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| **Committee:** | Central Health and Disability Ethics Committee |
| **Meeting date:** | 28th March 2023 |
| **Zoom details:** | 965 0758 9841 |

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| **Time** | **Review Reference** | **Project Title** | **Coordinating Investigator** | **Lead Reviewers** |
| 12:00-12:30pm | 2023 FULL 13887 | PALEO: A trial of palliative chemotherapy, radiation and immune treatment for oesophageal cancer | Dr Angela Mweempwa | Ms Kate O’Connor & Mx Albany Lucas |
| 12:30-1:00pm | 2023 EXP 13764 | A pilot study using Advantan® fatty ointment applied to the skin. | Dr Noelyn Hung | Dr Cordelia Thomas & Mr Barry Taylor |
| 1:00-1:30pm | 2023 FULL 13765 | Comparison of methylprednisolone fatty ointment applied to the skin | Dr Noelyn Hung | Ms Sandy Gill & Dr Patries Herst |
| 1.30-2.00pm |  | Break 30 mins |  |  |
| 2.00-2.30pm | 2023 EXP 15412 | The pharmacokinetics and dose response to ingestion of liposomal encapsulated creatine monohydrate | Assoc Prof David Rowlands | Mr Jonathan Darby & Ms Patricia Mitchell |
| 2:30-3:00pm | 2023 FULL 15239 | CEC-4/CEL: A study evaluating the efficacy and tolerability of ZED1227 in celiac disease subjects experiencing symptoms despite gluten-free diet" | Dr Penelope Jane Montgomery | Dr Cordelia Thomas & Mx Albany Lucas |
| 3.00-3.30pm | 2023 FULL 15469 | iSOoTH-study: Kids Sore Throat Study | Assoc Prof Nikki Moreland | Ms Kate O’Connor & Mr Barry Taylor |
| 3.30-4.00pm | 2023 FULL 15452 | ZB004-01-001: A Study to Evaluate ZB004 in Healthy Participants | Dr Cory Sellwood | Ms Kate O’Connor & Mx Albany Lucas |
| 4.00-4.30pm | 2023 FULL 15184 | BP43628: A Study Comparing How Fast RO7223280 is Processed and Cleared from the Body, in Adults with Varying Levels of Kidney Function | Dr Nick Cross | Ms Sandy Gill & Ms Patricia Mitchell |
| 4.30-5.00pm | 2023 FULL 15435 | C5261001: A Combined Modified RNA Flu and COVID-19 Vaccine Study in Adults 18 Years Age or Older | Dr Claire Thurlow | Mr Jonathan Darby & Mr Barry Taylor |
| 5.00-5.30pm |  | Break 30 mins |  |  |
| 5.30-6.00pm | 2023 FULL 13694 | South Asian Microbiota in Crohn's disease (SAM-C Study) | Dr Johnathan Bishop | Dr Cordelia Thomas & Dr Patries Herst |
| 6.00-6.30pm | 2023 FULL 15293 | Phase 3 study of darolutamide plus ADT compared with ADT in high-risk BCR | Mr Kevin Bax | Mr Jonathan Darby & Mx Albany Lucas |
| 6.30-7.00pm | 2023 FULL 15285 | A Phase 3, Randomized, Double-blind, Placebo-controlled, Event-driven Study to Demonstrate the Efficacy and Safety of Milvexian, an Oral Factor XIa Inhibitor, After a Recent Acute Coronary Syndrome | Dr Jocelyne Benatar | Ms Sandy Gill & Ms Patricia Mitchell |

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| **Member Name** | **Member Category** | **Appointed** | **Term Expires** | **Apologies?** |
| Mrs Helen Walker | Lay (Consumer/Community perspectives) (Chair) | 22/05/2018 | 22/05/2020 | Apology |
| 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) | 22/03/2020 | 22/03/2024 | Present |
| Ms Patricia Mitchell | Non-lay (Health/Disability service provision) | 08/07/2022 | 08/07/2025 | Present |
| Ms Julie Jones | Non-lay (Intervention studies) | 22/05/2020 | 22/05/2022 | Apology |
| 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 | Apology |
| Mr Jonathan Darby | Lay (the Law/Ethical and Moral reasoning) | 13/08/2021 | 13/08/2024 | Present |
| Mr Barry Taylor | Non-Lay (Intervention/Observational Studies) | 13/08/2021 | 16/08/2024 | Present |
| Ms Kate O’Connor | Lay (Ethical/Moral reasoning) (Chair) | 13/08/2021 | 16/08/2024 | Present |

## Welcome

The Chair opened the meeting at 11:30am and welcomed Committee members, noting that no apologies had been received from Mrs Helen Walker, Ms Jessie Lenagh-Glue and Ms Julie Jones.  
  
