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| **Committee:** | Central Health and Disability Ethics Committee |
| **Meeting date:** | 22 October 2024 |
| **Zoom details:** | 9650 7589 841 |

| **Time** | **Review Reference** | **Project Title** | **Coordinating Investigator** | **Lead Reviewers** |
| --- | --- | --- | --- | --- |
| 12:00 - 12:30pm | 2024 FULL 21233 | EPI-003-001: A Phase 1 Study to Evaluate EPI-003 in People with Chronic Hepatitis B | Dr Jing Hieng (Jeffery)  Ngu | Helen / Pat |
| 12:30 - 1:00pm | 2024 FULL 21190 | PBGENE-HBV-01: A Study to Evaluate PBGENE-HBV in Adults with Chronic Hepatitis B | Professor Edward Gane | Cordelia / Albany |
| 1:00 - 1:30pm | 2024 FULL 20122 | COG APEC1621F | Dr Karen Tsui | Sandy / Patries |
| 1:30 - 2:00pm | 2024 FULL 21346 | A Study Investigating the Efficacy and Safety of Intravitreal Injections of ANX007 in Participants with Geographical Atrophy. | Dr Anthony Wells | Jessie / Patricia |
| 2:00 - 2:30pm |  | **BREAK (30 mins)** |  |  |
| 2:30 - 3:00pm | 2024 FULL 20841 | The STUNNED Heart study | Dr Jocelyne Benatar | Cordelia / Albany |
| 3:00 - 3:30pm | 2024 FULL 21390 | A Study to Evaluate the Safety and Efficacy of ENV-101 in Patients with Lung Fibrosis | Dr Andrew Veale | Sandy / Patries |
| 3:30 - 4:00pm | 2024 FULL 21331 | BG-68501-101: A Study to Examine the Safety of Different Doses of BG-68501 Given to Participants with Advanced-Stage Tumors | Dr Michelle Wilson | Jessie / Patricia |
| 4:00 - 4:30pm | 2024 FULL 20874 | Agility First in Human Clinical Study | Dr Andrew Holden | 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 11:30am 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 24 September 2024 were confirmed.

## New applications

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| **1**   | **Ethics ref:**   | **2024 FULL 21233** |
|   | Title:  | A Phase 1, Open-Label, 2-Part (Single Ascending Dose and Dose Expansion) Study to Evaluate the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of EPI-003 in Select Nucleos(t)ide Analogue-Treated, Chronic Hepatitis B Patients. |
|   | Principal Investigator:  | Dr Jing Hieng (Jeffery) Ngu |
|   | Sponsor:  | Epigenic Therapeutics Inc. |
|   | Clock Start Date:  | 10 October 2024 |

Dr Jeffery Ngu, Professor Edward Gane, Ms Julia O’Sullivan, Ms Lucy Druzianic, Ms 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 Researcher confirmed the epigenetic intervention would not have implications for the genome of any children.
2. The Researcher confirmed the study may halt if there are safety reasons to do so but would not terminate solely for commercial reasons.
3. The Researcher clarified the difference in blood draw amounts between sites was due to different tube sizes used by the local labs. The Committee agreed to the Researcher’s suggestion to add “up to a maximum”.

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 page 9 of the information sheet states full reimbursement requires completion of all visits. The Committee queried if parking and travel expenses would be reimbursed during the study. The Researcher confirmed pro rata payment for attendance is available if participants withdraw and parking and travel expenses would be paid separate. The Committee requested this is clarified in the information sheet.

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

1. Please update the information on page 10 to state at each visit participants will be asked about any adverse events and this will be a verbal conversation and not a questionnaire.
2. Please include the anticipated likelihood of risks on page 10.
3. Please include more information on genetics and whakapapa in the cultural section.
4. Please add a statement that more information is available on the applicable page to the bullet point when a physical exam is first mentioned.
5. Please move the who can the take part in the study table to earlier in the sheet (eg page 4) so any participants with exclusions will know this sooner.
6. Please revise to use gender-neutral language (eg able to become pregnant) on page 5.
7. Please amend the clause in the consent form so participants opt-in to receive study results with a yes tick box instead of having to opt out if they do not wish to receive them.
8. Please state the study has approval from GTAC.
9. Please include a description of epigenetic therapy and explain what this means in lay language.

