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| **Committee:** | Southern Health and Disability Ethics Committee |
| **Meeting date:** | 12 March 2024 |
| **Zoom details:** | 965 0758 9841 |

| **Time** | **Review Reference** | **Project Title** | **Coordinating Investigator** | **Lead Reviewers** |
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| 10.30-11.00am | 2024 FULL 19431 | The effect of pre-operative antibiotics on the microbiome in Colorectal Surgery | Dr John Woodfield | Dr Maree Kirk and Dr Patries Herst |
| 11.00-11.30am | 2024 FULL 19569 | FASD YJ Study | Dr Joanna Chu | Mr Dominic Fitchett and Ms Amy Henry |
| 11.30am-12.00pm | 2024 FULL 19551 | ABI-4334-102: A Study to Assess the Safety and Tolerability of ABI-4334 in Participants with Chronic Hepatitis B Following Multiple Doses. | Professor Edward Gane | Ms Dianne Glenn and Dr Devonie Waaka |
| 12.00-12.30pm | 2024 FULL 19516 | A study to assess how safe and effective the study drug ZN-A-1041 is, when used alone or with other treatments for HER2-Positive solid tumours | Dr. Yeo Jeong (Jane) So | Dr Maree Kirk and Ms Amy Henry |

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| **Member Name** | **Member Category** | **Appointed** | **Term Expires** | **Apologies?** |
| Dr Devonie Waaka | Non-lay (Intervention studies) | 18/07/2016 | 18/07/2019 | Present |
| Mr Dominic Fitchett | Lay (the Law) (Chair) | 05/07/2019 | 05/07/2022 | Present |
| Ms Amy Henry | Non-lay (Observational studies) | 13/08/2021 | 13/08/2024 | Present |
| Ascc. Prof Nicola Swain | Non-lay (Intervention/Observational studies) | 22/12/2021 | 22/12/2024 | Apologies |
| Ms Dianne Glenn | Lay (Consumer/Community perspectives) | 08/07/2022 | 08/07/2025 | Present |
| Ms Neta Tomokino | Lay (Consumer/Community perspectives) | 08/07/2022 | 08/07/2025 | Apologies |
| Dr Maree Kirk | Lay (Consumer/Community perspectives) | 03/07/2023 | 02/07/2026 | Present |
| Mrs Carla Strubbia | Non-lay (Intervention Studies) | 03/07/2023 | 02/07/2026 | Present |
| Dr Patries Herst | Non-lay (Intervention studies) | 22/05/2020 | 22/05/2023 | Present |

## Welcome

The meeting was opened with a karakia at 10.00am and the Chair welcomed Committee members, noting that apologies had been received from Ms Neta Tomokino and Associate Professor Nicola Swain.  
  
The Chair noted that it would be necessary to co-opt members of other HDECs in accordance with the Standard Operating Procedures. Dr Patries Herst confirmed their eligibility and were co-opted by the Chair as a member of the Committee for the duration of the meeting.

The Chair noted that the meeting was quorate.

The Committee noted and agreed the agenda for the meeting.

## Confirmation of previous minutes

The minutes of the meeting of 13 February 2024 were confirmed.

## New applications

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| **1** | **Ethics ref:** | **2024 FULL 19431** |
|  | Title: | Colorectal Anastomosis and Bacterial Eradication (CABE) Trial: The effect of pre-operative antibiotics on the colonic microbiome in  Colorectal Surgery |
|  | Principal Investigator: | Dr John Woodfield |
|  | Sponsor: | University of Otago |
|  | Clock Start Date: | 29 February 2024 |

Dr John Woodfield, Kari Clifford, and Cole Melhopt 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.

Dr Devonie Waaka declared a potential conflict of interest and the Committee decided to recuse her from discussion.

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 confirmed this study isn’t being performed for commercial benefit, therefore any reference to commercial benefit should be removed from the data management plan (DMP).
2. There are discrepancies between the participant information sheets and DMP. Please make sure these align.
3. The application form stated 5 objectives. The 5th objective is specific differences in microbiome that may be different in Māori and Pasifika patients, which is not identified as an objective in the protocol. Please clarify population groups under objectives in the protocol.
4. The Committee requested clarification in the protocol surrounding the aim to include patients under objective 4 is in addition to the recruitment of 60.
5. The initial larger group of patients who are eligible are not identified clearly in the application form. Please ensure the protocol is clear around this.
6. The Committee noted that this study will need to be submitted to a WHO-approved clinical trials registry before commencing.

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

Both:

1. Participants should be explained the difference between de-identified, anonymous, and identifiable forms of data. Give examples of each and state who will have access. Mention future use of data, data being sent overseas. Refer to DMP plan for detail.
2. Remove tick box for GP being informed of significant abnormal results as this shouldn’t be optional. The GP being informed of significant abnormal results is also first only raised in the CF. Please ensure this is raised in the PIS too.
3. If data will be sent overseas (as per DMP), please state this and the associated potential risks in the PISs.
4. Please proofread all sheets generally for typos.
5. Please review for medical terms and explain them first in lay-language.