The Chair noted that it would be necessary to co-opt members of other HDECs in accordance with the Standard Operating Procedures. Ms Kate O’Connor, Mr Barry Taylor and Mr Jonathan Darby confirmed their eligibility and were co-opted by the Chair as members 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 28th February 2023 were confirmed.

## New applications

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| **1** | **Ethics ref:** | **2023 FULL 13887** |
|  | Title: | Phase II clinical trial of chemoradioimmunotherapy for the alleviation of oesophageal cancer complications |
|  | Principal Investigator: | Dr Angela Mweempwa |
|  | Sponsor: | Australasian Gastro-Intestinal Trials Group |
|  | Clock Start Date: | 16th March 2023 |

Dr Angela Mweepwa and Sophie Goodger were present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of resolved ethical issues

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

1. The Committee clarified that the study drug is registered but not funded in New Zealand. The drug would be a large cost burden for participants if they were paying for it.
2. The Committee clarified how the recruitment would occur and how pressure to participate would be reduced. The Researcher confirmed that a research nurse would be available for questions and there would be adequate time for consultation with friends, whānau and the potential participants’ general practitioner (GP) before the consenting would occur.
3. The Committee requested clarification as to whether the chemotherapy is Standard of Care (SoC). The Researcher noted that in this case the cancer would be inoperable and that there would be joint immunotherapy and radiotherapy which would be used to extend survival.

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 there be a safety plan for participants responding to the questionnaires regarding distress. It needs to be clear that this will be captured in some way and that there will be follow up for this with clinic staff.
2. The Committee queried how the SoC and research aspects of the application were separate and where the line between these two concepts lay.
3. The Committee requested that any travel for extra visits (outside of SoC) be reimbursed.

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

1. Please review the information pertaining to the combination of immunotherapy and radiotherapy. Specifically, the treatment that would be done regarding the metastatic tumours and stereotactic body radiation therapy.
2. Please clarify what is normal treatment- this could be done as an appendix.
3. Please include a “What will happen to my samples” section. Where the samples will be going, how they will be analysed and if karakia will be offered.
4. Please rephrase "your doctor believes this could be a suitable treatment option for you" as the doctor is also the study oncologist and should be clarified as such.
5. Please be clear and consistent with phrasing around “your doctor”. Specify if this is the study doctor or GP.
6. Please refer to the [HDEC PIS template](https://ethics.health.govt.nz/assets/Uploads/HDEC/templates/participant-information-sheet-consent-form-template-v4.0december2022.doc) for contraception and childbearing clauses as these are not gender neutral.
7. Please amend the repeated phrase "until your cancer worsens".
8. Please amend the mention of “Māori health support”. This should read “Māori cultural support”.
9. Please include the latest ACC statement as per the [HDEC PIS template](https://ethics.health.govt.nz/assets/Uploads/HDEC/templates/participant-information-sheet-consent-form-template-v4.0december2022.doc).
10. Please include that there will be potential skin damage around the throat/neck area due to radiation.

**Decision**

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

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

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

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| **2** | **Ethics ref:** | **2023 EXP 13764** |
|  | Title: | A pilot dose duration-response study using Advantan® fatty ointment (Leo Pharma Pty Ltd, Australia) to determine the appropriate dose duration (ED50) for use in a pivotal in vivo bioequivalence study and using 12 participants who demonstrate adequate vasoconstriction to topical steroids. |
|  | Principal Investigator: | Dr Noelyn Hung |
|  | Sponsor: | Nova Chem Australasia Pty Ltd |
|  | Clock Start Date: | 16th March 2023 |

Dr Noelyn Hung and Linda Folland 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 main ethical issues considered by the Committee and which require addressing by the Researcher are as follows.

1. The Committee requested flow charts showing the pathways for participants on the time required for screening and recruitment as there would be non-responders. Please include this in the information sheets.
2. The Committee noted that the insurance for QBE was expired, please provide the renewed insurance for review.
3. The Committee requested that the advertising be amended to provide more information.

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

1. Please amend the statement "if" you are accepted into the study rather than "once".
2. Please clarify what the “ventral forearm” is for the purpose of shaving. Please use a picture to demonstrate this. If people could be excluded, should they need to shave their arms, please explain this.
3. Please remove reference to HCG (human chorionic gonadotropin) as the explanation of pregnancy is sufficient without this.
4. Please rephrase the statement “if you leave you will be removed from the study” so it does not imply that withdrawal has been done by the participant if this occurs.
5. Please remove mention of the NuvaRing as this is not available in New Zealand or replace this with “contraceptive ring”.
6. Please clarify the meaning of “usual doctor”.
7. Please include that Covid-19 is a notifiable disease.
8. Please include the cultural statement as per the latest [HDEC template](https://ethics.health.govt.nz/assets/Uploads/HDEC/templates/participant-information-sheet-consent-form-template-v4.0december2022.doc).
9. Please amend the mention of “Māori health support”. This should read “Māori cultural support”.
10. Please amend the statement on the potential reproductive risks to state "There is no adequate data from the use of ADVANTAN® in pregnant women".

