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| **Committee:** | Northern A Health and Disability Ethics Committee |
| **Meeting date:** | 18 April 2023 |
| **Zoom details:** | 965 0758 9841 |

| **Time** | **Review Reference** | **Project Title** | **Coordinating Investigator** | **Lead Reviewers** |
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| 12:30pm-1:00pm | 2023 FULL 13557 | DUET CD -Efficacy and Safety of Combination Therapy with Guselkumab and Golimumab in Participants with Moderately to Severely Active Crohn’s Disease | Dr Di Jiang | Ms Dianne Glenn and Dr Andrea Forde |
| 1:00pm-1:30pm | 2023 FULL 15526 | The BEAD Feasibility Study | Dr. Jordon Wimsett | Mrs Helen Walker and Dr Sotera Catapang |
| 1:30pm-2:00pm | 2023 FULL 15343 | NiPPeR Child | Professor Wayne Cutfield | Mr Jonathan Darby and Ms Jade Scott |
| 2:00pm-2:30pm | 2023 FULL 12788 | CHAANZ CHD Registry | Dr Clare O'Donnell | Ms Dianne Glenn and Dr Kate Parker |
|  |  | **BREAK 10 MINUTES** |  |  |
| 2:40pm-3:10pm | 2023 FULL 15628 | Understanding Child Abuse Victim, Caregiver and Clinician Trauma Focused Cognitive Behavioural Therapy (TF-CBT) Treatment Experience | Mrs Audrey Kusasira-Sutton | Mrs Helen Walker and Ms Jade Scott |
| 3:10pm-3:40pm | 2023 FULL 15420 | A first in human study to evaluate the safety and tolerability of a new treatment in males with hair baldness. | Dr Simon Carson | Mr Jonathan Darby and Dr Kate Parker |
| 3:40pm-4:10pm | 2023 FULL 15637 | 89Zr-TLX250-CDx Biodistribution Study | Dr Andrew Williams | Ms Dianne Glenn and Dr Sotera Catapang |
| 4:10pm-4:40pm | 2023 FULL 16692 | Comparison of two iron polymaltose tablets with diet control | Dr Noelyn Hung | Mrs Helen Walker and Ms Jade Scott |
|  |  | **BREAK 10 MINUTES** |  |  |
| 4:50pm-5:20pm | 2023 FULL 15351 | A Phase 3 Active-controlled Study of Milvexian for Prevention of Cardioembolic Events in Participants with Atrial Fibrillation LIBREXIA-AF | Dr Martin Stiles | Ms Dianne Glenn and Dr Sotera Catapang |
| 5:20pm-5:50pm | 2023 FULL 13224 | Neuflo Water Electrolysis System for the Treatment of Benign Prostatic Hyperplasia | Professor Peter Gilling | Mrs Helen Walker and Dr Kate Parker |
| 5:50pm-6:20pm | 2023 FULL 15313 | A safety and efficacy study to evaluate tildacerfont in the reduction of Glucocorticoid Steroid Doses in Adult CAH (SPR001-204) | Dr Simon Young | Mr Jonathan Darby and Dr Andrea Forde |
| 6:20pm-6:50pm | 2023 FULL 15306 | A dose ranging study to evaluate the safety and efficacy of tildacerfont in adults with classic Classic Congenital Adrenal Hyperplasia (CAH) (SPR001-203) | Dr Simon Young  Dr Simon Young | Mr Jonathan Darby and Dr Andrea Forde |

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| **Member Name** | **Member Category** | **Appointed** | **Term Expires** | **Apologies?** |
| Mr Derek Chang | Non-lay (Intervention studies) | 08/07/2022 | 08/07/2025 | Apologies |
| Dr Kate Parker | Non-lay (Observational studies) | 11/02/2020 | 11/02/2023 | Present |
| Dr Andrea Forde | Non-lay (Intervention studies) | 22/12/2021 | 22/12/2024 | Present |
| Ms Catherine Garvey | Lay (the Law) (Chair) | 19/03/2019 | 19/03/2022 | Apologies |
| Dr Sotera Catapang | Non-lay (Observational studies) | 11/02/2020 | 11/02/2023 | Present |
| Mr Jonathan Darby | Lay (the Law/Ethical and Moral reasoning) | 13/08/2021 | 13/08/2024 | Present |
| Ms Jade Scott | Non-lay (Intervention/Observational studies) | 15/08/2021 | 15/08/2024 | Present |
| Mrs Helen Walker | Lay (Consumer/Community perspectives) (Chair) | 22/12/2020 | 22/12/2024 | Present |
| Ms Dianne Glenn | Lay (Consumer/Community perspectives) | 08/07/2022 | 08/07/2025 | Present |

## Welcome

The Chair opened the meeting at 12.00PM and welcomed Committee members, noting that apologies had been received from Ms Catherine Garvey and Mr Derek Chang.  
  
