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| **Committee:** | Central Health and Disability Ethics Committee |
| **Meeting date:** | 23 April 2024 |
| **Zoom details:** | <https://mohnz.zoom.us/j/9738756003> |

| **Time** | **Review Reference** | **Project Title** | **Coordinating Investigator** | **Lead Reviewers** |
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| 12:00 - 12:30pm |  | **Committee Welcome** |  |  |
| 12:30 - 1:00pm | 2024 FULL 19740 | Testing a new approach for assessing head injuries in the emergency department | Professor Alice Theadom | Cordelia / Patricia |
| 1:00 - 1:30pm | 2024 EXP 19869 | Validating the Diagnostic Accuracy of an Artificial Intelligence Tool Intended to Enhance Dermatology Referrals in New Zealand. | Dr Hamish Wu | Jessie / Albany |
| 1:30 - 2:00pm | 2024 FULL 18600 | PEAARL-FS | Dr. Zachary DeBoard | Sandy / Patries |
| 2:00 - 2:30pm | 2024 FULL 19700 | ABI-2280-401: A study using a vaginal insert to treat persistent human papillomavirus (HPV) infection of the cervix. | Dr Claire Thurlow | Helen / Patricia |
| 2:30 - 3:00pm |  | **BREAK (30 minutes)** |  |  |
| 3:00 - 3:30pm | 2024 FULL 19988 | STC-004-CS-001: A Study to Evaluate the Safety and Tolerability of STC-004 in Healthy Participants | Dr Chris Wynne | Cordelia / Albany |
| 3:30 - 4:00pm | 2024 FULL 19999 | BP45135: A Study to Evaluate Single Ascending and Multiple Ascending Doses of RO7504109 in Healthy Participants. | Dr Millie Wang | Jessie / Patricia |
| 4:00 - 4:30pm | 2024 FULL 19947 | ALN-ANG3-HV-2348: A Study to Evaluate ALN-ANG3-HV-2348 in Healthy Participants | Dr Jane Kerr | Sandy / Albany |
| 4:30 - 5:00pm | 2024 FULL 19663 | GP44942: A Study to Evaluate the Effect of Highly Reduced Kidney Function on the Processing of Fenebrutinib in the Body | Dr. Nick Cross | Helen / Patries |
| 5:00 - 5:30pm | 2024 FULL 19709 | GP44943: A Study to Evaluate the Effect of Various Degrees of Reduced Liver Function on the Processing of Fenebrutinib in the Body | Professor Edward Gane | Helen / Patries |

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

## Welcome

The Chair opened the meeting at 12:00pm and welcomed Committee members, noting that no apologies had been received.

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 26 March 2024 were confirmed.

## New applications

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| **1** | **Ethics ref:** | **2024 FULL 19740** |
|  | Title: | Screening and managing mild traumatic brain injury in the emergency department |
|  | Principal Investigator: | Professor Alice Theadom |
|  | Sponsor: | Auckland University of Technology |
|  | Clock Start Date: | 11 April 2024 |

Professor Alice Theadom was not present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of outstanding ethical issues