**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 Dr Cordelia Thomas and Mr Barry Taylor.

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| **3** | **Ethics ref:** | **2023 FULL 13765** |
|  | Title: | A pivotal in vivo bioequivalence study comparing methylprednisolone aceponate fatty ointment (Nova Chem, Australia) to Advantan® fatty ointment (Leo Pharma Pty Ltd, Australia), using the ED50 for Advantan® fatty ointment calculated from the pilot dose durationresponse study and using 90 responders with the expectation to have 40-60 subjects who meet the responder and detector criteria (“evaluable”). |
|  | Principal Investigator: | Dr Noelyn Hung |
|  | Sponsor: | Nova Chem Australasia Pty Ltd |
|  | Clock Start Date: | 16th March 2023 |

Dr Noelyn Hung and Linda Folland 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 main ethical issues considered by the Committee and which require addressing by the Researcher are as follows.

1. The Committee requested that the advertising be amended to provide more information pertaining to the study. In particular, the inclusion of information that this was a skin ointment study that would involve a patient stay.
2. The Committee noted that Dr Hung had been identified as the Sponsor, this needs to be amended.
3. The Committee noted that the insurance for QBE was expired, please provide the renewed insurance for review.
4. The Committee requested flow charts showing the pathways for participants on the time required for screening and recruitment, particularly in the case of non-responders. Please include this in the information sheets.
5. The Committee requested clarification around the initial visits, particularly when mentioning the consent visit.

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

1. Please remove the sentence stating that participants cannot leave the study site.
2. Please clarify what the “ventral forearm” is for the purpose of shaving. Please use a picture to demonstrate this. If people could be excluded, should they need to shave their arms, please explain this.
3. Please remove reference to HCG (human chorionic gonadotropin) as the explanation of pregnancy is sufficient without this.
4. Please include the cultural statement as per the latest [HDEC template](https://ethics.health.govt.nz/assets/Uploads/HDEC/templates/participant-information-sheet-consent-form-template-v4.0december2022.doc).
5. Please amend the mention of “Māori health support”. This should read “Māori cultural support”.

**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 evidence of ACC-equivalent compensation available to all participants in the event of injury during the study. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 17.1).*
5. Please update the advertisements, taking into account the feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 11.12).*

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:** | **2023 EXP 15412** |
|  | Title: | The pharmacokinetics and dose response to ingestion of liposomal encapsulated creatine monohydrate (The LipoCre Study) |
|  | Principal Investigator: | Associate Professor David Rowlands |
|  | Sponsor: | Pharmako Biotechnologies |
|  | Clock Start Date: | 16th March 2023 |

Associate Professor David Rowlands 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 queried the exclusion of women from the study as there appeared to not be adequate reasoning for this. Please amend this in your protocol and participant information sheet to not exclude this group. The Committee requires more robust reasoning, both ethical and scientific, to exclude women. A second study only in women would also be accepted.
2. The Committee queried what would happen should there be more than 3 dropouts.
3. The Committee requested that the insurance certificate list the protocol and New Zealand as a territory for the policy.
4. The Committee requested that the advertisement and all other participant facing information be reviewed for spelling and grammar issues.
5. The Committee noted that the “databank” mentioned was in fact just the database for the study.
6. The Committee requested that the advert be amended to change "adult" to "men", and state participation involves blood and urine sampling.
7. The Committee noted the answer to C4 in the application form was patronising and requested the Researcher be mindful of this for any future applications. The Committee explained that the Treaty of Waitangi should not be cited as a health benefit and equal access to participate for Māori should not need to be stated as this is the default expectation. The Committee recommended including any statistics of the prevalence of the disease in Māori (or an explanation if unknown) when answering C4 for any future applications.

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

1. Please review all documents for lay language as well as spelling and grammar.
2. Please describe urination in a way other than “voiding”.
3. Please amend wording around withdrawal. “Practicable” should be replaced with “at any time”.
4. Please include a statement on whether karakia is available.
5. Please consider utilising a table to chronologically order and lay out clearly the study procedures.
6. Please clearly explain the timing around visits 2-6.
7. Please remove mention of a “databank” as this is not accurate.
8. Please specify how the lean mass and fat will be measured.
9. The Committee requested the inclusion of the HDEC cultural tissue statement to the PIS as per the [HDEC Template.](https://ethics.health.govt.nz/assets/Uploads/HDEC/templates/participant-information-sheet-consent-form-template-v4.0december2022.doc)
10. Please explain what “blinding” is.
11. Please explain if urine should be collected overnight and not only in the morning.
12. Please indicate who the “trained person” will be the first time this is mentioned.
13. Please amend the statement on storage of data and samples as “up-to ten years” is too vague. Please clearly outline what would happen should withdrawal occur.
14. Please explain what is meant by how people will learn about studies at Massey or AUT as mentioned. Or remove as necessary.
15. Please note that “property” may not be the correct term when used in context with the samples that are collected, however this cannot entirely be returned to them. This needs to be specified.
16. Please amend the approving HDEC to be from “Northern” to “Central”.
17. Please remove “normal” from “normal healthy males”.