The Secretariat noted that it would be necessary to co-opt members of other HDECs in accordance with the Standard Operating Procedures. Mrs Helen Walker and Ms Dianne Glenn confirmed their eligibility and were co-opted by the Committee as members of the Committee for the duration of the meeting, with Mrs Helen Walker acting as Chair.

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 21 March 2023 were confirmed.

## New applications

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| **1** | **Ethics ref:** | **2023 FULL 13557** |
|  | Title: | A Phase 2b Randomized, Double-blind, Active- and Placebo-controlled, Parallel-group, Multicenter Study to Evaluate the Efficacy and Safety of Induction and Maintenance Combination Therapy with Guselkumab and Golimumab in Participants with Moderately to Severely Active Crohn’s Disease |
|  | Principal Investigator: | Dr Di Jiang |
|  | Sponsor: | Janssen Cilag (New Zealand) Limited |
|  | Clock Start Date: | 06 April 2023 |

Dr Di Jiang 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 asked about the provision of drugs and placebo. The Researcher explained that placebo less than 10 percent of participants will be on placebo, and 50 percent will have combination therapy. All participants will have access if needed for rescue therapy and will have the option to have the drug at the end of the trial.
2. The Committee asked about the mental health questionnaire and if it is validated. The Researcher confirmed that all questionnaires are validated.
3. The Committee asked if there can be a separation of participant and investigators, and someone in between them can be the first person to talk to potential participants. The Researcher explained that they can happily implement someone from the research team to talk to potential participants for screening.
4. The Committee noted that the cover letter refers to getting provisional approval from Northern B, but submission did not provide further information. The Researcher confirmed this was an error in the letter as Northern B are providing approval for a different 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 noted that the risk of delaying vaccines for six months in infants who were exposed in utero to the study medicine should be clarified with the participant and the participant’s GP and addressed in the study documentation.

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

Main PIS/CF:

1. Please proofread and check for errors and grammar errors.
2. On page 2, it states participation and withdrawal of the study but there is no text underneath. Please check whether the information is below it and just needs to be clearer.
3. On page 3 please add "or a non-participating but qualified clinician" to remove pressure on participants, please also insert this on first page of the flow chat.
4. On page 4 please amend the blue number 1 screening chart, it has words missing at the end.
5. On page 5, Study Requirements, please check for grammar errors.
6. On page 11 please amend the first paragraph, "participants" is misspelled twice.
7. On page 13 please remove "not" from "are not known".
8. Some diseases and terminology could be included in a Glossary or explained in brackets or with common name.
9. Please explain if karakia is at all possible and at what time point.
10. Please ensure there is a question answered above about those on placebo who will be discontinued from the study.
11. Please check the risk rection for grammar errors and repeated words.
12. Please ensure that the statement, availability of an interpreter is at the beginning of the participant information sheet.
13. Please clarify the difference between de-identified and anonymized.
14. Please clarify that the patient identification number will not be the NHI.
15. The HDECs review and approve the ethical aspects of the study only, please amend statement that implies HDECs approve the study overall.
16. Please include "de-identified" to the 6th statement of the consent form.
17. Within the CF, item that HIV, HPV and HCV are notifiable diseases which must be reported to the Medical Officer of Health is missing.

Optional PIS/CF:

1. Please ensure that the statement re availability of an interpreter is at the beginning of the PIS.

PIS/CF for Genetic Research

1. Please ensure that the statement re availability of an interpreter is at the beginning of the PIS.
2. Provide space in the CF on right-hand side for ticks

**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 Dianne Glenn and Dr Andrea Forde.

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| **2** | **Ethics ref:** | **2023 FULL 15526** |
|  | Title: | The BEAD Feasibility Study: Baby Head Elevation device at full dilatation caesarean section |
|  | Principal Investigator: | Dr Jordon Wimsett |
|  | Sponsor: | University of Auckland |
|  | Clock Start Date: | 06 April 2023 |

Dr Jordon Wimsett and Dr Charlotte Oyston 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 commended the work that had been done with the re-submission of this study.
2. The Committee asked about the recruitment process. The Researcher explained that the information about the study would be available during the pregnancy, the idea of who can be enrolled is aimed at people who are 10cm dilated and needing a c-section by that point. This would be identified by the clinician at the time of transfer to theatre for assisted delivery.
3. The Committee asked about the pillow tool that is being used and who will be operating/using the tool. The Researcher explained that the obstetrician will be using the study tool/pillow on the participant.
4. The Committee asked about other trials like this study. The Researcher explained that there is one like the study happening in Auckland with a small participant group currently.
5. The Researcher explained that the balloon is currently not in use at Middlemore, however the research team will create standard of care for the balloon so every clinician will be able to use it correctly.

