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| **Committee:** | Northern B Health and Disability Ethics Committee |
| **Meeting date:** | 04 July 2023 |
| **Zoom details:** | 965 0758 9841 |

| **Time** | **Review Reference** | **Project Title** | **Coordinating Investigator** | **Lead Reviewers** |
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| 11.30am-12.00pm | 2023 FULL 15345 | Adherence to myopia control spectacle wear in children aged 7 to 12: a comparison of two lens designs. | Miss Emily Benefer | Ms Kate O'Connor and Mrs Leesa Russell |
| 12.00-12.30pm | 2023 FULL 17972 | The Australasian Malignant PLeural Effusion (AMPLE)-4 Trial | Dr Elaine Yap | Mr Ewe Leong Lim and Ms Joan Pettit |
| 12.30-1.00pm | 2023 FULL 18055 | Cognitive Stimulation Therapy (CST) - Chair Yoga Sleep Study for people with Mild Dementia | Dr Kathy Peri | Ms Maakere Marr and Mr Barry Taylor |
| 1.00-1.30pm | 2023 FULL 18204 | Services Your Way: Evaluating a Youthline national counselling program | Dr Jessica Stubbing | Ms Alice McCarthy and Dr Amber Parry-Strong |
|  | *Break (30)* |  |  |  |
| 2.00-2.30pm | 2023 FULL 17806 | Parent Perceptions of a Communication Support for Autistic Children | Ms Siobhan Gardiner | Ms Kate O'Connor and Mrs Leesa Russell |
| 2.30-3.00pm | 2023 FULL 16791 | A study to assess the long-term safety of astegolimab in participants with chronic obstructive lung disease - HDEC | Dr Michael Epton | Mr Ewe Leong Lim and Ms Joan Pettit |
| 3.00-3.30pm | 2023 FULL 18146 | A 1st in human study that will compare the effects and safety of an anticancer drug called BGB-26808 that is given alone or in combination with tislelizumab in adult participants with advanced cancer. | Dr Sanjeev Deva | Ms Alice McCarthy and Mr Barry Taylor |

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

## Welcome

The Chair opened the meeting at 11.00am 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 06 June 2023 were confirmed.

## New applications

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| **1**   | **Ethics ref:**   | **2023 FULL 15345** |
|   | Title:  | Adherence to myopia control spectacle wear in children aged 7 to 12: a comparison of two lens designs. |
|   | Principal Investigator:  | Miss Emily Benefer |
|   | Sponsor:  | The University of Auckland |
|   | Clock Start Date:  | 15 June 2023 |

Emily Benefer and Dr John Phillips 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 discussed recruitment with the Researcher and noted that they are in favour of the vision bus also being used as that widens the reach to recruit. It was further noted that the usual enrolment through the clinic may not be a representative New Zealand sample, but the vision bus will help bridge that gap.
2. The Committee confirmed with the Researcher that the decision for what is being prescribed is a decision independent from the study.
3. The Committee confirmed that there are no preferred lenses, and both are effective and approved for use in New Zealand, so this is in equipoise. There is a preferred frame type for it (circular) but these lenses look normal.
4. The Committee clarified with the Researcher that the parents will be able to speak of their child’s experience in full as the child will also be present to confirm or correct details.
5. The Committee confirmed that the frames and lenses provided are standard and adjustment or changes can be done by any optometrist, not just their practice.

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 to amend references to 10–12-year-olds to be “older” children, not “old” across study documentation.
2. The Committee queried what the Researchers will do if they find out the glasses wear of the participant is sub-optimal (not 8-12 hours a day). The Researchers responded that usual advice as given at the clinic will be followed. The Committee noted that normally they would see this protocolised for consistency if there are multiple investigators. While this study does not have multiple investigators, the Committee recommended doing this just in case.
3. The Committee noted that there is no plan in protocol for managing incidental findings but is referred to in the participant information sheet (PIS). After discussion, it was clarified that it would likely be encountered before engaging in the study. If there is a chance that there are incidental findings as part of the study, please amend PIS and protocol because if it is through a process, you are not actively engaged in, the Researcher’s ability to control or interact with it is limited in terms of the study responsibilities. If there isn’t a chance and it happens outside of the study entirely, this reference can be removed.
4. The Committee requested clarification in the Data Management Plan that the sensors are not free or reword that they are free to participants but purchased by the study as this currently implies commercial ties.
5. The Committee noted that some side effects looked for in the survey, they are not clear in other documentation that these are common side effects and whether its specific to these people using this type of glasses. After discussion, the Committee suggested including a small adverse event section in the protocol that outlines what to do when children present with anything that would go wrong. The current plan could be strengthened and make it clear and standardized how you will manage it.