**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 advertisements, taking into account the feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 11.12).*

After receipt of the information requested by the Committee, a final decision on the application will be made by Mr Jonathan Darby and Ms Patricia Mitchell.

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| **5** | **Ethics ref:** | **2023 FULL 15239** |
|  | Title: | CEC-4/CEL: A phase IIb, double-blind, randomised, placebo-controlled trial to evaluate the efficacy and tolerability of ZED1227 in celiac disease subjects experiencing symptoms despite gluten-free diet |
|  | Principal Investigator: | Dr Penelope Montgomery |
|  | Sponsor: | Novotech New Zealand |
|  | Clock Start Date: | 16th March 2023 |

Dr Penelope Montgomery, Kshemina Mhaskar and Krsytal Zvarec were present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of resolved ethical issues

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

1. The Committee clarified that the placebo-only run-in was due to the requirement for refractive symptoms for treatment.
2. The Committee clarified that there was going to be a blood test at screening to determine if the potential participants had managed to maintain a gluten-free diet.

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 mention of a legally appointed representative be removed from the e-consent protocol.
2. The Committee requested that there be someone not directly related to the study make the initial approach to avoid undue persuasion.
3. The Committee noted that the access of potential participants records should be avoided and forwarding by the person’s general practitioners (GP) etc., to avoid this access without consent. Consent may also be sought to access their records.
4. The Committee noted that there are risks unidentified in the participant information sheet (PIS) related to the questionnaires. Please provide a safety plan in the PIS to this effect as well as a timeline for review and response for the questionnaires and how concerns that arise will be managed.

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

1. Please more clearly explain the arms of the study and the use of placebo. A diagram, flowchart or table to this effect would be of use to define each arm for participants.
2. Please remove the statement “Your physician knows when to use placebo”.
3. Please amend all mention of the study “treatment”.
4. Please remove the inclusion criteria of eating in restaurants and replace with “maintaining your normal diet”.
5. Please specify that there will be a blood test at screening to ascertain if the participants are maintaining a gluten-free diet and that the results will be communicated back to them.
6. Please include a lay title for the study.
7. Please review for font consistency, grammar and spelling.
8. Please be clear about which doctors are being referred to and amend to be consistent.
9. Please refer to page 6 instead of mentioning “various procedures”.
10. Please note that the withdrawal visit statement should include “with consent”.
11. Please note that the statement “no additional costs” should read as “no cost”.
12. Please specify how much the reimbursement will be and what may be reimbursed.
13. Please specify boundaries for abuse with drugs and alcohol as this is quite variable. “This could be discussed with a study doctor”, could be included.
14. Please amend the statement around contacting the GP as this should be mandatory and if it is not mandatory as listed in the PIS this should be amended to be consistent.
15. Please specify what would be required of the physical exam and whether this may require undress.
16. Please remove or amend the statement "may or may not continue" to be in the study if the participant tests positive for COVID.
17. Please include contraception in the section “what do I have to do”.
18. Please specify that the additional duodenal biopsies and blood samples will be taken at both visits "for future celiac disease related exploratory analyses” is mandatory and not future unspecified 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 provide more detail in study documentation to ensure participant safety if there are potential concerns with their well-being raised as part of this study *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 8.4-8.6, 8.9)*

After receipt of the information requested by the Committee, a final decision on the application will be made by Dr Cordelia Thomas and Mx Albany Lucas.

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| **6** | **Ethics ref:** | **2023 FULL 15469** |
|  | Title: | Rapua te mea ngaro ka tau: Facilitating Strep A vaccine development for Aotearoa New Zealand (iSOoTH-study: Kids Sore Throat Study) |
|  | Principal Investigator: | Associate Prof Nikki Moreland |
|  | Sponsor: | The University of Auckland |
|  | Clock Start Date: | 16th March 2023 |

Dr Julie Bennett, Associate Professor Nikki Moreland, Abby March, Angela Chong, and other members of the research team were present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of resolved ethical issues

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

1. The Committee clarified that the study nurses would be handling the transport and collection of samples.
2. The Committee clarified that there were no specific targeting of Māori or Pasifika people in this study. The Researcher noted that there was no increased rate amongst those groups of Strep A infection. The Committee clarified that the group were not oversampling for Māori by searching in the efficacy trials in lower-risk cases.
3. The Committee clarified that there would be no ethnicity-based analyses.
4. The Committee noted that in the application there was mention specifically of strep throat being a prevalent disease in Māori. The Researcher responded that the application was referring to the larger initiative and was at odds to the wish to avoid stigmatization by the research team.
5. The Committee clarified that there would only be an expected 25% convalescence.
6. The Committee clarified that no data would be going overseas.