**Summary of outstanding ethical issues**

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

1. Please include in study documentation that the ethical aspects of this study have been approved by Northern A HDEC.
2. Please include measurable outcomes of the objectives of the study in the protocol.

**Decision**

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

* please address all outstanding ethical issues raised by the Committee.

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| **3** | **Ethics ref:** | **2023 FULL 15343** |
|  | Title: | Nutritional Intervention Preconception and During Pregnancy to Maintain Healthy Glucose Metabolism and Offspring Health Child  Follow Up Study |
|  | Principal Investigator: | Professor Wayne Cutfield |
|  | Sponsor: | University of Auckland |
|  | Clock Start Date: | 06 April 2023 |

Professor Wayne Cutfield and Jaz Lyons-Reid 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 asked about the mandatory analysis. The Researcher explained that it’s not a measure of the genes themselves, but what is attached the genes rather than epigenetic activation and is needed for study evaluation phase.
2. The Committee asked how long the intervention is from preconception to pregnancy for the participant. The Researcher explained that the intervention is planned to all of pregnancy up to a year of pre-pregnancy phase. Anywhere between 12 months and 21 months in total, the intervention will stop at delivery.
3. The Committee asked about neuro-behavioural overview and the tests. The Researcher explained that the tests are standardized across all the sites and overseen by the Singapore team who are international experts in neuro-behavioural areas.
4. The Committee asked about the questionnaires. The Researcher explained that some tests/questionnaires are children specific, and some tests/questionnaires the parents will do online, and the questionnaires are standardized across all sites.

**Summary of outstanding ethical issues**

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

1. Please include in the data management plan what is collected and where the data will be stored from the wristwatch.
2. The Committee noted that there would be two separate participant sheets, main and future unspecified uses. Please split these into separate documents.

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

Parent PIS/CF:

1. Please add the how/where will my data be stored section from the protocol into the participant information sheet.
2. Please include information on the data collection for the wristwatch
3. Please explain what a BIA analysis and a DXA scan involve in lay language if possible, then the parents can then explain it to their child.
4. Please provide more detail on how to withdraw for participants, outlining the steps involved.
5. Please explain epigenetic analysis in lay language.

Assent Form:

1. Please add a contact phone number in the assent form.
2. Please change wear actigraph watch for 1 week to 10 days as per protocol.

**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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| **4** | **Ethics ref:** | **2023 FULL 12788** |
|  | Title: | Congenital Heart Alliance of Australia and New Zealand Congenital Heart Disease Registry and NZ Paediatric Heart Disease Registry |
|  | Principal Investigator: | Dr Clare O’Donnell |
|  | Sponsor: |  |
|  | Clock Start Date: | 31 March 2023 |

Dr Clare O’Donnell and Dr Jordan McIntyre 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 asked about Māori data and the data that is going overseas. The Researcher explained that the data is overseen by an Australian company, the Researcher however will go back to the sponsor and explain the importance for this study of Māori data sovereignty.
2. The Committee asked about the choice to use opt-out for participants instead of opt-in. The Researcher explained that they have chosen opt-out due to past studies having low sign-ups using opt-in, and past studies using opt-out have higher turnout rates, the Researcher also wanted it to be known that the participant can opt-out anytime they can.
3. The Committee noted the application outlines the justification for a waiver clearly and were satisfied with the rationale.
4. The Committee asked about if a participant is included through the waiver and comes back to the study 2 years later and decides to opt-out, how the data handling will occur. The Researcher explained they will be in the retrospective cohort, the point where the participant opts out, no data will be collected from that point forward and their data will be made silent.
5. The Committee asked what making data silent means. The Researcher explained silent means the data still exists within the registry, however future data extraction will occur not using the silent data of the participant.
6. The Committee asked about the participant information sheets and the informed consent procedure. The Researcher explained the participant information sheets are available on internet and paper forms, however the research team is aware not to give potential participants too many pieces of information at once/too many pieces of paper as they do not want to miss any potential participants.

**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 to include information in the participant information sheet/brochure around the governance of the data as this may help aid the decision to remain in the study or opt-out.
2. Further, the Committee noted that the information leaflet has Te Whatu Ora branded and makes it seem like it’s a New Zealand-based registry. Please make it clearer that all data is kept overseas.
3. The Committee noted that a caregiver cannot consent for someone under 16, must be parent or guardian.
4. The poster should mention that it applies to people being treated for congenital heart condition. In addition, please proofread the poster for typos, such as “yours and your child’s”.
5. In the Data Management Plan, some wording around breach of privacy differs from the [HDEC template](https://ethics.health.govt.nz/guides-templates-and-forms/data-and-tissue-management-plan-templates/). The Committee suggested ensuring they are the same.