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

All:

1. Please use photographs rather than drawing so the children have a sense of the frames they can choose from, and the sensor, etc.

Children PIS/Assent:

1. The children’s assent is not appropriate for a 7-year-old. Make a more simplified one. The current sheet is fine for the 12-year-olds, but a fresh information sheet for younger children is required.

Parent PIS/CF:

1. Please review for technical language, such as the eligibility criteria. We assume this is accompanied with a face-to-face explanation but are asking for this to be simplified in written form.
2. A table of what happens at each visit will be helpful. Protocol workflow table would be a useful insertion.
3. Under costs on page 5, please state that you are reimbursing the cost of travel/parking for any extra study-related visits. The Committee noted that participants should not be out of pocket for making extra travel outside of normal visits.
4. Please add in clarification of what the standard treatment offered would be and what is different about these new glasses, if anything, or what else differs between their standard of care and participation in the trial.

**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 forms, 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 Mrs Leesa Russell.

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| **2**   | **Ethics ref:**   | **2023 FULL 17972** |
|   | Title:  | The Australasian Malignant PLeural Effusion (AMPLE)-4 Trial: Topical Antibiotic Prophylaxis for Infections of Indwelling PleuralCatheters in Patients with Malignant Pleural Effusions |
|   | Principal Investigator:  | Dr Elaine Yap |
|   | Sponsor:  | University of Western Australia |
|   | Clock Start Date:  | 22 June 2023 |

Dr Elaine Yap and Hannah Burden 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 confirmed this was not a commercial 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 noted the peer review provided is the ethics review from Australia. Please provide independent expert peer review. See the [template on the HDEC website](https://ethics.health.govt.nz/guides-templates-and-forms/scientific-peer-review-submissions-guidance/) for guidance.
2. The Committee recommended performing a skin patch test for allergies for the investigational product.
3. The Committee noted that the total participant numbers are inconsistent across documentation. Please amend.

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

1. Please explain what else is different as being part of this study such as additional phone calls.
2. Please refer to the [HDEC template](https://ethics.health.govt.nz/guides-templates-and-forms/participant-information-sheet-templates/) for the consent form as wording differs slightly in places.
3. Please detail what other usual practice is so that participants in the control group still feel they are getting adequate care.
4. Please do not refer to the investigational product as a “treatment” as it is not currently used as a treatment for this.
5. Amend reference to 5 cent coin as it’s no longer in use in New Zealand. 10 cent is more appropriate here.

**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 supply an independent peer review for the current version of the study protocol. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.26).*

After receipt of the information requested by the Committee, a final decision on the application will be made by Mr Ewe Leong Lim and Ms Joan Pettit.

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| **3**   | **Ethics ref:**   | **2023 FULL 18055** |
|   | Title:  | Ageing Well through Eating, Sleepoing, Socialising and Mobility (AWESSoM care Home Project; AWESSoM Care Home Project Oral Health sub study; Cognitive Stimulation Therapy (CST) - Chair Yoga Sleep Study for people with Mild Dementia |
|   | Principal Investigator:  | Dr Kathy Peri |
|   | Sponsor:  | University of Auckland and Ministry of Business, Innovation and Employment |
|   | Clock Start Date:  | 22 June 2023 |

Dr Kathy Peri was present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of resolved ethical issues

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

1. The Committee confirmed the CI has an existing relationship with the villages involved in the study.
2. The Committee confirmed that the carers will be trained in activating the button to push when the participant goes to sleep at night.

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 inclusion criteria should either be only the milder end of dementia where people can consent for themselves, or if the Researcher thinks there is potential benefit for those who are more advanced in their capacity issues, then Right 7(4) of the code must be met for best-interests. Please return the submission with an outline of why there is benefit to their participation versus not participating. The Researcher noted regardless, most of the participants would be on the milder end. The Committee would be supportive of either approach provided the argument for which decision is stepped out. The Consent Form for the EPOA can be dropped out altogether. A supported decision model should be outlined in the study documentation as to what that looks like. (*National Ethical Standards for Health and Disability Research and Quality Improvement, para 6.6, 6.10, 6.11, & 7.59-7.71)*
2. The Committee noted that a simple sleep diary could be implemented for those with capacity to provide their own consent as they could be able to fill it in themselves.
3. The Committee noted that the University’s research office should be folded into as they count as a Sponsor.
4. The Committee requested to document what is being used to collect data, such as demographic forms, ways of measuring their condition, and detail what information the Researchers are getting such as accessing health records and why.
5. Please review documentation for typos of Māori words.

