz/assets/Uploads/HDEC/templates/main-assent-7-11-years-clinical-trial-v4.0-December-2022.docx) form for this age group.

Assent Form (11-15):

1. The Committee requested that this form be designed to promote as much autonomy as possible in this slightly older age group. Please refer to the [HDEC template assent](https://ethics.health.govt.nz/assets/Uploads/HDEC/templates/future-scientific-research-genetic-icf-assent-age-12-15-v2july2022.docx) form for this age group.

**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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| **2** | **Ethics ref:** | **2022 FULL 14009** |
|  | Title: | Comparative evaluation of pain among the patients treated with different available external splintage devices for simple wrist fracture during the first two weeks of splintage |
|  | Principal Investigator: | Dr Pranesh Kumar |
|  | Sponsor: |  |
|  | Clock Start Date: | 12 January 2023 |

No one from the research team was present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of 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 comparison of three splints should be allocated through randomisation. The Committee believes that the non-randomisation would invite bias into the study and could compromise the validity of the research. This was also raised in the scientific review and has not been addressed adequately. *(National Ethical Standards* para 9.25 – 9.32)
2. The Committee noted that this is an intervention study and this will either need to be adequately reframed as an intervention study.
3. The Committee requested provision of the pain scales and information as to whether or not they are validated.
4. The Committee queried why the parents are reporting on the child’s pain when the child should be asked directly, even if a visual pain scale is used. (*National Ethical Standards* para 6.25 – 6.27)
5. The Committee noted that the study design could be stronger if only the target splint was tested in a larger population as an open label study.
6. The Committee noted that as there was a conflict of interest of the Researcher with one of the splints as they own shares in the device. This should be noted first thing in all participant information sheets.
7. The Committee noted that it may be less distressing for parents and more cognisant of potential parent or child trauma if recruitment was conducted 24 hours after presentation.
8. The Committee recommended going over the comments from the Committee who previously declined this application as not all points they made had been addressed and they are still valid.
9. The Committee requested the following changes to the Data Management Plan (DMP) (*National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15a*):
   1. Please include the details surrounding what will be accessed i.e., medical records
   2. Please specify what steps will be taken to process data, particularly regarding anonymisation, any indication of overseas storage and where this may be.
   3. Please specify if participants may access and correct their records.

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

Main PIS/CF:

1. Please include a statement that clearly states that this is for parents and guardians only at the beginning of the document. Please be consistent with language used regard “you and your child”.
2. Please specify that the study is voluntary at the start of the PIS/CF, not after explaining what the study is about.
3. Please include a footer with versioning, dates and institutions associated with the study.
4. Please include a Māori cultural support contact.
5. Please provide a clear and detailed consent form. Consider following the [HDEC PIS/CF template](https://ethics.health.govt.nz/assets/Uploads/HDEC/templates/participant-information-sheet-consent-form-template-v4.0december2022.doc). (*National Ethical Standards* para 7.19, 7.15 & 7.16)

Assent form 7-11:

1. Please simplify this document in terms of content and language to make it more appropriate for this age group. (*National Ethical Standards* para 6.25 – 6.27 & 7.19)
2. Please show the pain scales rather than naming them.
3. Please note assent should be spelt “assent” not “ascent”. *(National Ethical Standards* para 6.25 – 6.27)

Assent form 12-15:

1. Please include information as to what will happen to the children’s information. (*National Ethical Standards* para 6.25 – 6.27 & 7.19)
2. Please note assent should be spelt “assent” not “ascent”. (*National Ethical Standards* para 6.25 – 6.27)

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

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| **3** | **Ethics ref:** | **2022 FULL 12763** |
|  | Title: | Randomised controlled trial of online cognitive behavioural therapy as an initial treatment for patients waiting for in-person therapy |
|  | Principal Investigator: | Professor Richie Poulton |
|  | Sponsor: | University of Otago |
|  | Clock Start Date: | 12 January 2023 |

Dr Hayley Guiney 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 Researcher clarified that there would be crisis lines made immediately available.
2. The Committee clarified that there should be best practice applied to the response times.
3. The Committee was assured that the participants could go away and consider the participant information sheet before coming back and consenting.
4. The Committee clarified with the Researcher the cultural diversity of “Just a Thought”. The system is built on a Western psychological model but includes Māori and Pasifika characters and detailed analysis of this has shown equal benefit between Māori and Non-Māori participants. The Researcher noted that retention was the key issue with Māori but that this was being taken into account. Māori consultation was being undertaken and was an ongoing key part of the study.