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

All:

1. Please use lay friendly study title instead of full title.
2. Include a glossary for diseases or explain diseases where they appear
3. Please review and correct grammar and typos.
4. As New Zealand has national data linkage across hospitals for patients, but Australia doesn’t, the issue would be moving from New Zealand to Australia. Please clarify that data linkage already exists in New Zealand and linkage to Australia would occur in this instance only.
5. Please replace the Ethics 0800 number in the PISs as per the guidance on the [HDEC website.](https://ethics.health.govt.nz/updates/changes-to-the-0800-number-in-participant-information-sheets/)

Master/Adult PIS:

1. The Committee noted the proposed amendment via a comment on page 4 would be better to include than the current text.

**Decision**

This application was *approved* with non-standard conditions 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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| **5** | **Ethics ref:** | **2023 FULL 15628** |
|  | Title: | Understanding Child Abuse Victim, Caregiver and Clinician Trauma Focused Cognitive Behavioural Therapy (TF-CBT) Treatment Experience |
|  | Principal Investigator: | Audrey Kusasira-Sutton |
|  | Sponsor: |  |
|  | Clock Start Date: | 31 March 2023 |

Audrey Kusasira-Sutton 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 asked about the interviews, and where they will be taken place. The Researcher explained that the interviews will be taken place at the site where the participants are getting therapy and will begin once the research team has ethics approval.
2. The Committee asked if the questionnaire is validated. The Researcher explained the research team made the questionnaire and it is not validated at this time.
3. The Committee asked how the research team will deal with distress. The Researcher explained there will be a clinician on site that can assist with de-escalation, and the research team offers withdrawal if needed.
4. The Committee asked about stigmatization and what the research team is doing to avoid as much as they can. The Researcher explains they are actively trying to avoid stigmatization; however, they will still honour the data, and the intentions are to lower stigmatization and honour the participants as much as they can.

**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 to update references to Health Information Privacy Code where they state 1994 instead of 2020.
2. The Committee requested submission of the independent peer review and any comments or queries raised during the peer review process to HDECs. The [HDEC guidance](https://ethics.health.govt.nz/guides-templates-and-forms/scientific-peer-review-submissions-guidance/) states this can happen, but we do require to see the process and any comments to be provided in lieu of seeking a peer review that follows our template.
3. The Committee raised the possibility that someone may raise current abuse or harm as part of their participation. The Committee noted that this should be incorporated into the participant information and consent form somehow.
4. The Committee requested more details in the study documentation if the interviews will occur after therapy sessions or sometime later.

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

All:

1. Please ensure the version number is present in all PIS/CFs
2. Please include where and when will the interviews take place. This is currently not clear.
3. Please amend the retention of data section, it is 10 years following someone turning 16.
4. Please state that If participants become uncomfortable during an interview, they have the right to end it, not just have a break to do exercises to help them.
5. Please make it clear they can withdraw at any time.

Clinician PIS/CF:

1. Missing certain information sections typical of participant information sheets such as why you are being asked to participate and what is required of them. Please see template.

Assent:

1. Please amend the Rangatahi assent form, it needs age clarification as this term crosses over age restrictions for consent. Please put the age brackets back in. Even if someone may use a different one, it is much clearer with its inclusion.
2. Please include a statement that the decision to participate/not participate will not impact therapy.
3. Please amend the consent form, it should consent to disclosure of current harm.

**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 Jade Scott and Mrs Helen Walker.

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| **6** | **Ethics ref:** | **2023 FULL 15420** |
|  | Title: | OLX72021-01: A Multi-Centre, Randomized, Double-Blind, Placebo-Controlled, Single Ascending Dose Phase 1 Study to Evaluate the  Safety, Tolerability and Pharmacokinetics of OLX72021 in Healthy Males with Androgenetic Alopecia. |
|  | Principal Investigator: | Dr Simon Carson |
|  | Sponsor: | OliX Pharmaceuticals, Inc. |
|  | Clock Start Date: | 06 April 2023 |

Dr Simon Carson 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 asked about section D9 of the application. The Researcher explained that this section was made mainly for a potential participant that calls the site and asks for participant information ahead of time. The Committee were assured that all participants will be shown the participant information sheets when needed.
2. The Committee asked why there are multiple tissue biopsies. The Researcher explained the second one is done to establish what study dosage is working well with the participant.
3. The Committee asked if there is a New Zealand representation on the safety review committee. The Researcher explained there is no New Zealand representation. The sponsor will look at all results in one cohort before going to the next level, all questions asked by participants will be respected and open for answering by the research team and doctors.
4. The Committee noted that the insurance across New Zealand and Australia is enough to cover for the study and does include New Zealand wording. The Committee were happy with the amount despite the two territories.
5. The Committee asked about future registration. The Researcher explained that it is too early in the study to determine registration, however they know the sponsor will want to reach as many markets are possible with this product. So, registration is most likely going to occur, if successful.

