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| **Committee:** | Northern B Health and Disability Ethics Committee |
| **Meeting date:** | 06 June 2023 |
| **Zoom details:** | <https://mohnz.zoom.us/j/9738756003> |

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| **Time** | **Reference / Project ID** | **Title** | **Coordinating Investigator** | **Primary Reviewers** |
| **11:00-11:30am** |  | **Committee Welcome** |  |  |
| 11:30-12:00pm | 2023 FULL 16757 | Management of musculoskeletal chest pain - a feasibility study | Dr Ewan Kennedy | Kate / Amy |
| 12:00-12:30pm | 2023 EXP 13643 | Exploring 'task challenge' in stroke rehabilitation | Associate Professor Nada Signal | Alice / Amber |
| 12:30-1:00pm | 2023 FULL 15134 | Paediatric Eye Health Services in New Zealand | Dr Rebecca Findlay | Ewe Leong / Barry |
| 1:00 - 1:30pm | 2023 FULL 13189 | EMA Follow Up Trial | Associate Professor Michelle Wise | Maakere / Joan |
|  |  | **BREAK (20 mins)** |  |  |
| 1:50-2:20pm | 2023 FULL 13624 | FEISTY II: Fibrinogen Early In Severe Trauma studY II | Dr James Moore | Alice / Joan |
| 2:20-2:50pm | 2023 FULL 17969 | An open-label, Phase 2 study to assess the safety and efficacy of EQ101 in adult subjects with moderate to severe alopecia areata | Dr Penny Montgomery | Maakere / Amber |
| 2:50-3:20pm | 2023 FULL 15583 | Spontaneous Venous Pulsation Prediction Study | Dr Kelechi Ogbuehi | Maakere / Amy |
| 3:20-3:50pm | 2023 FULL 17999 | EVOLUTION (EValuating glucose contrOL Using a next generaTION automated insulin delivery algorithm in patients with type 1 and type 2 diabetes) | A/Prof. Martin de Bock | Kate / Barry |
|  |  | **BREAK (10 mins)** |  |  |
| 4:00-4:30pm | 2023 FULL 16663 | PARAGON-2: A phase 2 study of the combination of letrozole plus alpelisib and letrozole plus ribociclib as treatment for hormone resistant or metastatic gynaecological cancers | Dr Michelle Wilson | Ewe Leong / Amy |
| 4:30-5:00pm | 2023 FULL 15319 | GO44010: A study to evaluate the safety and activity of RO7496353 in combination with Atezolizumab or Nivolumab with or without SOC chemotherapy in solid tumours. | Dr Peter Fong | Alice / Joan |
| 5:00-5:30pm | 2023 FULL 17907 | BRN-002 in Adult Participants with High-Risk Atherosclerotic Cardiovascular Disease or Homozygous Familial Hypercholesterolemia | Mr Andrew Edwards | Kate / Amber |
| 5:30-6:00pm | 2023 FULL 17878 | R7544-HV-22109: A study to evaluate REGN7544 in healthy participants for the potential treatment of hypotension, hypovolemia and other related disorders | Dr Chris Wynne | Ewe Leong / Barry |

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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 | Apologies  |
| 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 | Apologies |
| 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 |
| Ms Amy Henry  | Non-lay (Observational studies) | 13/08/2021 | 13/08/2024 | Present |

## Welcome

The Chair opened the meeting at 11:00am and welcomed Committee members, noting that apologies had been received from Mrs Leesa Russell and Ms Alice McCarthy

The Chair noted that it would be necessary to co-opt members of other HDECs in accordance with the Standard Operating Procedures. Ms Amy Henry of the Southern HDEC confirmed her eligibility and was co-opted by the Chair as a member of the Committee for the duration of the meeting.

The Chair noted that the meeting was quorate.

The Committee noted and agreed the agenda for the meeting.

## Confirmation of previous minutes

The minutes of the meeting of 02 May 2023 were confirmed.

## New applications

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| **1**   | **Ethics ref:**   | 2023 FULL 16757 |
|   | Title:  | Improving health services for people with musculoskeletal chest pain - a randomised controlled feasibility trial |
|   | Principal Investigator:  | Dr Ewan Kennedy |
|   | Sponsor:  | University of Otago |
|   | Clock Start Date:  | 25 May 2023 |

 Dr Ewan Kennedy 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 requested an explanation of the study design and blinding. The Researcher explained they would be asking participants who had been discharged from the hospital emergency department to consent to undergo a screening process to determine eligibility. Eligible and willing participants would then be randomised into one of the two study arms. One arm includes the standard of care, which is an education session, and the other is the physiotherapy. The Researcher stated this was a feasibility trial to manage musculoskeletal chest pain and the outcome would be used to plan a future randomised controlled trial.
2. The Committee queried the deception involved in the recruitment process. The Researcher explained they would be seeking consent from participants to enter into the study without knowing what the other arm would involve. The Researcher justified the deception to avoid participant bias.