Main:

1. Page 6 has the ‘What will happen to my information’ section missing. The sentence about privacy that is currently there is not sufficient. Please see the [HDEC template](https://ethics.health.govt.nz/guides-templates-and-forms/participant-information-sheet-templates/) for guidance. A lot of this can be lifted from the DMP too. Patients need to see what happens to their tissues and information.
2. Please also clarify if the small sample taken from the colon is optional.
3. Please ensure that only the ethical aspects of the study are stated to have been approved by the Southern HDEC.
4. Please add a cultural paragraph regarding data and tissue. The HDEC template has examples of what this can look like.
5. Add paragraph on what are my rights that covers:
   1. Participation is voluntary.
   2. Participant can pull out at any time.
   3. The participant can see info gathered about them and correct any errors.

Rectal Swab PIS:

1. Please clarify that the rectal swab component is an optional sub-study in the title and throughout the document.

**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 Maree Kirk and Dr Patries Herst.

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| **2** | **Ethics ref:** | **2024 FULL 19569** |
|  | Title: | The need for FASD intervention: Prevalence and Knowledge in Youth Justice |
|  | Principal Investigator: | Dr Joanna Chu |
|  | Sponsor: | University of Auckland |
|  | Clock Start Date: | 29 February 2024 |

Dr Joanna Chu, Valmai Copeland, Associate Professor David Newcombe, Professor Anita Gibbs, Ashley Seaford, Felicity Ware, Jessica McCormack, Holly Wilson 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 Wechsler intelligence scale has been shown to disadvantage persons not from a western cultural background and the Committee queried if this or other listed measures have been adapted to the New Zealand context. The Researchers confirmed there will be New Zealand guidelines around use coming out, but these are not yet available.

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 acknowledged that finalising details of the study may be an ongoing process and stated that any changes made to documentation will need to be submitted for review.
2. The Committee noted the significant capacity for consent issues for this research in a vulnerable population and discussed the following with the Researcher *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 6.6-6.12, 6.20-6.30, 7.59-7.74)*:
   1. Confirmed that capacity to consent for research participation will be assessed by the Researchers through conversation with the person but also liaising with their case managers.
   2. Those 16 and above should be assessed for capacity to provide their own consent, but those 10-15 should also be assessed for their capacity to provide their own consent and seek paired consent with the parent and guardian as well (especially as they are also participants).
   3. 18-year-olds have limited options for someone consenting on their behalf, as the study involves more than minimal risk. While it would be acceptable for 18-year-olds to provide consent with supported decision making, if someone is unable to consent with that support, they should be excluded.
   4. The assessment of capacity needs to be documented in the participant’s study notes to detail that someone with appropriate experience and training has undertaken that assessment of capacity to determine whether they should provide assent or consent.
   5. Those aged 18 years who independently consent to study participation should not require additional parent or guardian consent in order to take part in the study. In these cases parental consent should be limited to their own participation in the study.
   6. Oranga Tamariki is involved as a Sponsor for the study. Where the young person’s legal guardian is the Chief Executive of Oranga Tamariki, any potential participant where whanau opinion cannot be ascertained should be excluded from participation due to this significant conflict of interest.
   7. Please provide a simplified version of the main participant information form for younger participants or participants who may require a simplified version of the PIS.
3. Children should be told of their diagnosis, and consent from the parent/guardian should not be sought to inform the participant of their own health information. The way this is delivered can be adjusted on a case-by-case basis, but the parent/guardian should not prevent the young person from being advised of their diagnosis.
4. More information is needed about the focus group referenced in the protocol and application form, as their inclusion in the research is not clear. These participants will also need their own participant information sheet (PIS).
5. 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. Clarify what identifiable data will be held in REDCAP as it says “some”.
   2. Amend the data retention information, as health data should be kept for 10 years following a participant turning 16.
   3. Provide detail about the the management of audio recordings in the Identifiable Information sections, as voice is considered a biometric identifier. This should include where and how it is stored, who has access to the recordings, and how long the recordings are retained.
   4. Please include a statement about whether potentially identifiable information will be redacted from the transcript.
6. Please ensure the above points regarding data management are outlined to participants in the PISs.
7. Please provide a robust plan of action on what procedures are in place if a participant discloses something concerning to the researchers. If there are existing guidelines, please provide these.
8. The Committee queried if there will be issue with participants accessing the resources that these participants will be directed to once they have their diagnosis. The Researchers should ensure participants have access to adequate support or follow-up after a diagnosis of this nature. Please make it clear in the PIS that resources are limited, so diagnosis doesn’t necessarily mean help will be readily available for participants and their whanau.
9. The Committee queried if those who decline the workshop will be provided with a more private opportunity to discuss the diagnosis and available resources, as not everyone will want to receive this information in a workshop setting with others present. For those that are not comfortable with, or unable to attend the workshop, please ensure other options for discussion are available.
10. The recruitment email invitation states contributions are anonymous, but this is not correct. Please amend.
11. The Committee requested to be provided a copy of peer reviewers comments from the HRC review. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.26).*