**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 review for typos and grammar errors.
2. Please clarify in the tissue statement whether a karakia is available on tissue disposal.
3. There are references to State Health Authorities which are Australian-specific, please change this to Medical Officer of Health
4. Please remove section on benefits of the study as benefits are currently overstated, or lead with a statement saying it is unlikely they receive benefit.
5. Please clarify what information may be collected from hospital records and GP and why.
6. Couple of blanks in PIS/CF, such as type of tissue, who has been consulted. Ensure those are filled in.
7. Please ensure it is made clear that participants will be asked questions around erectile dysfunction.

**Decision**

This application was *approved with non-standard conditions* 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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| **7** | **Ethics ref:** | **2023 FULL 15637** |
|  | Title: | A phase 1, prospective study to compare safety, tolerability, biodistribution and pharmacokinetics of a single dose of 89Zr-DFOgirentuximab with the antibody produced by ADRM-free adapted cell lines or original cell lines in patients with indeterminate renal masses. |
|  | Principal Investigator: | Dr Andrew Williams |
|  | Sponsor: | Telix international Pty Ltd. |
|  | Clock Start Date: | 06 April 2023 |

Brenda Cerquieira, Rosane Joseph, Ceylan Karaduman and Andrew Henderson 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 study would be registered with the World Health Organisation (WHO) prior to commencement.
2. The Committee clarified that the application had been submitted to be reviewed by the Standing Committee on Therapeutic Trials (SCOTT).
3. The Committee clarified that late presenting participants would not be disadvantaged, particularly in the case of Māori participants, who are noted to have a high rate of incidence of the condition under investigation.
4. The Committee clarified that there was an error in the data section of the submission and that data would be deidentified prior to publishing.
5. The Committee clarified that the intervention would be diagnostic only.
6. The Committee clarified that there would be a requirement for imaging only for the diagnosis of the renal mass and therefore inclusion into the study.
7. The Committee clarified that there would be comparison of immunogenicity of the participants and their tumours with cohorts from previous studies.
8. The Committee clarified that there would be site-based and specific guidance for the protection from radiation.
9. The Committee clarified that there would be no pressure on participants to go ahead in the study if the participants have claustrophobia and feel uncomfortable.
10. The Committee clarified that the sponsor would not stop publication of results but would potentially request that the paper be delayed due to the commercial sensitivity of the study.
11. The Committee clarified what the definition of “vulnerable participants” was as referred to in the exclusion criteria and who would be determining this and how people would be included were they potentially vulnerable.
12. The Committee clarified the inclusion of rates of side effects as included in the submission and study documentation.
13. The Committee clarified that the participants would be forwarded from a urologist and that a letter for their general practitioner would be made available if necessary.
14. The Committee clarified the process for biopsy results being requested by the study should they occur within 90 days of the trial. They would only be receiving results from biopsy performed per standard of care.
15. The Committee clarified how the researchers would ensure equity of access given that the main site for the study is at Mercy hospital and therefore has primarily private patients. The researcher reassured the Committee that all the public hospitals in Auckland would be included as points of referral.

**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 correct conclusion date be amended to be correct.
2. The Committee requested that there be nurse coordinators to conduct the first contact with participants and ensure that there are no feelings of unnecessary inducement by the study doctors and that this be documented in the Participant information sheets (PIS).
3. The Committee requested provision of the letter showing consultation with Dr Helen Wihongi.
4. The Committee noted that the study cannot end solely for commercial reasons and that this must be included in relevant study documentation.
5. The Committee requested that the specific location (Germany) of the assessment of baseline imaging be listed.

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

1. Please use the short study title for clarity and ease of understanding.
2. On page 2, please clarify for participants that there are two groups that will receive different treatments.
3. Please clarify for participants if karakia may be available for tissue samples at the time they are to be sent overseas.
4. Please include the potential benefits to the study prior to the risks section.
5. Please ensure that the Medicines New Zealand guidelines are supplied for participants to read as per the recommendations in the PIS.
6. Please remove the requirement of production of receipts as a condition for reimbursement.
7. Please ensure that mention of glomerular filtration rate is specified as the estimated glomerular filtration rate (eGFR).
8. Please ensure that the statement noting that tumour tissue will be sent overseas in the consent form as this tissue will not be sent overseas.
9. Please clarify the process for collection of biopsy results as taken through standard of care.
10. On page 9, please include the possible benefits before the risk section.
11. Please ensure that anaphylaxis or other severe adverse event, is communicated immediately, or as soon as practicable to the principal investigator and safety monitoring board, rather than the participant being advised to attend ED without ensuring the provision of information in respect of the adverse event to the PI.
12. Please include patient safety requirements e.g., toileting, limiting contact with others, subsequent to radiation exposure, etc.
13. Please specify the amount (in millilitres) of blood sample drawn per time point and total amount for the procedure
14. Please clarify the plan and capacity of the sites in dealing with claustrophobia as this may pose an issue for some participants undertaking MRI scanning.