Summary of outstanding ethical issues

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

1. The Committee requested a robust risk management plan that addresses the timeliness of response and how appropriate this response would be for each participant. The Committee noted that 48 hours is too long a period for crisis response and that this will need to be shortened and incorporated into a better risk response plan. The Committee suggested considering the agency and emotional literacy of the participants at the start of the study and that the screening take into account the timelines of response.
2. The Committee noted that having only a single study clinician is not practical given the potential volume of participants.
3. The Committee acknowledged that online therapy could exacerbate suicidality and mental health crises in general and that this should be more carefully addressed particularly around the timeline for review and the ability for after-hours responses to crises.
4. The Committee noted the phone line and online support may not meet the needs of participants experiencing a mental health crisis
5. The Committee noted that there was an intention to keep and access sensitive data without consent by Tamaki Health for the recruitment of participants and that this is a breach of the law. The Committee requested that the clinicians identify the potential participants and obtain their consent to have their details forwarded to the team.
6. The Committee suggested having a participant information sheet for people on the waiting list to prevent unlawful access of private data.
7. The Committee requested provision of the composition of the advisory committee and the feedback that had been provided by them on the study.

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

1. Please amend the HDEC of approval to be Central HDEC, not Southern.
2. Please ensure terminology remains consistent – e.g., ''in person therapy'' as opposed to therapy.
3. Please consider replacing the schedule of amendments with the table in the protocol, even if this requires amending to be participant facing.
4. Please provide the timeframes where required for study activities.
5. Please provide the information video for review.

**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 the full Committee.

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| **4** | **Ethics ref:** | **2022 FULL 13947** |
|  | Title: | First in Human and Early Feasibility Clinical Study of the FloStent System |
|  | Principal Investigator: | Professor Peter Gilling |
|  | Sponsor: | RiverMark Medical Inc |
|  | Clock Start Date: | 12 January 2023 |

Rachael Hamill, Deborah Bell, Adam Kadlec, and Flora Yuen 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 resolved ethical issues

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

1. The Committee clarified that the Sponsor would cover the deductibles for insurance.

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 submission stated that the study utilizes Kaupapa Māori methodology but this did not appear to be accurate.
2. The Committee requested detail be provided for reimbursement and how this will be managed including “reimbursements for costs up to-”. This will need to be addressed in the participant information sheet (PIS) as well.
3. The Committee requested provision of an actual insurance document.
4. The Committee noted that the amount for medical expenses per participant was low and will need to be changed in the insurance document.
5. The Committee queried why the inclusion of pregnancy risk was present in the PISs as this is unnecessary if there is no actual risk.
6. The Committee noted that the study may not be ended for commercial reasons and that this will need to be amended in the study documentation.

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

1. Please address whakamā as the study involves sexual function questionnaires. Please clearly explain when and where these questionnaires will be undertaken.
2. Please define in lay terms what haematuria is.
3. Please amend the side effect table and review for ease of reading and missing information.
4. Please include expected occurrence for risks outside of the table.
5. Please be incredibly specific and clear around the description of what will be discussed.
6. Please consider and address gender matching participants with interviewers where it may culturally be required.
7. Please remove the option for General Practitioner (GP) notification as this should not be optional.
8. Please clarify by which “standard practice” participants may be identified. This should include who would be the first point of call for participants.
9. Please set out in the PIS what may occur should suicidal intend be identified in participants.
10. Please clarify what having the stent may be less traumatic than.
11. Please specify if withdrawal from the study requires stent removal.
12. Please provide a more thorough Māori cultural statement. Consider using the [HDEC PIS templated](https://ethics.health.govt.nz/assets/Uploads/HDEC/templates/participant-information-sheet-consent-form-template-v4.0december2022.doc) statement.
13. Please specify that urine and blood will be taken for analysis and ensure this information is consistent across forms.
14. Please proofread for errors and typos.