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

1. The Committee noted the questionnaires contained mental health questions which could potentially be upsetting and there was no safety plan for if a participant indicated severe distress or suicidal ideation. Please update the protocol to include a safety plan for responding to participant distress and include information in the information sheet explaining the nature of questions that will be asked and what will happen if concerning responses are received (ie appropriate referral and follow-up will be arranged). *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 11.25).*
2. The Committee requested a copy of the HRC reviewer comments.
3. The Committee queried how soon questionnaires would be reviewed following completion and requested this information is included in the protocol. The Committee noted this would need to be timely to ensure any concerning responses can be addressed. The Committee noted permission should not be sought to contact a participant’s GP and if a participant is indicating severe distress the Researchers are obligated to address this (such as arranging a referral).
4. The Committee noted a discrepancy on recruitment numbers. The application stated 980 participants, the PIS mentions 950 participants and then states 425 people who receive the current way of working and 450 people assessed with the new process which equals 875. Please clarify what is intended.
5. The Committee noted the simplified PIS contained an error in the footer (“What sorts of tasks do men find easier than others within Ara Poutama”) and did not contain required information such as the right to access and correct information, the right to withdraw, ACC information and a cultural statement. The Committee requested the form is not used and participants with capacity to consent are provided the main PIS. The Committee noted if this sheet is intended to be used with supported decision-making the Researcher would need to demonstrate how capacity would be assessed.
6. The Committee noted people with a cognitive impairment would be excluded from the research and queried how this would be assessed/determined.
7. The Committee queried why consent would be audio recorded. The Committee noted the Code of Health and Disability Services Consumers' Rights 1996 requires consent to be in writing. The Committee advised that a researcher may record the consent in writing but it will need to be written and an audio file will not suffice.
8. The Committee noted the study involves six separate surveys and queried the time taken to complete all of them. The Committee noted $30 koha seemed low for the time and effort required. The Committee requested the information is updated to indicate a reasonable time to complete six surveys, information about the safety plan for responding to concerning responses is included and the koha is increased to reflect the time required.
9. The Committee noted the response to question C5 in the application form and advised that tapu of the head, whakamā and importance of whānau being part of the process are pertinent issues that were not addressed. The Committee suggested the Researcher consider these.

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

1. Please undertake a general revision to correct any typos.
2. Please revise the sheet to state that participation will have no individual benefit to participants and the study is to assess how they are doing after their injury.
3. Please add in the contact number referenced in the protocol for participants to opt-out of being contacted by a research nurse.
4. Please add page numbers to the PIS.
5. Please include a statement in the participation and withdrawal section advising that data may be used up until the point of withdrawal. Please specify whether data collected up to that point may be deleted or if it will continue to be used if a participant withdraws. Please include a clause on the consent form regarding this.
6. Please revise the statement that participants experiencing difficulties at the time of the call will have a referral to the GP to state participants will be advised to visit their GP. Please consider what support may be offered if a participant does not have a GP.
7. Please include information on the safety plan and what will happen if a participant indicates concerning responses to the questionnaires.
8. Please insert a cultural paragraph that includes an acknowledgement of the tapu of the head.
9. Please remove any ‘yes / no’ tick boxes from the consent clauses unless they are truly optional (ie the participant can answer ‘NO’ and still participate).
10. Please remove the ‘yes / no’ tick box regarding notifying the participant’s GP as this should be mandatory in a study of this nature.

**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 responding to participant distress or concerning responses to mental health questionnaires *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 11.25).*

After receipt of the information requested by the Committee, a final decision on the application will be made by Dr Cordelia Thomas and Mrs Patricia Mitchell.

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| **2** | **Ethics ref:** | **2024 EXP 19869** |
|  | Title: | Validating the Diagnostic Accuracy of an Artificial Intelligence Tool Intended to Enhance Dermatology Referrals in New Zealand |
|  | Principal Investigator: | Dr Hamish Wu |
|  | Sponsor: | Health New Zealand Waikato |
|  | Clock Start Date: | 11 April 2024 |

Professor Amanda Oakley 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 why it would not be practicable for the researcher to gain consent.
2. The Researcher clarified that [Pasifika consultation](https://pacificdatasovereignty.com/) had not yet been undertaken but there were plans to engage with those groups. The Committee suggested involvement with these groups as early as possible as much as possible to help build capacity and to help in data sovereignty concerns.
3. The Committee clarified that the images would not become the Sponsor’s intellectual property.
4. The Committee clarified that the dataset would not be submitted into the Kaggle competition that was suggested by the Researcher’s colleague.
5. The Committee queried whether control images with normal skin and other skin conditions that it is not currently trained on would be used. The Researcher said this might be included.
6. The Committee clarified the first 100 images noted in the protocol were proof of concept not the entire sample size.
7. The Committee clarified that the research has not started.

