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| **Committee:** | Northern B Health and Disability Ethics Committee |
| **Meeting date:** | 03 October 2023 |
| **Zoom details:** | 965 0758 9841 |

| **Time** | **Review Reference** | **Project Title** | **Coordinating Investigator** | **Lead Reviewers** |
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| 11:30am - 12:00pm | 2023 FULL 18604 | Defining the Genetics of Developmental Disorders | Professor Stephen Robertson | Kate / Leesa |
| 12:00 - 12:30pm | 2023 FULL 18301 | Gut Bugs for C. Difficile Infection | Professor Wayne Cutfield | Ewe Leong / Amber |
| 12:30 - 1:00pm | 2023 FULL 18677 | Project Village | Dr Julia de Bres | Alice / Barry |
| 1:00 - 1:30pm | 2023 FULL 18372 | BP44773: Non-Randomised, Open-Label, Multiple-Dose Study of Zosurabalpin in Healthy Participants | Dr Nick Cross | Kate / Joan |
| 1:30 - 2:00pm | Lunch (30 mins) |  |  |  |
| 2:00 - 2:30pm | 2023 FULL 17916 | FEBrile CONvulsion - Emergency Department (FEBCON-ED) study | Professor Stuart Dalziel | Ewe Leong / Leesa |
| 2:30 - 3:00pm | 2023 FULL 18748 | Select SLE Study | Dr Mark Sapsford | Alice / Amber |

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

## Welcome

The Chair opened the meeting at 11:30am and welcomed Committee members noting that apologies had been received from Ms Maakere Marr.

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 05 September were confirmed.

## New applications

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| **1**   | **Ethics ref:**   | **2023 FULL 18604** |
|   | Title:  | Defining the Genetics of Developmental Disorders |
|   | Principal Investigator:  | Professor Stephen Robertson |
|   | Sponsor:  | University of Otago |
|   | Clock Start Date:  | 21 September 2023 |

Professor Stephen Robertson was present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of resolved ethical issues

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

1. The Committee queried whether child participants would be able to provide assent. The Researcher stated it was likely most would not be able. The Researcher stated it was possible some children may have limited capacity and so an assent form was created.
2. The Researcher confirmed supported decision-making would be available for adults with limited capacity to consent and the study would use existing supported consent processes.
3. The Committee advised locality approval would only be required from the site with the national coordinating centre.
4. The Committee requested the Researcher note which overseas sites are performing tests in the annual progress reports for the study, confirming that cultural appropriate tissue handling and disposal procedures are in place at each new site.
5. The Committee queried how results from novel tests would be managed if these are not validated diagnostic tests. The Researcher stated they would have a discussion to validate the test in a clinically certified lab in New Zealand, and agreed to revise the protocol to make it clear that the participant’s clinician would not have that responsibility. The Researcher stated the report back to the clinician would include discussion of the uncertainty of unvalidated tests.

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 suggested creating a placeholder in the protocol to include additional laboratories to process samples in the future as well as limiting it to state samples will not be provided to commercial entities.
2. The Committee requested the Researcher develop an assent form for a sibling with capacity to assent.
3. The Committee advised the storage time for samples was ten years from the time the participant turns 16 (e.g. a sample from an infant would require a 26 year storage). Please update the protocol, information sheet and data and tissue management plan to reflect this.

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

1. Please include information on non-paternity in the protocol and risks section of the information sheet.
2. Please include information on the registry.
3. Please revise the risks section for easier readability.
4. Please emphasise the information regarding the implications for medical insurance in the risks section.
5. Please include information advising the need to notify or engage with broader family members if the study uncovers a finding that may affect the wider family.
6. Please include information advising an approximate timeframe for when a participant can expect results back.
7. Please insert an appropriate contact number into the information sheet so potential participants may discuss the trial with someone with appropriate expertise who is not their direct clinical provider.
8. Please include a lay-friendly explanation of what genes are and what they do.
9. Please make it clear that the sample may be retested in the future if appropriate new tests are developed.
10. Please make it clear that data obtained from the sample may be analysed again in the future.
11. Please remove the child registry consent from the family member PIS as only adults will be signing this sheet.