Optional long term PIS/CF:

1. Please proofread the first line on page 2 “you will be follow up”.
2. Please amend headings to be more readable as the black on blue is hard to read.
3. Please proofread for errors and typos.

**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 Jessie Lenagh-Glue and Mr Barry Taylor.

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| **5** | **Ethics ref:** | **2022 FULL 13434** |
|  | Title: | Partnering Early to Provide for Infants At Risk of Cerebral palsy (PĒPI ARC)- Evaluating the feasibility of implementing the New Zealand Best Practice Recommendations for Early diagnosis of Cerebral Palsy through a regional early diagnosis Hub. |
|  | Principal Investigator: | Dr Angelica Allermo Fletcher |
|  | Sponsor: |  |
|  | Clock Start Date: | 12 January 2023 |

Sian Williams and Dr Angelica Allermo Fletcher 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 resolved ethical issues

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

1. The Committee clarified with the Researcher the meaning of life-limiting conditions as used in the exclusion criteria.
2. The Committee clarified that there would be some support for access to funds for travel and other reimbursement but there was no funding within the study for this. Plans were in place to try and not require attendance to the clinic and provide flexibility to participants. Please explain this in the participant information sheet.
3. The Committee queried if APGAR scores, traumatic delivery etc., would be inclusion criteria. The Researcher clarified that this would make the potential participant pool too large but would be used as potential risk factors for the assessment of inclusion. As such only children in NICU would be considered.

Summary of outstanding ethical issues

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

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

1. Please ensure that no new information is introduced in the consent form for example access to information and auditing. Consider including information as provided in the data management plan.
2. Please specify where the information will be held, the difference between coded and identifiable information, who will have access to the data, if it will be used in the future for research and if any data will be sent overseas.
3. Please amend Māori health support to Māori cultural support.
4. Please include how long the interview and any questionnaires may take.
5. Please clearly explain what is meant by life-limiting conditions.
6. Please specify what criteria must be present for inclusion.
7. Please include the participants right not only to access but also to correct information.

**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).*

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| **6** | **Ethics ref:** | **2022 FULL 13929** |
|  | Title: | Platelet Rich Plasma injections for vocal fold atrophy and scarring |
|  | Principal Investigator: | Dr Georgia Mackay |
|  | Sponsor: |  |
|  | Clock Start Date: | 12 January 2023 |

Dr Georgia Mackay 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 clarified that the approach is made to the participant during an initial appointment made after voice-complaint. The Researcher clarified the situations under which recruitment may occur as opposed to access to treatment without research.
2. The Committee clarified that the research approach would not be made by the clinician but by the Researcher.
3. The Committee noted that there was a consent for the procedure separate from that of the research.
4. The Committee noted that there was no koha currently planned but there would be possible provision of fuel vouchers.

Summary of outstanding ethical issues

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

1. The Committee requested to see the Likert scale for review.

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

1. Please review for lay language.
2. Please amend wording to note that any left-over blood will be returned to participants should they request it.
3. Please amend wording around “If you decide to be part of the study” in the enrolment section.
4. Please remove wording of “benefit to society in general” as this is untrue and coercive.
5. Please amend wording around “positive effects” of the research as this is not a certainty.
6. The Committee requested the removal of the ‘yes / no’ tick boxes from the consent form unless it is for a clause that is truly optional (i.e. the participant can answer ‘NO’ and still participate in the study).
7. Please use the ACC statement from the [HDEC PIS template](https://ethics.health.govt.nz/assets/Uploads/HDEC/templates/participant-information-sheet-consent-form-template-v4.0december2022.doc).
8. Please ensure no new information is introduced in the consent form.
9. Please include a contact for Māori cultural support.
10. Please update logos to Te Whatu Ora.
11. Please amend “potential candidate” wording to refer to the participant as a person.
12. Please review spelling of Te Reo words.
13. Please state who pays for the study.
14. Please ensure the same time is stated for monitoring post intervention.
15. Please state more clearly what happens to the information collected in the study. Please refer to the [HDEC PIS template](https://ethics.health.govt.nz/assets/Uploads/HDEC/templates/participant-information-sheet-consent-form-template-v4.0december2022.doc) to ensure adequate detail is provided.
16. Please include a statement on the right to request information and for the right to correct this information if it is wrong. Please see the [HDEC PIS template](https://ethics.health.govt.nz/assets/Uploads/HDEC/templates/participant-information-sheet-consent-form-template-v4.0december2022.doc) for reference.