Summary of outstanding ethical issues

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

1. The Committee queried the context of the screenshot attached to the application and the consent statement therein. The Committee also queried where this was from. The Researcher noted that this was done for the participants not by the participants. The Committee informed the Researcher that this is not sufficient for consent informed or otherwise as the Researcher (nor any adult) may consent on behalf of another adult and the way this is presented is not informed. This is not sufficient for research and does not comply with New Zealand law.
2. The Committee noted that the definition of health information is determined by the Privacy Commissioner and that they should be the authority approached on this matter.
3. The Committee noted that there is no standing consent for the use of the images for research and that this would be the assumption going forward. The Researcher clarified that there are roughly 90,000 images proposed for use in this study. The Committee noted that the images might be deidentified but the NHI number would be attached. The Committee clarified the metadata that would be requested for analysis per the waiver of consent and requested rationale for why all the metadata would be required. The Researcher noted that only certain categories were necessary for the study and the Committee clarified these should be the only points included.
4. The Committee requested that the Researcher only use the 4 data points that are needed for diagnosis.
5. The Committee requested independent peer review. This can be from overseas. Please use the [HDEC template](https://ethics.health.govt.nz/ethicsrm/ethics-rm-manual/) for this.

**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 an independent peer review for the current version of the study protocol. (National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.26).
5. Please supply evidence of Māori and Pasifika consultation to ensure the study is appropriate for a New Zealand context *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 3.7).*

After receipt of the information requested by the Committee, a final decision on the application will be made by Mx Albany Lucas and Ms Jessie Lenagh-Glue

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| **3** | **Ethics ref:** | **2024 FULL 18600** |
|  | Title: | Prophylactic Exclusion of the Left Atrial Appendage for Rheumatic Heart Disease via Epicardial Ligation: Feasibility Study |
|  | Principal Investigator: | Dr. Zachary DeBoard |
|  | Sponsor: | Health New Zealand Waikato |
|  | Clock Start Date: | 11 April 2024 |

Dr Zachary DeBoard was not present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of outstanding ethical issues

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

1. Please include a picture / diagram of the clip in the information sheet.
2. Please remove any ‘yes / no’ tick boxes from the consent clauses unless they are truly optional (ie the participant can answer ‘NO’ and still participate).
3. Please include an optional ‘yes / no’ tickbox to offer participants a summary of study results.
4. Please remove the compensation provisions clause on the consent form as participants will be eligible for ACC.
5. Please revise the statement on page 5 regarding ‘usual doctor’ and the consent form which states ‘GP or current provider’. Please use the same expression and clarify whether usual doctor refers to a cardiologist or GP.

**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).*

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| **4** | **Ethics ref:** | **2024 FULL 19700** |
|  | Title: | A RANDOMIZED, PLACEBO-CONTROLLED STUDY TO EVALUATE CLEARANCE OF HIGH-RISK HUMAN PAPILLOMAVIRUS AND SAFETY AFTER ADMINISTRATION OF ABI-2280 VAGINAL INSERTS |
|  | Principal Investigator: | Dr Claire Thurlow |
|  | Sponsor: | Antiva Biosciences, Inc. |
|  | Clock Start Date: | 11 April 2024 |

Dr Claire Thurlow, Dr Vandana Mathur, Ms Stacy Tsukayama and Ms Kim Huljich 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 exclusion for a positive HIV or STI test. The Researcher stated a positive STI should be treated first and then after participants may enrol. The Researcher stated the HIV exclusion is due to the antiviral nature of the insert and if a participant is on other antiviral medications it may be contraindicated. The Researcher stated they would study HIV positive people in a future study but this population may require different doses or have confounding adverse events so are excluded from this protocol. The Researcher confirmed the site could provide treatment in the event of a positive STI.
2. The Committee queried how the study would manage whakamā around sexual health or a positive STI result. The Researcher stated they have considered this and would address any issues on an individual basis with a discussion between the participant and doctor.
3. The Committee advised that a study cannot be terminated solely for commercial reasons 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 the advertising material stated compensation would be provided for phone visits but this is not discussed in the information sheet. Please add information to the sheet regarding this or if compensation is not available for phone visits please remove it from the advertisements.
2. The Committee noted $82 compensation is low for the time and effort provided and requested this is increased.
3. The Committee noted the response to question E4 in the application stated if abnormal results are found the participant would be encouraged to seek care. The Committee requested if abnormal results are found the research team should arrange an appropriate referral and not leave it to the participant who may feel whakamā about the situation. Please update the information sheet accordingly to state if abnormal results are found referrals will be arranged.
4. The Committee requested the advertising uses the Aotearoa-specific advertising with the representative images.