**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).*
* please update the data management plan *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15a)*

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| **2**   | **Ethics ref:**   | **2023 FULL 18301** |
|   | Title:  | Encapsulated fecal microbiome transfer versus oral vancomycin treatment for recurrent or refractory C. difficile infection |
|   | Principal Investigator:  | Professor Wayne Cutfield |
|   | Sponsor:  | The University of Auckland |
|   | Clock Start Date:  | 21 September 2023 |

Professor Wayne Cutfield, Dr Ben Albert, Dr Taygen Edwards 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 Researcher confirmed the capsules were produced in compliance with Good Manufacturing Practice (GMP).
2. The Researcher confirmed a registered nurse would provide the capsules to participants at their home.
3. The Researcher confirmed that the project did not have any commercial potential, and if successful, the mode of administration would be available similarly to a blood service.

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 the Researcher supply a home-visit safety protocol. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 11.62).*
2. The Committee requested an update to the protocol to describe the manufacturing process of the capsules and confirm they are produced in a sterile and safe manner. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.7).*
3. The Committee requested the Researcher provide details about the content of the capsules similar to, for example, a certificate of analysis.
4. The Committee requested the Researcher supply the donor declaration.

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

1. Please include information describing the capsule as a novel mode of administration and that this is being tested in addition to the faecal microbiome transfer.
2. Please include information on the risks of microbiome transfer (e.g. infection, other side effects) and the strenuous screening process to minimise these risks.
3. Please remove the statement that the capsules are “safe and effective”, as that is what the trial intends to explore. Add information about the use of the capsules in previous trials and whether they were tolerated or caused adverse events.
4. Please refer to the capsules as an investigational or study product and not a “treatment”.
5. Please replace “gut microbiome transfer” on page 1 with “faecal microbiome transfer.” Clarify that faecal matter is merely the source of the microbiome material; the transfer itself does not include faecal matter.
6. Please revise the statement on page 2 regarding unsuccessful treatment to make it clear that there are three arms and if a participant is not responsive to one arm they will cross-over.

**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).*
4. Please supply a safety plan for home visits. (*National Ethical Standards for Health and Disability Research and Quality Improvement, para 11.62).*

After receipt of the information requested by the Committee, a final decision on the application will be made by Mr Ewe Leong Lim and Dr Amber Parry Strong.

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| **3**  | **Ethics ref:**   | **2023 FULL 18677** |
|   | Title:  | It takes a village: picturing family support for transgender young people in Aotearoa |
|   | Principal Investigator:  | Dr Julia de Bres |
|   | Sponsor:  | Massey University |
|   | Clock Start Date:  | 21 September 2023 |

Dr Julia de Bres and Mr Kyle Tan 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 determined the study was out of scope for HDEC review and would be more suitably reviewed by Massey University’s institutional ethics committee.
2. The Committee noted minors under 16 may have sufficient capacity to provide their own consent without parental consent and encouraged the Researcher to discuss this with Massey’s institutional committee.
3. The Committee noted that the confidentiality protections could be improved by coding the data.

**Decision**

This application was determined to be *out of scope* by consensus, as the Committee did not consider that the study falls within the definition of health research described in the HDEC Standard Operating Procedure.