**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 Mrs Helen Walker and Mrs Patricia Mitchell.

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| **2**   | **Ethics ref:**   | **2024 FULL 21190** |
|   | Title:  | A Phase 1, Open-Label, First-in-Human, Dose Escalation (Part 1) and Expansion (Part 2) Study to Evaluate the Safety, Tolerability, Pharmacokinetics, and Antiviral Activity of PBGENE-HBV in Participants with Chronic Hepatitis B (ELIMINATE-B) |
|   | Principal Investigator:  | Professor Edward Gane |
|   | Sponsor:  | Precision BioSciences, Inc. |
|   | Clock Start Date:  | 10 October 2024 |

Professor Edward Gane, Dr Murray Abramson, Ms Julia O’Sullivan, Ms Lucy Druzianic, and Ms 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 when the dose for cohorts 4 and 5 would be determined. The Researcher confirmed this would be updated once it was confirmed and before participants were consented onto the sheet. The Researcher confirmed the maximum dose would not be above 1mg/kg.
2. The Researcher confirmed insurance would be renewed for the duration of the study.

Summary of outstanding ethical issues

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

1. The Committee requested section 7.3 is removed from the data management plan if this is not applicable.

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

1. Please move the who can the take part in the study table to earlier in the sheet so any participants with exclusions will know this sooner.
2. Please include more information on genetics and whakapapa in the cultural section.
3. Please state lidocaine *will* be applied on page 8 of the part 2 PIS.
4. Please amend the statement on page 12 “you will be allowed to discontinue” as this infers participants may have to continue otherwise and participants have the right to withdraw at any time.
5. Please amend the consent information at the bottom of page 12 ‘by signing this document..’ to include a statement that participants may withdraw at any time as it currently reads as an indefinite commitment to attend.
6. Please define the acronym LNP.
7. Please include a statement advising the intervention will not have an effect on any future children/whakapapa.
8. Please include gender neutral language (eg change women of childbearing potential to ‘able to become pregnant’).
9. Please amend the information on withdrawing as it states they must contact two people.
10. Please include a brief description of what the long-term follow-up involves when it mentions a separate consent (eg a separate study and participants will be contacted via phone call).
11. Please amend the clause in the consent form so participants opt-in to receive study results with a yes tick box instead of having to opt out if they do not wish to receive them.
Please correct muscle biopsy to liver biopsy on page 8.
12. Please consider including figure 1 from the protocol in the sheet so participants understand their place in the study.

**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 data management plan (*National Ethical Standards for Health and Disability Research and Quality Improvement*, para 12.15a).
* 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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| **3**   | **Ethics ref:**   | **2024 FULL 20122** |
|   | Title:  | COG APEC1621F NCI-COG Paediatric MATCH (Molecular Analysis for Therapy Choice) - Phase 2 Subprotocol of Ensartinib in Patients with Tumours Harbouring ALK or ROS1 Genomic Alterations |
|   | Principal Investigator:  | Dr Karen Tsui |
|   | Sponsor:  | Children’s Oncology Group |
|   | Clock Start Date:  | 10 October 2024 |

Dr Karen Tsui and Ms Paula Murray 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 advised it is not permissible to terminate a trial solely for commercial reasons in New Zealand.

Summary of outstanding ethical issues

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

1. Please submit the missing assent forms in the provisional approval response.
2. Please state how many adults this has been tested in to give reassurance it has been used before.
3. Please state this is not an approved medicine in New Zealand on page 2 under why the study is being done.
4. Please include the study has been approved by SCOTT when HDEC approval is mentioned.
5. Please review to remove any repetition (e.g. “the dose will not be increased but could be decreased..” across pages 1 and 3).
6. Please include a statement that in the unlikely event the drug is not available for the extent of the study other care will be provided.
7. Please state that information and tissue samples will be sent overseas and where.
8. Please include a ‘yes / no’ option on the consent form for participants to request a summary of study results.
9. Please include a clause for samples and information to be sent overseas in the initial consent form for the main study and the reconsent form.
10. Please review the sheet for gendered language (eg ‘father a child’ ‘female and pregnant’).
11. Please amend the statement if participants withdraw this will be without penalty or loss of benefits to state it will not affect the care they receive.
12. Please specify the age of reconsent is 16.

**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 supply the assent forms in the provisional approval response.
3. 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 Sandy Gill and Dr Patries Herst.