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 PI cannot sign as the Sponsor and that the academic head of the university will need to sign it as the Sponsor.
2. The Committee requested provision of any posters, direct text scripts or advertisement material to be used for recruitment.
3. The Committee requested how the details of potential participants to directly text. The provision of this private information to any body should not occur as they have not given consent to the groups to have access to these numbers. The practice could request permission through a message but cannot consent on the behalf of potential participants.
4. The Committee requested that a researcher safety plan be provided for review.
5. The Committee noted that the assent forms should be provided based on competency rather than on age.
6. The Committee requested provision of the survey for review.
7. The Committee requested provision of the questions that will be used to collect the baseline demographics.
8. The Committee noted that if there was to be future unspecified research that this would need to be separately consented.
9. The Committee noted that reimbursement for “time” would make the koha taxable. Rephrase this.
10. 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. The Committee stated more information around data management is required than what is available in the study documentation satisfy the Committee that privacy and confidentiality is protected and that Standard 12.15a is met. Use of the HDEC template from the [HDEC website](https://ethics.health.govt.nz/guides-templates-and-forms/) is not mandatory but is encouraged to be adapted or used as a guide/starting point.
    2. The Committee requested the University of Auckland governance structure be listed.

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

Main PIS/CF:

1. Please clarify if the participant is the child or the parents. Please clarify with a statement such as “where referring to the participant, “you” refers to “you and your child””.
2. If the child is the participant, please consider the koha to be connected to the child participants as this may create pressure where the koha may be inducing to parents.
3. Please remove reference to samples being sent overseas.
4. Please clarify the research that may be done with specimens and remove mention of future unspecified research as this is misleading.

Older Children PIS/CF:

1. Please include more information and acknowledge that these children can understand more.
2. Please include more information about storage and use of participants samples and information.

**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 provide a researcher safety plan addressing the concerns raised by the Committee *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 11.62).*

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

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| **7** | **Ethics ref:** | **2023 FULL 15452** |
|  | Title: | A SINGLE ASCENDING DOSE (SAD) STUDY TO EVALUATE THE SAFETY AND PHARMACOKINETICS (PK) OF ZB004 IN HEALTHY VOLUNTEERS |
|  | Principal Investigator: | Dr Cory Sellwood |
|  | Sponsor: | Zenas BioPharma (USA), LLC |
|  | Clock Start Date: | 16th March 2023 |

Courtney Rowse, Julia O’Sullivan and Dr Corey Sellwood were present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of resolved ethical issues

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

1. The Committee clarified that tuberculosis was excluded due to possibility for reinfection.
2. The Committee clarified why the study was New Zealand only.
3. The Committee clarified that there was no unspecified research on data planned in 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 that the advertisements be updated to note that contraception would not be ‘prescribed’.
2. The Committee requested an amendment to the radio advertisement to correctly mention the number of follow-up visits.

**Decision**

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

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

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| **8** | **Ethics ref:** | **2023 FULL 15184** |
|  | Title: | A MULTIPLE-CENTER, NON-RANDOMIZED, OPEN-LABEL STUDY TO INVESTIGATE THE EFFECT OF VARIOUS DEGREES OF RENAL IMPAIRMENT ON THE PHARMACOKINETICS OF A SINGLE INTRAVENOUS DOSE OF RO7223280. |
|  | Principal Investigator: | Dr Nick Cross |
|  | Sponsor: | F. Hoffmann-La Roche Ltd |
|  | Clock Start Date: | 16th March 2023 |

Courtney Rowse and 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 resolved ethical issues

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

1. The Committee clarified that the self-referral would be due to only mild kidney impairment.
2. The Committee clarified that there was an established database and as such there would be no advertisement.
3. The Committee clarified that whilst the PI would make the initial approach, the study co-ordinator would then approach after an expression of interest to prevent persuasion or feelings of coercion.

Summary of outstanding ethical issues

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

1. Please provide more context as to why the participants have been approached.

**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:** | **2023 FULL 15435** |
|  | Title: | C5261001: A PHASE 1/2/3 STUDY TO EVALUATE THE SAFETY, TOLERABILITY, AND IMMUNOGENICITY OF COMBINED MODIFIED RNA VACCINE CANDIDATES AGAINST COVID-19 AND INFLUENZA IN HEALTHY INDIVIDUALS |
|  | Principal Investigator: | Dr Claire Thurlow |
|  | Sponsor: | Pzifer New Zealand Limited |
|  | Clock Start Date: | 16th March 2023 |

Amal de Silva, Dr Claire Thurlow, and Tristan Riley were present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of resolved ethical issues

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

1. The Committee clarified the reimbursement charter, and that this information would be standardised across sites.
2. The Committee clarified that the e-consent company was not the CRA but a vendor for the e-consenting only.
3. The Committee clarified that participant ‘would’ be sent the participant information sheet, not ‘may’.
4. The Committee clarified that the data would be maintained in an identifiable form for safety.
5. The Committee clarified that there were paper copies and mail order available as work arounds for people who are less versed in technology.
6. The Committee clarified that the safety of the individual vaccines was safe enough that the 30-minute observation period was sufficient.