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

1. Please rewrite any gendered language as there may be participants who identify as male and who have a vagina.
2. Please include a picture of the insert sized against a regular item to give participants an idea of its size.
3. Please revise inconsistencies in the sheet as it currently states testing isn’t required and then describes a positive result.
4. Please identify which STIs will be tested for and state what treatment will be provided if a positive result is detected. Please include a statement advising once treatment is complete participants will be eligible to participate.
5. Please include a statement advising that participants who are HPV positive are still eligible for an HPV vaccine.
6. Please clarify who the ‘regular doctor’ refers to (eg a GP or gynaecologist).
7. Please specify how many participants will be in New Zealand under the study design section.
8. Please specify that the opportunity to practice insertion under the observation of the study doctor is optional (eg “if you choose”).
9. Please specify whether the observing doctor can be someone of the same gender as them and if they can bring a support person with them.
10. Please add “with consent” to the information continuing study visits after withdrawal on page 13.
11. Please remove the ‘yes / no’ tickbox for GP notification in the consent form if this is mandatory. If it is optional please include a statement in the sheet advising this.   
    Please use the non-highlighted cultural statement and remove the highlighted one.
12. Please review the sheet for duplicate information and remove any repetition.
13. Please add any known numbers to the frequency of side effects on page 9 (eg “between 1 – 10 out of 100 people experience..”).
14. Please be specific about what sexual activity participants must refrain from during the study.
15. Please specify the eligibility criteria for the funded HPV vaccine and the costs for those ineligible.
16. Please insert an optional line regarding the VISA card that sites may remove if they do not have this option available for reimbursement.

**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 ensure the Aotearoa-specific advertising material is used.

After receipt of the information requested by the Committee, a final decision on the application will be made by Mrs Helen Walker and Mrs Patricia Michell.

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| **5** | **Ethics ref:** | **2024 FULL 19988** |
|  | Title: | A Phase 1, Randomized, Double-Blind, Placebo-Controlled, Single and Multiple Ascending Dose Study to Evaluate the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of STC-004 |
|  | Principal Investigator: | Dr Chris Wynne |
|  | Sponsor: | SiteOne Therapeutics |
|  | Clock Start Date: | 11 April 2024 |

Dr Chris Wynne, Ms Lucy Druzianic, Ms Kayla Malate, Ms Julia O’Sullivan and Ms Li Luo were present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of outstanding ethical issues

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

1. Please include the definition of alcohol abuse from the protocol and specify whether drug abuse includes prescription drugs.
2. Please correct the typo under restrictions for screening and follow-up visits that states participants must be ‘faster’.

**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).*

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| **6** | **Ethics ref:** | **2024 FULL 19999** |
|  | Title: | A PHASE I, RANDOMIZED, INVESTIGATOR/PARTICIPANT-BLIND, PARALLEL-GROUP, PLACEBO-CONTROLLED, SINGLE AND MULTIPLE ASCENDING DOSE STUDY TO DETERMINE THE SAFETY, TOLERABILITY, PHARMACOKINETICS, AND PHARMACODYNAMICS OF RO7504109 IN HEALTHY PARTICIPANTS. |
|  | Principal Investigator: | Dr Millie Wang |
|  | Sponsor: | Roche Products (New Zealand) Ltd |
|  | Clock Start Date: | 11 April 2024 |

Dr Millie Wang, Dr Rohit Katial, Ms Lucy Druzianic, Ms Kayla Malate, Ms Julia O’Sullivan and Ms Li Luo 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 clarified “Sunrise” in the advertising material is a codename for the study.