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| **4**  | **Ethics ref:**   | **2024 FULL 21346** |
|   | Title:  | A Phase 3, Multicenter, Randomized, Parallel-Group, Double-Masked, 2 Arm, Sham Controlled Study of the Efficacy, Safety, and Tolerability of ANX007 Administered by Intravitreal Injection in Patients with Geographic Atrophy (GA) Secondary to Age-Related Macular Degeneration (AMD) |
|   | Principal Investigator:  | Dr Anthony Wells |
|   | Sponsor:  | Annexon Inc. |
|   | Clock Start Date:  | 10 October 2024 |

Ms Joanna van Zyl, Dr Wendy Murahashi, Ms SzXian Lee, Ms Youngmi Park, Ms Megan Wright, Ms Anna Lisa McLafferty 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 advised a clinical trial may not be terminated solely for commercial reasons in New Zealand. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 11.37).*

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 advised the insurance document will require updating for the duration of the trial. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 17.1).*
2. The Committee requested identifiers are not attached to samples that go overseas. A study code is required. Please update the data and tissue management plan. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 14.16; 14.19).*
3. The Committee queried how soon quality of life questionnaires would be reviewed after completion. The Researcher stated they would confirm with sites. The Committee noted if someone indicates distress on one of these the study is responsible for managing this and making referrals or offering support if required. The Committee requested this safety plan is detailed in the protocol.
4. The Committee queried if koha or reimbursement is available. The Researcher stated this was being negotiated. The Committee noted participation incurs an expense of time and associated costs with travel or parking and encouraged the Researcher to offer appropriate reimbursement and to be mindful of tax obligations.

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

1. The Committee suggested increasing the font size and line spacing to 1.5.
2. Please remove mention of Scout if this is not available in New Zealand.
3. Please include a line at the beginning of the sheet advising that if participants struggle to read it someone may read the sheet verbally.
4. Please state this is an experimental drug and how many people it has been tested in before.
5. Please amend the statement if participants withdraw this will be without penalty or loss of benefits to state it will not affect the care they receive.
6. Please adapt the cultural statement from the HDEC template. Please include an acknowledgement of the tapu of the head.
7. Please define the ANA acronym the first time it is used.
8. Please correct the typo on page 14 (‘your or your partner’).
9. Please remove the reference to flipping a coin when describing randomisation.
10. Please state control group instead of ‘sham’ and state they will not know whether they will receive the control or active substance.
11. Please state whether the control group has risk for damage to the eye.
12. Please state data will be kept for 15 years.
13. Please update reimbursement and koha and state the amount available.
14. Please include reasons why the study may be terminated on page 2.
15. Please state what the physical exam involves and whether participants may have a support person present and whether the exam may be gender matched (i.e. the person performing the exam is the same gender as the participant).
16. Please include a contact number for Māori cultural support.
17. Please state either corneal scrape or corneal abrasion for consistency.
18. Please remove the line regarding notifying the medical officer of health if no notifiable diseases will be tested for.
19. Please remove the reference to the legal guardian.
20. Please specify what tissue samples will be sent overseas.
21. Please review the imaging section to remove repetition.
22. Please remove reference to the ethics committee ensuring rights and wellbeing are safeguarded and state the ethical aspects of the study has been approved by Central HDEC.
23. Please simplify the information on antibodies and remove the more detailed technical information (e.g. about bacteria, fungi, chemical).
24. Please state 5 in 100 people instead of 5% for people who may not understand percentages.
25. Please specify vision loss when discussing risk (eg partial or complete, temporary or permanent).

**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 update the data and tissue management plan. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 14.16).*

After receipt of the information requested by the Committee, a final decision on the application will be made by Ms Jessie Lenagh-Glue and Mrs Patricia Mitchell.

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| **5**   | **Ethics ref:**   | **2024 FULL 20841** |
|   | Title:  | Randomized study evaluating effects of rationalizing medication in those who have stunning of if the heart due to a heart attack |
|   | Principal Investigator:  | Dr Jocelyn Benatar |
|   | Sponsor:  | Auckland City Hospital |
|   | Clock Start Date:  | 10 October 2024 |

Dr Jocelyne Benatar 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 discussed safety concerns involved with withholding medication and was reassured by the Researcher this would not increase the risk to participants.
2. The Committee advised relevant cultural issues for the study include that information is a taonga, the importance of whānau and the potential for whakamā.