**Decision**

This application was *approved with non-standard conditions* 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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| **8** | **Ethics ref:** | **2023 FULL 16692** |
|  | Title: | A single dose, double-blind, balanced, randomised, two-treatment, two period, two sequence, two-way crossover pilot study comparing 1 x 370 mg Iron Polymaltose tablet (equivalent to 100 mg of elemental iron) with 1 x 370 mg Maltofer® tablet (equivalent to 100 mg of elemental iron) in iron deficient participants under fed conditions with diet control. |
|  | Principal Investigator: | Dr Noelyn Hung |
|  | Sponsor: | Nova Chem Australasia Pty Ltd. |
|  | Clock Start Date: | 06 April 2023 |

Dr Noelyn Hung 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 the caffeine restriction of the study is due to increased urinary frequency as caffeine is a diuretic.
2. The Committee clarified that it is unlikely that students will require any form of exemption due to the study but that this was being flagged to ensure that participants were aware that there was a possibility of the study impacting their ability to take exams.
3. The Committee asked if there any placebo in place for the participants. The Researcher explained that there will be no placebo at any stage of the study.
4. The Committee suggested that caution be taken in future studies with the inclusion of statements pertaining to availability of the study or stating it may be “accessible to all” where using social media. Some disabled individuals/communities are more likely to have lower income and may not have regular access to technology.

**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 provision of the SCOTT approval letter once it is made available and any other supporting documentation concerning the safety and use of the study treatment.
2. The Committee noted that the meals will be low iron etc and queried if dietary requirements are considered. If so, please include this in study documentation.

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

1. Please clarify if the rooms for participants staying on site are shared and/or mixed gendered.
2. On page 13 please check for grammar errors in the statement “it is very important you do not become pregnant during this study drug”.
3. Please clarify that the diet whilst in the study is the only diet available and there will be no accommodation of other dietary preferences.
4. On page 18 “The Southern Health and Disability Ethics Committee has approved this study”, please change this to Northern A.
5. Please include that the study team cannot assist in procurement of an exam exemption as part of participation should some adverse event occur.
6. Please include the measurable outcome/end point of the objectives
7. Please include the amount of blood for each time point for pharmacokinetic determination.

**Decision**

This application was *approved* with non-standard conditions 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 15351** |
|  | Title: | A Phase 3, Randomized, Double-Blind, Double-Dummy, Parallel Group, Active-Controlled Study to Evaluate the Efficacy and Safety of Milvexian, an Oral Factor XIa Inhibitor, Versus Apixaban in Participants with Atrial Fibrillation LIBREXIA-AF |
|  | Principal Investigator: | Dr Martin Stiles |
|  | Sponsor: | Janssen Research & Development |
|  | Clock Start Date: | 06 April 2023 |

Dr Martin Stiles 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 the options for karakia.
2. The Committee clarified the data matching process using national death registries.
3. The Committee clarified that participants would potentially be at a higher risk of bleeding due to the utilisation of three anti-coagulants, but that there is guidance for managing this as per standard of care.

**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 planned study start and conclusion date do not match those dates of the insurance policy, please check and amend if needed.
2. The Committee requested that the manufacturer be requested to provide the study drug on compassionate grounds once the trial is completed should any participants respond well to the treatment.
3. The Committee noted that there was a statement in the PIS concerning the treatment of side effects and placing the cost and onus on the participant to manage these side effects. This is unethical and must be amended as any side effects incurred as a part of the study are the responsibility of the sponsor to treat and fund.
4. The Committee queried how the pharmacodynamics cohort would be allocated.
5. The Committee requested that the use of Omnitrace be documented in the Data and Tissue Management Plan.
6. The Committee requested clarification as to the “legal acceptable representative” please remove this or amend as relevant to the New Zealand context.

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

1. Please amend the description of participation on page 2. This is repetitive and should be simplified and proof-read for duplication of information.
2. On page 2, please explain the purpose of a placebo as taken with each treatment, or remove if this is a typo or not relevant to this study.
3. Please explain why an anti-coagulant may be offered as part of the follow-up process
4. Please provide a safety plan will be included in Home healthcare Guidelines.
5. Please move the “Medicines” title to page 6 as the page breaks in an awkward position.
6. Please ensure Māori participants understand specifically who to contact for possible karakia at tissue disposal/sent overseas.
7. Please provide the Medicines New Zealand Guidelines as noted and suggested for participants to read. Should this be unnecessary please remove or amend.
8. Please ensure that there is consistency in statements concerning what data the sponsor will receive. This must not be identifiable.
9. Please ensure that the option to have an interpreter is given at the beginning of the PIS rather than so far through the document.
10. Please provide tick boxes for the consent form.
11. Please clarify on page 6 why there is a ‘cc’ amount for a tablet treatment. Please amend this to be a New Zealand relevant measurement and to make more sense for participants.
12. Please specify the laboratory location in Singapore and the address of this lab.