Summary of outstanding ethical issues

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

1. The Committee queried whether the limit of 1L per day for cola is appropriate and requested a limit in grams for chocolate.
2. The Committee noted the limit for tobacco was “a maximum of 10 cigarettes per day or the equivalent amount of tobacco” and queried whether this included equivalent nicotine for vaping or tobacco only. The Researcher agreed to clarify with the Sponsor if this extends to vaping nicotine or patches as well.

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

1. Please include the number of pages in the line instructing participants to read and understand all pages in the information sheet and consent form.
2. Please include reference to side effects in the preclinical studies, noting the dosage in animal testing was much higher than in humans.

**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).*

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| **7** | **Ethics ref:** | **2024 FULL 19947** |
|  | Title: | A Phase 1, Randomised. Double-Blind, Placebo-Controlled Study of the Safety, Tolerability, and Pharmacokinetics of ALN-ANG3 in Otherwise Healthy Adult Participants |
|  | Principal Investigator: | Dr Jane Kerr |
|  | Sponsor: | Regeneron Pharmaceuticals, Inc. |
|  | Clock Start Date: | 11 April 2024 |

Dr Jane Kerr, Ms Lucy Druzianic, Ms Kayla Malate, and Ms Julia O’Sullivan were present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of outstanding ethical issues

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

1. Please strengthen the ‘encouraged to refrain from donating eggs’ language on page 12 to be more definitive.
2. Please change ‘may’ to ‘will’ discuss regarding the study doctor learning information about participant health during study procedures on page 17.
3. Please include the number of pages in the line instructing participants to read and understand all pages in the information sheet and consent form.

**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).*

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| **8** | **Ethics ref:** | **2024 FULL 19663** |
|  | Title: | A PHASE I, OPEN-LABEL, SINGLE-DOSE STUDY TO EVALUATE THE EFFECT OF SEVERE RENAL IMPAIRMENT ON THE PHARMACOKINETICS OF FENEBRUTINIB |
|  | Principal Investigator: | Dr Nick Cross |
|  | Sponsor: | Genentech, Inc |
|  | Clock Start Date: | 11 April 2024 |

Dr Nick Cross, Ms Lucy Druzianic, Ms Kayla Malate, and Ms Julia O’Sullivan were present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of outstanding ethical issues

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

1. Please review the sheet to reflect that a single dose is given as some statements imply ongoing participation “(If you are not truthful about the side effects you may harm yourself by staying in the study” on page 9; “because the study drug can cause dizziness avoid stairs when taking the study drug” on page 12). If an ongoing risk of dizziness after the study visit has concluded is expected please clarify this.

**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).*

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| **9** | **Ethics ref:** | **2024 FULL 19709** |
|  | Title: | A PHASE I, OPEN-LABEL, SINGLE-DOSE STUDY TO EVALUATE THE EFFECT OF MILD OR MODERATE HEPATIC IMPAIRMENT ON THE PHARMACOKINETICS OF FENEBRUTINIB |
|  | Principal Investigator: | Professor Edward Gane |
|  | Sponsor: | Genentech, Inc. |
|  | Clock Start Date: | 11 April 2024 |

Dr Nick Cross, Ms Lucy Druzianic, Ms Kayla Malate, Ms Julia O’Sullivan and Mr Isaiah Gepiga were present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of outstanding ethical issues

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

1. Please review the sheet to reflect that a single dose is given as some statements imply ongoing participation “(If you are not truthful about the side effects you may harm yourself by staying in the study” on page 9; “because the study drug can cause dizziness avoid stairs when taking the study drug” on page 12). If an ongoing risk of dizziness after the study visit has concluded is expected please clarify this.

**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).*

## General business

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

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| **Meeting date:** | 28 May 2024 |
| **Zoom details:** | To be determined |

The following members tendered apologies for this meeting.

* Jessie Lenagh-Glue

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 3:30pm.