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 advised coded data from this study may be used in future studies but this would require a separate consent. The Committee requested this option is included in the consent form along with information about it (e.g. whether it may be sent overseas). *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.24).*
2. The Committee requested the application form is completed with more detail in the resubmission and the answers are accurate (e.g. the screening section states tissue is used and then later the form states it is not).
3. The Committee requested the data management plan is updated with more detail on how data is deidentified and stored (e.g. in Redcap not a databank). *(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) *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17)*:

1. Please review the HDEC information sheet template and ensure all applicable prompts are included.
2. Please undertake a revision to check for typos and grammar errors.
3. Please amend the statement about it not affecting current or future care to state participants who do not participate will receive standard care.
4. Please state what happens at each echocardiogram (e.g. if something concerning is found at 6 months what will happen)
5. Please insert the cultural statement from the HDEC template.
6. Please specify it is the right to access and request correction of information per the template.
7. Please add more information about what happens to data collected during the study if a participant withdraws (e.g. whether they can withdraw their data or if data collected up to that point will continue to be used).
8. Please state parking and travel expenses will be reimbursed for additional study visits (up to a maximum amount).
9. Please include contact information for study doctors.
10. Please amend the statement about an interview to describe what it involves.
11. Please remove the clause in the consent form that the treatment will be stopped if it appears harmful if this is the standard of care.

**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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| **6**   | **Ethics ref:**   | **2024 FULL 21390** |
|   | Title:  | A Phase 2, Multi-Center, Randomized, Double-Blind, Controlled Trial Evaluating the Safety and Efficacy of ENV-101 in Patients with Lung Fibrosis |
|   | Principal Investigator:  | Dr Andrew Veale |
|   | Sponsor:  | Endeavor Biomedicines |
|   | Clock Start Date:  | 10 October 2024 |

No researcher was present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of outstanding ethical issues

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

1. The Committee noted the dosing diary was clear about two bottles but the information sheet was not. Please add a paragraph in the sheet as it is unusual to have two bottles and take a pill from each.
2. The Committee requested section 7.3 of the data management plan is deleted if data will not be anonymised. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15a)*
3. The Committee requested the Researcher update the protocol to include a safety plan to manage any participant distress. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.7).*

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

1. The Committee noted page 8 of the information sheet states “It is possible that treatment with ENV-101 may permanently damage your ovaries for women or testes in men”. Please clarify if there is an opportunity for participants to bank eggs/sperm and include this information in the sheet. If this will not be available please make this clear.
2. Please undertake a general revision for typos (e.g. ‘woh’ instead of ‘who’)
3. Please ensure macrons are used correctly.
4. Please clarify the reimbursement (e.g. maximum amount that may be claimed).
5. Please state how many participants from New Zealand will be recruited.
6. Please state whether a karakia is available at the time of tissue collection or destruction.
7. Please include information about requesting a lay summary of results to the text of the sheet to align with the option on the consent form.
8. Please include more information about the quality of life questionnaire, what it will ask, who will look at it and when and what will happen if a participant indicates distress.
9. Please make the sheet gender neutral (e.g. removing ‘for female participants’ after mentioning pregnancy or ‘if you are male’ and able to father a child).
10. Please specify the sponsor will follow information about the pregnancy and baby with consent.
11. Please be consistent between ‘must not’ and ‘should not’. If something is not truly optional then replace it with ‘must’.
Please include a clause on the consent form for participants to agree to their data being used for future research.

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

After receipt of the information requested by the Committee, a final decision on the application will be made by Ms Sandy Gill and Dr Patries Herst.

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| **7**   | **Ethics ref:**   | **2024 FULL 21331** |
|   | Title:  | BG-68501-101: A Phase 1a/1b Study of BG-68501, a Selective CDK2 Inhibitor, in Participants With Advanced Solid Tumors |
|   | Principal Investigator:  | Dr Michelle Wilson |
|   | Sponsor:  | BeiGene NZ Unlimited |
|   | Clock Start Date:  | 10 October 2024 |

Dr Michelle Wilson and Ms Ruta Padalkar 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 advised it is not permitted to terminate a clinical trial solely for commercial reasons in New Zealand.
2. The Researcher confirmed insurance would be renewed for the duration of the trial.