**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 Mrs Patricia Mitchell and Dr Cordelia Thomas.

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| **7** | **Ethics ref:** | **2022 FULL 13890** |
|  | Title: | BIO|MASTER.CSP: Pivotal study of the Amvia pacemaker and Solia CSP S pacing lead on conduction system pacing. |
|  | Principal Investigator: | Dr Matthew O’Connor |
|  | Sponsor: | IOTRONIK Australia Pty Ltd |
|  | Clock Start Date: | 12 January 2023 |

Mandy Fish and Dr Matthew O’Connor 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 clarified that the recommendations in the peer review about the end point would be incorporated to ensure the safety of the device in participants long term.
2. The Committee clarified that the pacemaker is similar to previously studied ones and that there is no undue risk from the device.
3. The Committee clarified there is sufficient time between being given the participant information sheets and providing consent.
4. The Committee suggested that an independent person from the study treatment oversee the consenting process, if possible, to remove undue influence or feelings of coercion.
5. The Committee clarified that the site was disability accessible.
6. The Committee queried the justification for exclusion of breastfeeding women. The Researcher noted that there would be a higher level of radiation used in the study that would be a risk to breastfeeding participants.

Summary of outstanding ethical issues

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

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

1. Please amend heading to be white text on blue for readability.
2. Please move assurances of the device’s safety and possible risks up further in the PIS to remove undue concern.
3. Please clarify what potential residual risks are.
4. Please ensure that there is reimbursement for participants for study visits not under standard of care.
5. Please remove the yes/no box for notification of general practitioners. This should not be an option for participation.

**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).*

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| **8** | **Ethics ref:** | **2022 FULL 14050** |
|  | Title: | RAVEN: A PHASE I/II TRIAL TREATING RELAPSED ACUTE LYMPHOBLASTIC LEUKEMIA WITH VENETOCLAX AND NAVITOCLAX |
|  | Principal Investigator: | Dr Siobhan Cross |
|  | Sponsor: | Australian & New Zealand Children’s Haematology/Oncology Group (ANZCHOG) |
|  | Clock Start Date: | 12 January 2023 |

Dr Siobhan Cross and Katherine Denton 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 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 if identifiable information is held at St. Jude. After discussion, it was clarified that St. Jude would have only the study number and store de-identified information, however samples sent for safety reasons would have identifiers attached. The Committee requested this is detailed in study documentation, and outlined to participants what information is stored, attached to samples, who has access, etc.
2. The Committee noted the response to C4 of the application, and that it would have been good to know whether there is a statistically significant difference in Māori and non-Māori for this disease.

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

1. Dose escalation is not currently explained clearly. Please clarify what is meant by the different doses and escalation/de-escalation to lower doses or include a diagram.
2. State that a karakia will not be available for disposal of samples sent overseas.
3. Please ensure you change Māori health support to Māori cultural support.
4. All PISs refer just to Christchurch and its being run in both Christchurch and Starship. Please ensure Auckland participants have locality-specific information with references to Starship.
5. Please review all sheets for gendered language and amend, such as just stating “if you can become pregnant” etc. over specifying woman or female.
6. It is not clear whether participants will be hospitalised for the course of Block 1. Please be explicit that this is for treatment of their condition rather than specifically for study reasons.
7. There is discussion of future research in main PIS, but it should refer to there being more information on a separate sheet.
8. The Continuation PISs have lots of references to Australia. Please amend to make relevant to New Zealand and New Zealand laws.
9. In the Block 1 PIS, please include more information about how to prevent pregnancy. There is an [HDEC template](https://ethics.health.govt.nz/guides-templates-and-forms/participant-information-sheet-templates/) for this that can be used.
10. Assent forms should explain that it’s the parents who give consent and you give assent, but even if parent gives consent, nothing happens unless the child provides assent.
11. 7-10 assent should include a statement for extra tests that explains the invasive testing such as bone marrow is part of routine testing and does not have to be undertaken twice for the study. This is in the 11+ assent form but should be included in 7-10 too.
12. The Reconsent form states that the person is no longer receiving treatment in the study but data still needs to be collected. This may not necessarily be the case. Please ensure the language reflects the possibility that they might still be receiving treatment.