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

1. Please ensure the PIS is as simple as possible.

**Decision**

This application was *declined* by consensus, as the Committee did not consider that the study would meet the ethical standards referenced above and felt that the study would benefit from a cleaner submission addressing the consent and capacity issues. Please detail how capacity to consent will be ascertained in terms of confirming eligibility at screening and throughout the intervention period.

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| **4**   | **Ethics ref:**   | **2023 FULL 18204** |
|   | Title:  | FORMAL FULL TITLE |
|   | Principal Investigator:  | Dr Jessica Stubbing |
|   | Sponsor:  | Youthline and University of Auckland |
|   | Clock Start Date:  | 22 June 2023 |

Dr Jessica Stubbing and Anna Williamson 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 if Māori and Pasifika peoples were being targeted. The Researcher responded that there is broad advertisement, but Youthline will develop more targeted ads if there is lack of Māori or Pasifika participants.

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 more than one sponsor can be listed, and the University should be a co-sponsor to go through the human ethics office. This can be done via a sub form in Ethics RM.
2. The Committee raised the following for the Advertisements:
	1. some overuse of exclamation marks.
	2. Doesn’t mention the evaluation part at all. Please ensure the ads offer the research opportunity as well as the new service
	3. It is currently unclear whether they can still partake in SYW if they don't want to be part of the study. Advertisements just talk about the new service and don't mention anything about the study.
3. The Committee stated that it is not clear from protocol whether the study is collecting disability data, although the application form states it will be. The Researcher responded that Youthline asks a single question about it as part of their intake form, but the study won’t be asking about it in any follow up surveys. The Committee noted may be a missed opportunity in the follow up questionnaires.
4. The Committee requested to build in a supported decision-making process that Youthline use into the protocol.

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

1. Page 4 about future research with coded information that may be used with other researchers or companies. The bit about companies is only mentioned here. Please clarify this further as to what they are consenting to.

**Decision**

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

* please address all outstanding ethical issues raised by the Committee
* please update the Participant Information Sheet and Consent Form, taking into account the feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17).*

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| **5**   | **Ethics ref:**   | **2023 FULL 17806** |
|   | Title:  | Parent Perceptions of a Communication Support for Autistic Children |
|   | Principal Investigator:  | Ms Siobhan Gardiner |
|   | Sponsor:  | Victoria University  |
|   | Clock Start Date:  | 22 June 2023 |

Siobhan Gardiner and Dr Hannah Waddington 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 Researcher had determined the device that will be used for the trial. This would be the application that is specified in the protocol.
2. The Committee clarified that the app would be purchased for participants by the researcher, this would depend on the participants having an Apple device. One device would be available should there be a family that does not have a device. This device would not be permitted to be left with the family as it is the property of the university.
3. The Committee clarified the provision of the application and the way in which it functions and the way in which it has been validated for use. The Researcher noted that there was no ability to program for Te reo and that this was something that they recognised as a limitation to the study.
4. The Committee clarified the age range of child participants.

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 raised that the provision of something that could be useful or beneficial for the participant families which would then be taken away from the families is unethical. The Committee requested that the university consider that the provision of a method of communication for a child that is then taken away at the end of the study is not acceptable and that the Committee suggest reconsideration of this.
2. The Committee requested that the application be named in the protocol and that the limitations and functions and purchase details are noted. The Committee suggested approaching the developers of the application for a discount given this is research.
3. The Committee requested provision of a Researcher safety plan.
4. The Committee requested that signals or consent decisions from the children in the study be documented and the protocol reflect this.
5. The Committee noted that the 2-week contingency is tight given that if there are several children in a household that if one of them gets sick it could take a short while for the other(s) to become symptomatic. The Committee suggested that this may impact the feasibility of this study and that it may be necessary to plan around this given the staggered approach.
6. The Committee noted that as the video data would be supplemented/ documented by raw written notes it would be possible for these videos to be destroyed after the collection of data to ensure the safety of participants, particularly as videos are extremely identifiable.
7. The Committee noted that adverse events need to be collected. This would include cases where people do not understand training or have some reaction to the application or failures in the application that create frustration etc., The Committee suggested looking over the relevant section of the NEAC standards concerning adverse events.
8. The Committee noted that the adverts must include that the sessions will be recorded and that there may be an observer present.
9. The Committee requested a written response to the peer review from the researchers.
10. The Committee requested provision of all questionnaires that may be used during the study for review.
11. The Committee queried why the university would be receiving deidentified information. If this is incorrect, please revise this in the data management plan.