**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 Dianne Glenn and Dr Sotera Catapang.

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| **10** | **Ethics ref:** | **2023 FULL 13224** |
|  | Title: | Neuflo Water Electrolysis System for the Treatment of Benign Prostatic Hyperplasia |
|  | Principal Investigator: | Professor Peter Gilling |
|  | Sponsor: | ProstaCare Pty Ltd. |
|  | Clock Start Date: | 06 April 2023 |

Professor Peter Gilling 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 the changes in the device.
2. The Committee clarified that the researchers had an external, independent urologist review the protocol and provided their feedback on the device and study.
3. The Committee clarified that routine blood samples would be taken and tested at local sites. The tissue would not be retained and karakia would not be available.
4. The Committee clarified that there was no advertising material for this application and that there had been an error indicating this in the submission. Should adverts be required these documents will be provided as an amendment.
5. The Committee clarified that there would be no extra cystoscopy as part of the study and that this would only be done as part of standard of care (SoC).
6. The Committee clarified the process for recordings made and that these would only be used for future training. The video would only be stored and shared internally. All recordings would be deidentified.
7. The Committee clarified that licensure would be sought in New Zealand.
8. The Committee clarified that the questionnaires are self-administered.

**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 an insurance certificate be provided once it is available.
2. The Committee requested that a study nurse or coordinator be the person to make the first approach to potential participants so as to avoid feelings of coercion.

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

1. Please remove all references to cups and teaspoons as a form of measurement for blood. Millilitres should be used instead.
2. Please amend the pregnancy risks section to be consistent with advice in other parts of the PIS concerning the maintenance of fertility.
3. Please state how long the foley catheter will be in situ after removing the study device, if this is per clinical discretion then state this is lay terms.
4. Please remove mention of the cystoscopy from the study procedures if this is only done per SoC.
5. Please include an option to accept or decline recording of procedures in the consent form.
6. Please remove reference of tissue being sent overseas from the consent form.
7. Please clarify the procedure for recording device use and proof-read this section for grammar and spelling.
8. On page 2 please check for grammar errors.
9. Please amend the section “stopping the treatment” as this is a single-use treatment. Please clarify if this relates to discomfort or discontinuing the single treatment process.
10. Please state how the questionnaires will be conducted.
11. Please make it clear that a karakia will not be available for participants.
12. Please clarify the requirement of both an invasive and non-invasive method of imaging of the bladder.
13. Please avoid use of terms such as “voiding” as these are non-lay terms and may be confusing to participants. Please replace with plain English terms.

**Decision**

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

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

After receipt of the information requested by the Committee, a final decision on the application will be made by Dr Kate Parker and Mrs Helen Walker

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| **11** | **Ethics ref:** | **2023 FULL 15313** |
|  | Title: | A Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy and Safety of SPR001 (Tildacerfont) in Reducing Supraphysiologic Glucocorticoid Use in Adult Subjects with Classic Congenital Adrenal Hyperplasia |
|  | Principal Investigator: | Dr Simon Young |
|  | Sponsor: | Spruce Biosciences, Inc |
|  | Clock Start Date: | 06 April 2023 |

Dr Simon Young 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 other trials in this study had not been conducted in New Zealand but had been carried out overseas.
2. The Committee clarified the placebo control for this study was due to the pharmacokinetics of current best-case treatments.
3. The Committee clarified that there would be no significant deterioration of participants on the placebo arm of the study.
4. The Committee clarified what the exclusion criteria “psychiatric conditions” does and does not include.

**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 section C18.2 Disability was incomplete and should include what the researchers have in place to assist people with disabilities to participate.
2. The Committee requested the Standing Committee on Therapeutic Trials (SCOTT) approval letter, or a peer review document as listed in the submission (*National Ethical Standards* para *9.25-9.32).*
3. The Committee queried why there were no direct benefits to the study. This may need to be clarified in the protocol and participant information sheets.
4. Throughout the application, please ensure consistency when it comes to documentation of data usage and explain that the data will be de-identified and not anonymised.
5. The Committee requested that the researcher submit a completed data management plan (DMP), as the current one uploaded is a draft document.
6. The Committee noted that all adverse events should be covered by the sponsor. Amend this in the application.
7. The Committee noted that the amount of cover for insurance was not sufficient for the period to be covered. Please amend this. (*National Ethical Standards* para *17.1-17.6).*
8. The Committee noted that the diseases noted in the footer are all notifiable in New Zealand. Please amend this.
9. The Committee requested that the study documentation states that the study is approved by an Institutional Review Board and this is not the case as HDECs only approve the ethical aspects of studies.