Summary of outstanding ethical issues

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

1. The Committee requested that the research adverts be moderated to not permit comments on the social media platforms to create a safer place to view the information provided.
2. The Committee noted that the recruitment material that speaks to “helping the community” needs to be amended to not overplay the participation of participants in the study.
3. The Committee noted that reimbursement was low. The Committee also suggested that the notion of reimbursement for ‘time’ would make the amount taxable. This should be phrased as reimbursement for costs, travel etc.
4. The Committee suggested consulting with a tax attorney to determine correct wording around reimbursement. The Committee suggested utilizing wording such as the following:

*“You will be reimbursed the sum of X (before tax), following the final study visit. However, the timing of reimbursement is flexible and can be adjusted to suit your needs – please discuss this with study staff if you have any concerns regarding your reimbursement. We are required to deduct withholding tax at the applicable rate you have declared in the IR330C form. You will be responsible for any other tax obligations (e.g., ACC). If you are GST registered, it may be possible for you to submit a GST invoice. Contact [insert email] if you would like to discuss this further.*

*The payment will be made after you complete the study, to cover your time and inconvenience. If you are receiving a benefit or allowance, your usual payments may be affected. Your tax statement will state that you were paid from your dosing day through to your final study visit.”*

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

1. Please include a box at the top of the PIS stating that this is the first time this combination of vaccines has been used in humans.
2. Please provide contact methods for the research team for the process of withdrawal.
3. Please specify where samples will be sent.
4. For the sentence "For every two participants assigned to group 1, one will be assigned to group 2, and one to group 3 (a ratio of 2:1:1)" please review for clarity or add “one additional participant will be assigned to group 2”.
5. For the sentence "It is possible your condition or health may improve, worsen, or stay the same" please rephrase as the study is with healthy participants.
6. For the sentence "This study is for research purposes only. Your alternative is to not take part in this study" please remove that first sentence, as this does not make sense: people will be getting vaccinated.

**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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| **10** | **Ethics ref:** | **2023 FULL 13694** |
|  | Title: | Prospective observational study of sequential changes to faecal microbiota of children of different ethnicities undergoing exclusion  enteral nutrition therapy for Crohn's disease in New Zealand. |
|  | Principal Investigator: | Dr Johnathan Bishop |
|  | Sponsor: |  |
|  | Clock Start Date: | 16th March 2023 |

Dr Jonathan Bishop, Dr Jane Alsweiler,and Dr Vivek Rajasekaran were present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of resolved ethical issues

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

1. The Committee clarified what occurred during the period between initial review by the institutional ethics committee and HDEC review.
2. The Committee clarified that due to the large amount of data generated from a small sample size would ensure that the study was adequately powered. The researcher clarified that this number was realistic as well as a good starting point given the large potential for future work.
3. The Committee clarified the classification of “Southern Asian”.
4. The Committee clarified that ethnic identity would be assessed during recruitment.
5. The Committee clarified the response to peer review addressing the small sample size.
6. The Committee clarified that all participants would receive nutritional therapy.

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 how the researchers had responded to the “racialised biological hypothesis,” given that the total people participating would be 26 participants. The researcher responded that there were more cases in children of immigrants and that this was biologically linked as well as environmentally.
2. The Committee noted that the ethnic thrust of the study was not represented in the PIS.
3. The Committee requested more information as to how the recruitment would occur, specifically the recruitment of those with confounding factors and how matching may be carried out with respect to age, severity of condition etc.
4. The Committee noted that the access of records by the research team to recruit participants was a breach of privacy. The referring practitioner should be the person to decide and offer request consent for researchers to contact the potential participants.
5. The Committee requested that the HDEC approval statement be included rather than the university approval.
6. The Committee suggested that the information sheet could be attached to the referral response upon offering the appointment for endoscopy.
7. The Committee requested that the researcher utilize the [HDEC PIS template](https://ethics.health.govt.nz/assets/Uploads/HDEC/templates/participant-information-sheet-consent-form-template-v4.0december2022.doc) to better capture all the relevant information as required for HDEC review.
8. The Committee requested that additional koha be provided for each stool sample etc. and that these be provided in a form suitable for the child (not fuel vouchers).
9. The Committee suggested providing an executive summary of the study documentation for participants in different languages.
10. The Committee suggested having a “younger child” and “older child” assent forms as this should be assigned by level of understanding and not age.