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| **4**   | **Ethics ref:**   | **2023 FULL 18372** |
|   | Title:  | A NON-RANDOMIZED, OPEN-LABEL, NON-CONTROLLED, ADAPTIVE, MULTIPLE-DOSE STUDY TO INVESTIGATE THE SAFETY, TOLERABILITY, AND PHARMACOKINETICS OF ZOSURABALPIN FOLLOWING INTRAVENOUS ADMINISTRATION IN HEALTHY PARTICIPANTS |
|   | Principal Investigator:  | Dr Nick Cross |
|   | Sponsor:  | F. Hoffmann-La Roche Ltd; Pharmaceutical Research Associates New Zealand Limited |
|   | Clock Start Date:  | 21 September 2023 |

Dr Nick Cross, Julia O’Sullivan, and Kayla Malate 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 queried the risk of inserting a peripherally inserted central catheter (PICC). The Researcher stated higher doses of zosurabalpin can cause irritation to the veins and a PICC would reduce the risk from repeated injections.
2. The Committee noted the protocol (Section 8.4) specified that an accidental overdose by study personnel would not be an adverse event and queried how this would be reported. The Researcher stated if the wrong dose was administered but there were no adverse effects it would be reported to the Sponsor’s medical monitor. If the overdose caused harm, the study team would report the incident as a serious adverse event. The Committee noted that “accidental overdose” by research personnel is per se protocol non-compliance, and should be reported as such with an appropriate corrective action plan.

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 mandatory whole genome sequencing that is not related to a primary study outcome is inconsistent with the National Ethical Standards. In this protocol, the justification for the WGS does not meet that requirement. The Committee requested an update to the information sheet clearly identifying the mandatory tests and making whole genome sequencing optional. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 14.34).*
2. The Committee noted the study advertising states $1,200 instead of $12,000 and requested a correction.

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

1. Please revise any uses of the word ‘treatment’ as this is a study on healthy volunteers.
2. Please include a contact for the study doctor along with the Lifeline phone number in the C-SSRS questionnaire section on page 14.

**Decision**

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

1. 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).*
2. Please specify the mandatory genetic tests that will be done and make whole genome sequencing optional. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 14.34).*
3. Please provide more information about the definition of “protocol deviations” in Section 9.5 of the protocol.

After receipt of the information requested by the Committee, a final decision on the application will be made by Mrs Kate O’Connor and Ms Joan Petit.

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| **5** | **Ethics ref:**   | **2023 FULL 17916** |
|   | Title:  | FEBCON-ED study: A stepped-wedge cluster randomised controlled clinical trial of usual care vs regular antipyretics for children presenting with a FEBrile CONvulsion to the Emergency Department. |
|   | Principal Investigator:  | Professor Stuart Dalziel |
|   | Sponsor:  | Monash University; Starship Hospital |
|   | Clock Start Date:  | 21 September 2023 |

Professor Stuart Dalziel and Dr Libby Haskell 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 determined the research was an observational study of two processes within standard of care and approved the cluster design method.
2. The Researcher confirmed they would attempt to include New Zealanders in the consumer engagement group.
3. The Committee queried what data fields the NHI would be matched to. The Researcher stated this was not finalised as Te Whatu Ora’s IT infrastructure is in development and additional data fields may be available in the future. The Committee suggested defining it as health information about the participant’s condition and not broad unspecified use.
4. The Researcher confirmed the study app would not collect incidental data from the participant’s phone.

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 the Researcher update the data management plan to include a waiver of consent heading with a justification for a [waiver for secondary use of data consistent with the National Ethical Standards](https://neac.health.govt.nz/national-ethical-standards/part-two/12-health-data/) *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15a).*

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

1. Please define who the study Sponsor is.

**Decision**

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

* 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 data management plan to include a justification for a waiver of consent for secondary re-use of health information *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15a).*

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| **6**  | **Ethics ref:**   | **2023 FULL 18748** |
|   | Title:  | A Phase 3 Program to Evaluate the Safety and Efficacy of Upadacitinib in Subjects with Moderately to Severely Active Systemic Lupus Erythematosus |
|   | Principal Investigator:  | Dr Mark Sapsford |
|   | Sponsor:  | AbbVie |
|   | Clock Start Date:  | 21 September 2023 |

Dr Mark Sapsford, Dr Karen Stellpflug, Dr Kristin D’Silva, and Esther Ji 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 accepted the independent peer review and identified no further issues.

**Decision**

This application was *approved* by consensus.

## General business

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

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| **Meeting date:** | 14 November 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 2:35pm.