The Committee requested the following changes to the Participant Information Sheet and Consent Form (PIS/CF) *National Ethical Standards* para *7.15, 7.16 & 7.19*:

1. The Committee suggested proof-reading all PISCFs.
2. Please include a safety pan for the questionnaires that ask questions concerning suicidal ideation and depression. This should include how quickly after completion these questionnaires will be reviewed, what the follow up process will be and the timeliness of referral.
3. Please include a Māori cultural statement as per the [HDEC template](https://ethics.health.govt.nz/assets/Uploads/HDEC/templates/participant-information-sheet-consent-form-template-v5.0april2023.doc) or the cultural consultation undertaken and please include a statement offering karakia for the destruction of samples.
4. Please use [the HDEC template compensation statement](https://ethics.health.govt.nz/assets/Uploads/HDEC/templates/participant-information-sheet-consent-form-template-v5.0april2023.doc). The current one is not sufficient for HDEC review and please note that any delay is the responsibility of the sponsor not the participant and this needs to be amended.
5. Please remove reference to “legally authorised representative” as this is not a recognised thing in New Zealand.
6. Please amend documentation that notes that minors may be included in this study.
7. Please describe and clarify what the study intervention entails/is.

**Decision**

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

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| **12** | **Ethics ref:** | **2023 FULL 15306** |
|  | Title: | A Randomized, Double-Blind, Placebo-Controlled, Dose-Ranging Study to Evaluate the Efficacy and Safety of SPR001 (Tildacerfont) in Adult Subjects with Classic Congenital Adrenal Hyperplasia |
|  | Principal Investigator: | Dr Simon Young |
|  | Sponsor: | Spruce Biosciences, Inc |
|  | Clock Start Date: | 06 April 2023 |

Dr Simon Young 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 other trials in this study had not been conducted in New Zealand but had been carried out overseas.
2. The Committee clarified the placebo control for this study was due to the pharmacokinetics of current best-case treatments.
3. The Committee clarified that there would be no significant deterioration of participants on the placebo arm of the study.
4. The Committee clarified the accessibility of the primary site and the support that may be given to participants with a variety of disabilities.
5. The Committee clarified what the exclusion criteria “psychiatric conditions” does and does not include.

**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 section C18.2 Disability was incomplete and should include what the researchers have in place to assist people with disabilities to participate.
2. Please amend section C20 and explain if participants can have their own support people during consenting process.
3. The Committee requested the Standing Committee on Therapeutic Trials (SCOTT) approval letter, or a peer review document as listed in the submission *(National Ethical Standards* para *9.25-9.32).*
4. The Committee noted that the diseases noted in the footer are all notifiable in New Zealand. Please amend this.
5. The Committee noted that all adverse events should be covered by the sponsor. Amend this in the application.
6. The Committee noted that the Investigators Brochure was listed as an Australian document, this needs to be updated for New Zealand.
7. The Committee noted that the amount of cover for insurance was not sufficient for the period to be covered. Please amend this.
8. The Committee requested that the study documentation states that the study is approved by an Institutional Review Board and this is not the case as HDECs only approve the ethical aspects of studies.
9. Throughout the application, please ensure consistency when it comes to documentation of data usage and explain that the data will be de-identified and not anonymised.
10. The Committee requested that the researcher submit a completed data management plan (DMP), as the current one uploaded is a draft document.

The Committee requested the following changes to the Participant Information Sheet and Consent Form (PIS/CF) (*National Ethical Standards* para *7.15, 7.16 & 7.19)*:

1. The Committee suggested proof-reading all PIS/CFs.
2. Please include that the study drug was fetotoxic in the rabbit study.
3. Please include a safety pan for the questionnaires that ask questions concerning suicidal ideation and depression. This should include how quickly after completion these questionnaires will be reviewed, what the follow up process will be and the timeliness of referral.
4. Please include a Māori cultural statement as per the [HDEC template](https://ethics.health.govt.nz/assets/Uploads/HDEC/templates/participant-information-sheet-consent-form-template-v5.0april2023.doc) or the cultural consultation undertaken and please include a statement noting that karakia is or is not available for the destruction of samples.
5. Please describe and clarify what the study intervention entails/is.
6. The study booklet states: ‘you will take four pills by mouth (one row in the blister pack) each day-” please include this in the information sheets.
7. Please use [the HDEC template compensation statement](https://ethics.health.govt.nz/assets/Uploads/HDEC/templates/participant-information-sheet-consent-form-template-v5.0april2023.doc). The current one is not sufficient for HDEC review and please note that any delay is the responsibility of the sponsor not the participant and this needs to be amended.
8. Please remove reference to “legally authorised representative” as this is not a recognised thing in New Zealand.

**Decision**

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

## General business

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

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| **Meeting date:** | 16 May 2023 |
| **Zoom details:** | To be determined |

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 6.30PM.