**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).*

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| **9** | **Ethics ref:** | **2023 FULL 12707** |
|  | Title: | Improving health services for people with musculoskeletal chest pain - a randomised controlled feasibility trial |
|  | Principal Investigator: | Dr Ewan Kennedy |
|  | Sponsor: |  |
|  | Clock Start Date: | 12 January 2023 |

Dr Ewan Kennedy 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 minor typo of there being a missing word in the recruiters section of the protocol.
2. The Committee clarified with the Researcher that there is no exclusion to a broad range of people with disabilities, though those with cognitive impairment will require supported decision-making. There will be no physical barriers to accessing the premises for those with physical disabilities. The Committee requested this is made clear to participants as this may impact their decision of whether or not to participate.
3. The Researcher clarified that the reimbursement amount is $150 total, with $50 per visit. The Committee requested this is made explicit to participants that it is $50 per visit up to a total of $150. They also requested that it is clarified with IRD whether there are tax implications for this payment amount.
4. The Committee noted the use of the EQ-5D-5L questionnaire. They suggested that there should be a safety plan in place for whoever is receiving those results from the participant in case a participant has answered in a way that indicates mental distress, so the person knows how to respond and follow up on these results. After discussion, the Committee stated that this is about responding to immediate distress if it present and known to the Researchers rather than diagnosing depression or anxiety and is usual to ask Researchers who administer this questionnaire to have a response in place. Please inform participants that there will be questions relating to anxiety and depression, and if any of these questions are of concern to them, information on who they could speak to or what they could do about it.
5. The Committee discussed with the Researcher the rationale of maintaining blinding by not referring to the intervention of physiotherapy explicitly in the participant information sheet (PIS) and not describing what each study arm would receive in the way of care. This is well explained in the protocol with the useful figure 1 that could be included in the PIS. The control arm would not receive physiotherapy and the intervention arm would receive 5 sessions of physiotherapy. The Researcher noted that they could refer to health professionals as physiotherapists but that detailing what would happen in each arm of the research would unblind the study and potentially influence the participant’s expectations of how much pain they would have. This could compromise the validity of the research. The Committee noted that withholding information on the exact content of the intervention would not meet criteria for providing enough information for participants to give informed consent. The Committee recommended considering a “sham” control arm where some form of manual therapy was giving but that would not affect pain levels or else consider an unblinded approach, as deception to justify blinding is not acceptable.

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

1. Information about the website says “TBC”. Make it clear that the website hasn’t been built yet but will be provided to the participant once it has.
2. Please make it clear that those seen in Dunstan will receive treatment in Dunstan, not Dunedin. The Committee understand that Dunstan and Dunedin will have two different PISs, however the one presented for review has mixed-references to both.
3. Instead of referring to allied health professionals please refer to physiotherapists.
4. Please ensure that the PIS includes information on what participants can expect from being in the control arm and in the intervention arm would involve.
5. The Committee noted that the consent form item about GP being informed should appear in PIS first and not be first raised in the CF.

**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 full Committee.

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| **10** | **Ethics ref:** | **2023 FULL 13689** |
|  | Title: | A Multicenter, Double-blind, Randomized Phase 3 Study to Compare the Efficacy and Safety of Belzutifan (MK-6482) Plus  Pembrolizumab (MK-3475) Versus Placebo Plus Pembrolizumab, in the Adjuvant Treatment of Clear Cell Renal Cell Carcinoma  (ccRCC) Post Nephrectomy |
|  | Principal Investigator: | Dr Simon Fu |
|  | Sponsor: | Merck Sharp & Dohme (New Zealand) Limited (MSD) |
|  | Clock Start Date: | 12 January 2023 |

No one 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 requested a review of the data management plan and participant information sheet to make sure that all left-over information not relevant to the study from the template is removed.
2. The Committee requested that a plan of what should happen in the event of a mental health crisis be detailed in the study documentation.