The Committee requested the following changes to the Participant Information Sheet and Consent Form (PIS/CF) *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17)*:

1. Please provide simplified sheets for those with lower comprehension levels to provide their assent.
2. Statements regarding data privacy doesn’t match up across sheets. Please ensure these are consistent.
3. The study can’t promise someone won’t be mad at a potential participant for not wanting to take part. Please remove this statement from page 3.
4. Please clarify that participants cannot withdraw their data after two weeks of their final assessment due to the data being analysed.
5. Please amend interview information to state how long the interview will take, how data be stored, how long the recordings and notes will be kept for etc, and what will be done if anyone discloses anything that needs to be acted on.
6. Please include information that details the participation of whanau and staff in the study in the young person’s PIS.
7. Please acknowledge the potential of privacy breach in all PISs.

**Decision**

This application was *declined* by consensus, as the Committee did not consider that the study would meet the ethical standards referenced above. The Committee strongly encouraged the Researchers to resubmit to the Southern HDEC.

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| **3** | **Ethics ref:** | **2024 FULL 19551** |
|  | Title: | A Randomized, Blinded, Placebo-Controlled Dose-Ranging Phase 1b Study of the Safety, Pharmacokinetics, and Antiviral Activity of  ABI-4334 in Subjects with Chronic Hepatitis B Virus Infection |
|  | Principal Investigator: | Professor Edward Gane |
|  | Sponsor: | PPD, part of Thermo Fisher Scientific; TMF Group and Assembly Biosciences, Inc. |
|  | Clock Start Date: | 29 February 2024 |

Professor Edward Gane, Holly Thirlwall, Lucy Druzianic, and Grace Tougher 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 that while he would identify potential participants, members of the research team not involved with their clinical care would conduct most of the recruitment and consent process.

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 if there would be potential for participants down the track to be prevented from taking part in future therapeutically benefit trials due to their participation in this one, please mention it in the participant information sheet (PIS).
2. The final statement of C4 of app form is incredibly generic and does not apply to proof-of-concept studies of this nature. Please bear this in mind for future submissions.
3. The Committee requested amendment of Section 9.4 of the Data and Tissue Management Plan to make it clear that future use of tissue is subject to additional optional consent.

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

Main PIS/CF:

1. Please state at the top of the PIS that the participant should advise the researcher if an interpreter is required.
2. Please state whether the doses tested in the current study could be higher than the doses tested in previous studies.
3. Ensure that the ‘why are we doing this study’ heading that is at the bottom of page 1 is at the top of page 2 for readability.
4. Please ensure you can direct people to where they can find the Medicines New Zealand guidelines.

Optional PIS/CF:

1. To reduce reading burden for participants, compensation and core use of information sections etc, can be replaced with a statement to please refer to the main PIS/CF provided not too much time will have passed between sighting this form. Note that the return of results section differs and needs to be included in the optional document.

**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:** | **2024 FULL 19516** |
|  | Title: | A Phase 1 Clinical Study to Evaluate the Safety, Tolerability, Pharmacokinetics, and Efficacy of ZN-A-1041 Enteric Capsules as a Single Agent or in Combination in Patients with HER2-Positive Advanced Solid Tumors |
|  | Principal Investigator: | Dr Yeo Jeong (Jane) So |
|  | Sponsor: | PPD, part of Thermo Fisher Scientific and Suzhou Zanrong Pharma Limited |
|  | Clock Start Date: | 29 February 2024 |

Shivani Kumar 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 confirmed that clinicians will be referrers, but the research team will be consenting, not the clinicians.
2. The Committee confirmed with the Researchers that ethnicity data collection will be appropriate to the New Zealand context.
3. The Committee clarified with the Researchers the NZ cohort being only 3-5, with the Researchers responding that this study is an early phase study. The New Zealand cohort numbers is just a projection, not the maximum number of patients in New Zealand.

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 evidence of CI indemnity has expired and an updated one will need to be provided. This can be submitted as confirmation of non-standard conditions completion.
2. The Committee also noted that the Researcher had written in the submission that there may not be potential for stigmatisation of specific ethnicities because of this study. This is at odds to the overseas findings in the study documentation which stated that there were some stigmatisation as a result of findings. Please acknowledge this in the PIS/CF and other relevant documentation and ensure this information is consistent.

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

1. Replace efficacy with effectiveness on page 2 (and note that efficacy does not mean 'what effects ZN-A-1041 has on your body').
2. Stating there is no placebo in this study is redundant and can be deleted (page 3).
3. Review and where possible replace medical and technical terms with the bracketed lay explanation.
4. Simplify schedule of assessments table.
5. Re-write the risk section on page 11 using lay language and bullet points.
6. Include a tick-box option for being provided with a lay summary of study results.
7. There is no need to include life expectancy inclusion/exclusion criteria, they should be screened out beforehand by staff.
8. Be clear that karakia won’t be available at time of tissue destruction.

**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:** | 09 April 2024 |
| **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 12.10pm