Summary of outstanding ethical issues

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

1. The Committee queried if participants with undetectable or controlled HIV would be excluded. The Researcher agreed to clarify with the Sponsor. The Committee noted these participants should not be excluded unless there is a reasonable justification (e.g. safety).
2. The Committee queried why koha for time would not be offered. The Researcher stated koha above travel and parking costs could be potentially coercive or inducive. Other ways to be supported have been looked at such as food provided for participants and their whānau and support for family members travelling. The Committee requested this information is included in the information sheet and encouraged the Researcher to explore whether a koha for time is possible, being mindful of the tax implications of this.
3. The Committee queried why study data would be kept for 25 years as usually it is between 10-15. The Researcher agreed to clarify with the sponsor.
4. The Committee queried if data would be anonymised. If not then please remove section 7.3 in the data management plan.
5. The Committee queried if the study involved mandatory whole genome sequencing and if so then why. If this is intended please make this clear in the information sheet. The Researcher agreed to clarify with the Sponsor.

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

1. Please add the likelihood of risks and side effects (e.g. 10 in 100 people will experience..)
2. Please clarify that the study may be terminated due to safety issues.
3. Please rewrite the sentence +/- 7 days on page 14 to be plain language.
4. Please give comparisons between volume sizes.
5. Please simplify the dosing information or develop a supporting material (eg calendar).
6. Please state whether clothing would be removed for the physical exam. Please state whether a support person may be present and if the participant has the choice of the exam being gender matched (i.e. the person performing the exam is the same gender is the participant).
7. Please amend the statement if participants do not participate this will be without penalty or loss of benefits to state it will not affect the care they receive.
8. Please simplify the descriptions of body-to-drug interactions and drug-to-body interactions on pages 17, 27 and the future unspecified research form.
9. Please make the language gender neutral (e.g. remove ‘for female participants’ when discussing pregnancy).
10. Please review section 14 as it states there are no plans to provide the study drug after the study finishes but the next paragraph discusses continuing access.
11. Please clarify who ‘usual doctor’ is when this is mentioned (e.g. GP or usual oncologist).
12. Please state whether reimbursement for costs associated with the optional biopsy is available.
13. Please combine paragraphs 6 and 7 on page 3 as these are very similar.
14. Please remove the sentence after withdrawal about a member of the research team accessing medical records. If a participant withdraws then the expectation is they have withdrawn.
15. Please specify that information sent overseas will be coded and the linking key kept separate in New Zealand.
16. Please include a ‘yes / no’ tick box for participants to request a summary of study results.

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

After receipt of the information requested by the Committee, a final decision on the application will be made by Ms Jessie Lenagh-Glue and Mrs Patricia Mitchell.

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| **8**  | **Ethics ref:**   | **2024 FULL 20874** |
|   | Title:  | A Prospective, Multi-Center, Non-Randomized, Single-Arm Study of the BD Low ProfIle Vascular Covered Stent in PerIpheral Artery Disease |
|   | Principal Investigator:  | Dr Anrew Holden |
|   | Sponsor:  | BD |
|   | Clock Start Date:  | 10 October 2024 |

Dr Andrew Holden, Dr Andrew Hill, Ms Helen Knight and Ms Cindy Corne 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 advised whakamā is a cultural issue that was not addressed in the application.

Summary of outstanding ethical issues

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

1. The Committee queried if participants would be expected to take steps to avoid pregnancy as the sheet refers to unforeseen risks but the sheet does not instruct the use of contraception. The Researcher stated this was raised with the Sponsor and the information was removed from the sheet. While being pregnant at the beginning of the study is an exclusion there is no ongoing guidance against being pregnant during the study. The Committee queried if the study involved risk to a pregnant participant. The Researcher stated the only risk would be radiation exposure and while it would be extremely unlikely anyone of childbearing potential would be recruited this would be checked. The Committee requested this is made clear in the information sheet.

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

1. Please move the statement on page 3 that this device is investigational and not approved to page 2.
2. Please state that devices are approved by Medsafe after FDA approval and while similar stents are approved this one has not yet been.
3. Please use gender neutral language (e.g. change woman of childbearing potential to if you are able to become pregnant).
4. Please describe the post-operative physical exam includes examination of the groin and state whether this requires undressing. Please state whether this examination may be gender matched (ie the person performing the exam is the same gender as the participant).
5. Please review the sentence ‘unexpected blood result or new diagnosis of previously known condition’ on page 11 and correct to unknown if this is what is meant.
6. Please include more information about the questionnaires (eg these will ask about problems with walking) and what will happen if concerning or distressing responses are received (eg an appropriate referral will be made).

**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:

|  |  |
| --- | --- |
| **Meeting date:** | 26 November 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 4:30pm.