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

1. Please do not use acronyms without full explanation. The Committee suggested removing information about the specific biomarkers and instead referring to them as a group of biomarkers that could affect how a person reacts to the medication.
2. Please remove unnecessarily gendered language.
3. Please amend wording around notifiable diseases to be “or” not “and” where referencing Hepatitis B and HIV.
4. Please include an “access to and correction of information” statement as per the [HDEC template](https://ethics.health.govt.nz/guides-templates-and-forms/participant-information-sheet-templates/).
5. Please ensure that the headings are white on blue text rather than black on blue.
6. Please be explicit about the amount of reimbursement that will be given to participants.
7. Please amend “Māori health support” to “Māori cultural support”.

**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).*

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| **11** | **Ethics ref:** | **2023 FULL 13985** |
|  | Title: | A Phase 3 Open-label Clinical Study of Doravirine/Islatravir (DOR/ISL [100 mg/0.25 mg]) Once Daily for the Treatment of HIV-1 Infection in Participants Who Previously Received DOR/ISL (100 mg/0.75 mg) QD in a Phase 3 Clinical Study |
|  | Principal Investigator: | Dr Alan Pithie |
|  | Sponsor: | Merck Sharp & Dohme (New Zealand) Limited (MSD) |
|  | Clock Start Date: | 12 January 2023 |

Dr Alan Pithie 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 a pregnant participant/partner participant information sheet/consent form should only be submitted as an amendment in the event that a pregnancy occurs so it can be fit-for-purpose. The forms submitted have not been reviewed.
2. The Committee noted that the insurance is not protocol specific and is unclear how many trials this is meant to cover. Please ensure there is insurance that specifies this study and is at least ACC-equivalent or better.

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

1. Please state at the start that the participant has been invited as they previously participated in related trials (list them) and are invited to participate in this open label extension study receiving the same drugs with one of these at a lower dose.
2. Please ensure the PIS is New Zealand-specific. Currently there are parts that state “this may not be approved in your country” etc. It should just state whether it is or isn’t.
3. The Committee noted that the table of visits from the protocol can be helpful to include in PIS in a simplified form.
4. Latest Cultural statement around data sovereignty from the [HDEC template](https://ethics.health.govt.nz/guides-templates-and-forms/participant-information-sheet-templates/) should be used that also refers to information as taonga.
5. Please give some indication of what “common” means i.e., 10 out of 100 patients, etc. Please also list all different side effects including less common and rare and their indications.
6. Please include an optional tick box in the CF for participants to indicate if they would like to receive a lay summary.
7. The Committee noted the space for a signature of a witness in the event a participant cannot read the PIS. This is not necessary – please remove.
8. Please review for information that may not pertain to the current study.
9. A vaginal ring not available in New Zealand as a contraception option. Please remove.
10. Please amend wording around notifiable diseases to be “or” not “and” where referencing Hepatitis and HIV.

**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 Mrs Helen Walker and Dr Patries Herst.

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| **12** | **Ethics ref:** | **2023 FULL 15063** |
|  | Title: | A Double-Blind, Randomized, Placebo-Controlled, Single Dose Study to Investigate the Safety, Tolerability, and Pharmacokinetics of AB-161 Following Oral Administration in Healthy Subjects |
|  | Principal Investigator: | Professor Edward Gane |
|  | Sponsor: | Novotech (New Zealand) Limited |
|  | Clock Start Date: | 12 January 2023 |

No one from the research team was present via videoconference for discussion of this application as they were excused from attending as the Committee felt the application was to a high standard that their attendance was unnecessary.

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 acknowledged that the insurance amount was low but that this has historically been adequately justified.

Summary of outstanding ethical issues

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

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

1. Please provide other support numbers rather than only Lifeline.
2. Please clarify on page 7 that prescription medication is the limiting factor in terms of exclusion criteria, and that this does not relate to vitamins or other over the counter medications.
3. Please explain “half-lives” in lay-language; perhaps better to give a timeframe.

**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).*

## General business

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

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| **Meeting date:** | 28 February 2023 |
| **Zoom details:** | To be determined |

The following members tendered apologies for this meeting.

* Mrs Patricia Mitchell
* Dr Patries Herst

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 6.00pm