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

Main PIS/CF:

1. Please proof-read for grammar and spelling.
2. Please specify that this is a comparative study between South Asians and Non-South Asians.
3. Please detail the recruitment process and inclusion and exclusion criteria.
4. Please detail what the process for referral or recruitment would be with respect to the timelines of IBD identification to consent.
5. Please make it clear who is the participant- the child not the parent.
6. Please clearly detail what will happen at each step of the study. A flow chart may be of use to detail this for participants simply and in chronological order.
7. Please clarify what happens to stool samples after analysis.
8. Please specify the return and destruction of samples.
9. Please clarify and specify how the collection of stool samples would be additional to SoC.
10. Please amend storage of tissue to state that storage of tissue must be 10 years from when the youngest participant turns 16.
11. Please amend consent to “parent/guardian’ as caregivers should not generally be providing consent.
12. Please provide advocacy details.
13. Please remove the coercive statement concerning participation helping “friends, whanau and the Māori people”.

13-16-year-old Assent Form:

1. Please proof-read for grammar and spelling.
2. Please amend the order of procedures and collection of samples to clarify for participants.
3. Please provide cultural contacts.

**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 Cordelia Thomas and Dr Patries Herst.

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| **11** | **Ethics ref:** | **2023 FULL 15293** |
|  | Title: | A randomized, double-blind, placebo-controlled Phase 3study of darolutamide plus androgen deprivation therapy (ADT) compared  with placebo plus ADT in patients with high-risk biochemical recurrence (BCR) of prostate cancer |
|  | Principal Investigator: | Mr Kevin Bax |
|  | Sponsor: | Bayer New Zealand Limited |
|  | Clock Start Date: | 16th March 2023 |

No one from the research team 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 requested a more detailed recruitment plan that allows for timing, and an independent person to talk to regarding the study before consent. If possible, an independent person other than the clinical staff should approach potential participants. *National Ethical Standards* para *7.18*
2. The Committee requested that there be proof of equity of participation given that there would be reimbursement of the drug rather than up front giving of the drug without cost. This needs to be amended as it is not acceptable.
3. The Committee noted that in the application the researchers noted that they would use Kaupapa methodology, however this does not appear to be the case. Please clarify this.
4. The Committee requested that for cultural consideration that there be provision of gender matched research staff as medical discussions involving genitalia are sensitive, and there are gender considerations too.
5. The Committee noted that there needs to be a safety plan and gender appropriate provision of staff for the questionnaires. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 8.4-8.6, 8.9)*
6. The Committee noted that the sponsor may not terminate "at any time for any reason". This is not accurate, please amend.
7. The Committee queried if there would be provision of karakia overseas, please clarify.
8. The Committee requested justification on the follow up process as it seems long and has not been clearly planned out in terms of what follow up will occur.

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

Main PIS/CF:

1. Please clarify what “if appropriate” means in the sense of travel and food reimbursement.
2. Please note that cultural statements should be for all sites and not only that provided for Auckland hospital.
3. Please provide detail on how participants may withdraw from the study.
4. Please write acronyms out in full and explain them the first time that they appear.
5. Please clarify if the drug is approved for use for what types of cancer and if the drug is in fact used for “castrate-resistant cancer”.
6. Please amend current data safety section using the [HDEC PIS templated](https://ethics.health.govt.nz/assets/Uploads/HDEC/templates/participant-information-sheet-consent-form-template-v4.0december2022.doc) information as this is much easier to understand and less lengthy.
7. Please remove the need for receipts to reimburse participants as this can cause undue stress.
8. Please include the full compensation section as per the [HDEC PIS template](https://ethics.health.govt.nz/assets/Uploads/HDEC/templates/participant-information-sheet-consent-form-template-v4.0december2022.doc) and list any exclusions to this.
9. Please do not include abbreviations in the lay title.
10. Please ensure that the description for the word ‘placebo’ is immediately after it is first mentioned.
11. Please simplify the sentence, “which may be a luteinizing hormone-releasing hormone (LHRH) agonist or a LHRH antagonist, administered via injections” to simply say that they stop the testes from producing testosterone.
12. Please specify the name of the ADT that is going to be used in New Zealand for this trial.
13. Please remove the bulk of information regarding radiation therapy as this is not part of the trial treatment and should be consented separately as SoC.
14. Please review "Reports about research done with your samples will not be put in your health/medical record and will be kept confidential to the best of our ability within the law" as this is common practice.
15. Please remove the word “may”, where the action is mandatory, such as contacting participant’s general practitioner or storing data and samples.
16. Please clarify where data will be stored, what the ‘remote viewing’ entails and who will have access to this data.
17. Please use the contraception statement in the [HDEC PIS template](https://ethics.health.govt.nz/assets/Uploads/HDEC/templates/participant-information-sheet-consent-form-template-v4.0december2022.doc).
18. Please review the study procedures table as it is difficult to read due to the font size and formatting.
19. Where there is reference to "you must tell your study doctor or their co-workers" please amend to say, "must tell a member of the study team".
20. Please specify how many people will be in the trial both in New Zealand and internationally as well as giving the countries involved in the study.
21. Please specify how long people are likely to be in the trial for.