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

1. Please review for jargon and technical language as this is not appropriate for the participants who will be reading the information.
2. The Committee noted that there is a possibility that this study does not outline that there is a possibility that this may not help improve the verbosity of their child. Please clearly outline that this could be the case and that there could be no benefit.
3. Please note that as the results of this study will not determine whether this application will directly correlate to the improvement of the lives and ability to communicate in these children and their families. It needs to be clearly communicated to parents that this is a pilot study and that while there may be some potential for benefit, it is not a certainty.
4. Please include that there may be an observer to the sessions and what their role may be.
5. Please review for repetitions.
6. Please include information as to who will provide the iPad, what the app that is being used is called and how it works as well as who owns it and what participation will require. Clarify what will happen (to the app and the study device if used) once the study is over.

**Decision**

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

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

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

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| **6**   | **Ethics ref:**   | **2023 FULL 16791** |
|   | Title:  | A Phase III Open-Label Extension Study to Evaluate the Long-Term Safety of Astegolimab in Patients with Chronic ObstructivePulmonary Disease (COPD) |
|   | Principal Investigator:  | Dr Michael Epton |
|   | Sponsor:  | F. Hoffmann-La Roche Ltd. |
|   | Clock Start Date:  | 22 June 2023 |

Dr Michael Epton was present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of resolved ethical issues

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

1. The Committee clarified that one of the feeder studies had been done in New Zealand. In the future roll-over studies can be submitted as amendments to the parent study.
2. The Committee clarified that the participants will not be unblinded to what the participants originally received from the initial studies. The Researchers will not know which participants would be moving onto active treatment until the blinding data is unlocked.
3. The Committee confirmed the study product has been approved for use in China, but not New Zealand.

Summary of outstanding ethical issues

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

1. The Committee queried how the participants may be informed of the placebo process and how their treatment may change as a result. Please clarify this in the protocol and PISCF.

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

1. Please clarify for participants that those not continuing on the extension would be returning to standard of care.

**Decision**

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

* please address all outstanding ethical issues raised by the Committee
* please update the Participant Information Sheet and Consent Form, taking into account the feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17).*

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| **7**   | **Ethics ref:**   | **2023 FULL 18146** |
|   | Title:  | A Phase 1 Study Investigating the Safety, Tolerability, Pharmacokinetics, and Preliminary Antitumor Activity of HPK1 Inhibitor BGB26808 alone or in Combination with Anti-PD-1 Monoclonal Antibody Tislelizumab in Patients with Advanced Solid Tumors. |
|   | Principal Investigator:  | Dr Sanjeev Deva |
|   | Sponsor:  | BeiGene |
|   | Clock Start Date:  | 22 June 2023 |

Dr Sanjeev Deva, Eva Roriguez, Hala Bitar, Sophie Goodger, Valmir Silva, Karen Yang, and Brittany Walker 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 queried the paired biopsy process. Please clarify this in the protocol and all other relevant documentation as this will need to be documented in the participant information sheet (PIS) and tissue management. After discussion, the Committee suggested that biopsies should be as an additional optional consent form item or additional consent form appendix. They further suggested that the Researchers find a way to separate the content of the information sheet for this group and obtain additional mandatory consent.

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

1. Please clarify the paired biopsy in plain English and how people may be selected for this and the criteria and procedures required.
2. Please remove teaspoon references to blood amount and present this in millilitres or relate to another identifiable amount that isn’t related to food or consumption.
3. Take out the word treatment when using experimental products. Can be investigational product.

**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 Alice McCarthy and Mr Barry Taylor.

## General business

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

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| **Meeting date:** | 01 August 2023 |
| **Zoom details:** | To be determined |

 The following members tendered apologies for this meeting.

* Ewe Leong Lim
1. **Review of Last Minutes**

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

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

The meeting closed at 3.20pm