Future Unspecified Research (FUR) PIS/CF:

1. Please clearly explain the whole genome sequencing and please clarify if only genes relating to the drug or the condition. Please also clarify if there is there any chance that specific hereditary traits will be identified with this and other medical conditions.
2. Please explain the privacy risks associated with whole genome sequencing; particularly if those sequences are shared or uploaded somewhere accessible to others.
3. Please clarify how this data will be published and if whole genome sequences will be made available to other researchers as is often required by high quality scientific journals.
4. Please describe the insurance risks associated with whole genome sequencing.
5. Please specify if the optional tumour collection refers to archival tumour tissue or if it only applies to those who consent to a fresh biopsy at disease recurrence.

**Decision**

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

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| **12** | **Ethics ref:** | **2023 FULL 15285** |
|  | Title: | A Phase 3, Randomized, Double-blind, Placebo-controlled, Event-driven Study to Demonstrate the Efficacy and Safety of Milvexian, an Oral Factor XIa Inhibitor, After a Recent Acute Coronary Syndrome |
|  | Principal Investigator: | Dr Jocelyne Benatar |
|  | Sponsor: | Janssen-Cilag (New Zealand) Limited |
|  | Clock Start Date: | 16th March 2023 |

No one from the research team 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 queried how the recruitment would be balanced given the quick turn-around from the potential participants having recently had a heart/angina attack. The Committee requested detail how distress and undue pressure would be managed in these situations.
2. The Committee noted that any medication required due to side effects caused by the study should be provided at no cost to the participant by the study.
3. The Committee noted that milvexian is described as "safe and useful " in the participant information sheet. There is only one phase II study that suggests this drug may be helpful. This is still very much an experimental drug, which is why this is a phase III study; rephrase and do not overstate its efficacy.
4. The Committee requested that the full date of birth not be sent to the Sponsor.
5. The Committee advised the Researcher that relevant Māori cultural issues for this research would include blood samples as tapu, information as a taonga and the potential for whakamā in participants. The Committee requested the Researcher become familiar with these concepts and be mindful of this for future applications.
6. The Committee requested the inclusion of a cultural tissue statement to the PIS as per the [HDEC PIS Template](https://ethics.health.govt.nz/assets/Uploads/HDEC/templates/participant-information-sheet-consent-form-template-v4.0december2022.doc).
7. The Committee requested that the researchers use the [HDEC DTMP template](https://ethics.health.govt.nz/assets/Uploads/HDEC/templates/HDEC-data-tissue-management-template-Nov2022.docx).
8. The Committee noted that commercial reasons may not be the sole reason that a study is terminated. Please reflect this in the relevant study documentation.

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

1. Please include the other reasons for recruitment such as age and diabetes rather than only mentioning the heart/angina attack.
2. Please specify how long the data will be retained for and make sure this is consistent across all documentation.
3. Please clarify if the statement "There will be no clear benefit to you from your participation in this research" is true. The follow-ups are potentially a benefit.
4. Please provide a flowchart or diagram to better demonstrate the study procedures.
5. Please explain treatments and technical terms in lay language and be consistent with the terminology used throughout.
6. Please remove all vagaries surrounding “most, some” etc. as these could be misleading.
7. Please ensure that heading match the statements listed below them.
8. Please inform participants fully of the tracking with “omni-trace”.
9. Please amend the font of the headings for readability so that they are white text on a blue background.
10. Please include the cultural statement as per the [HDEC PIS template](https://ethics.health.govt.nz/assets/Uploads/HDEC/templates/participant-information-sheet-consent-form-template-v4.0december2022.doc).
11. Please amend the mention of “Māori health support”. This should read “Māori cultural support”.
12. Please refer to a general practitioner (GP) rather than using the term “family doctor”.
13. Please provide a link to the “industry guidelines”.

**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 more detailed data management plan to ensure the safety and integrity of participant data. This can be a standalone document or incorporated as part of the protocol *(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 Mrs Patricia Mitchell and Ms Sandy Gill.

## General business

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

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| **Meeting date:** | 26th April 2023 |
| **Zoom details:** | To be determined |

1. **Review of Last Minutes**

The minutes of the previous meeting were agreed and signed by the Chair and Co-ordinator as a true record.

1. **Matters Arising**
2. **Other business**
3. **Other business for information**
4. **Any other business**

The meeting closed at 6:20pm.