**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 why the researcher had not split the information sheet into two separate versions for the two arms as suggested by the Central HDEC. The Researcher stated this would create a selection bias as an unblinded design may influence a potential participant. The Committee stated a two-step consent process would be acceptable where participants consent to screening and then after randomisation are provided with an information sheet containing a description of what their arm involves and stating there is a second arm but participants will not be informed of what it involves until after the trial. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.33).*
2. The Committee noted the advertisement/ poster is deceptive as it promises care from a physiotherapist in line with best practice and up to six physiotherapy sessions. The Committee considered this problematic or two reasons: first, "best practice" now is an education session; the physiotherapy is experimental and has not been proven efficacious in this population. Second, it suggests that all participants will receive physiotherapy, but this will not be the case for participants randomised into the control arm. The Committee noted these participants would only receive an education session and no active physiotherapy treatment. The Committee requested this is reworded to state a study with two arms/ approaches to chest pain from the physiotherapy department and to remove mention of six sessions as this is not accurate for the participants who will be randomised into the control group and who would potentially be unblinded. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.32).*
3. The Committee noted the 12-week interview would need to be more disclosing of what participants were not told originally and should contain justifications for the blinding of the trial. The Committee requested a formalised description of the debrief session be included with the protocol. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.37).*
4. The Committee requested an extension to the protocol to offer participants in the control group the physiotherapy sessions they missed out on by being randomised into the control group. The Committee stated this would be a good faith gesture to restore participants to where they may have been had they been randomised into the experimental / active group instead. The Researcher stated they would need to confirm whether the funding was available for this. Should patient reported outcome data from these sessions have research value, then a waitlist-control design might be considered, which would eliminate the need to withhold information about the two arms. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.32).*
5. The Committee advised that Research and Enterprise at Otago would need to sign off the study as the local sponsor in the HDEC application system. (*HDEC Standard Operating Procedure*, para 175).

**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 Ms Amy Henry.

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| **2** | **Ethics ref:**   | 2023 EXP 13643 |
|   | Title:  | Exploring task challenge from the perspective of people with stroke and therapists in stroke rehabilitation using video-reflexive |
|   | Principal Investigator:  | ethnography. |
|   | Sponsor:  | Auckland University of Technology |
|   | Clock Start Date:  | 25 May 2023 |

Associate Professor Naga Signal and Miss Emma Gomes 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 noted a consent form for support people and queried their involvement. The Researcher stated previous experience has shown support people sometimes have a perspective to offer and it is useful to capture this data, though it is not necessary for all participants to have a support person. The Committee suggested developing a separate information sheet for support people or adding a section addressed to them in the main PIS. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17).*
2. The Committee requested more detail in the safety plan for visiting participant homes (e.g. how to manage dogs). *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 11.62).*
3. The Committee noted video footage could not be deidentified and requested detail about identified information in the data management plan. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15 - 12.15a).*
4. The Committee requested additional information in the information sheet and data management plan to include more detail about overseas co-investigators viewing the recordings and how this will be managed. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 - 7.17; 12.15 - 12.15a).*

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

1. The Committee noted a statement advising that a support person actively participating 'may' receive koha. The Committee requested a revision to state whether koha will be available or not to remove ambiguity.
2. The Committee requested removal of the ACC compensation statements for advocates and therapists as these are not necessary. Please include a statement advising that interviews will be recorded (and whether this is audio only or visual too).
3. Please include a statement advising that videos will not be viewed by anyone outside of the research team.

**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 safety plan to include more detail about visiting participant homes (National Ethical Standards for Health and Disability Research and Quality Improvement, para 11.62).
4. Please update the data management plan (National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15 - 12.15a).

After receipt of the information requested by the Committee, a final decision on the application will be made by Ms Kate O’Connor and Dr Amber Parry-Strong.

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| **3** | **Ethics ref:**   | 2023 FULL 15134 |
|   | Title:  | Paediatric Eye Health Services in New Zealand - An investigation into the prevalence of visual conditions in New Zealand 7-year-olds |
|   | Principal Investigator:  | Dr Rebecca Findlay |
|   | Sponsor:  | University of Auckland |
|   | Clock Start Date:  | 25 May 2023 |

Dr Rebecca Findlay and Miss Amelia Hardcastle 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 noted the study would provide a voucher for glasses if needed and queried whether participants could select an optometrist of their choice. The Researcher stated they could and confirmed the optometrist would charge the study and not the participant.
2. The Committee queried whether there was a consent process for involving schools. The Researcher confirmed there was and would receive locality sign off.
3. The Committee queried whether the study would recruit from a range of schools including both low and high deciles. The Researcher confirmed they would.
4. The Committee queried how long the eye drops cause a stinging sensation. The Researcher stated it varies from child to child but is usually approximately 10 seconds. The Committee queried whether children would be able to play after the eye drops. The Researcher stated they can cause blurred vision up close and may be more sensitive to glare but the study will provide sunglasses. The Committee queried whether children may participate in the study without receiving the eye drops. The Researcher stated they were necessary to obtain an accurate measurement.

**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 an explanation of the novel device to be used. The Researcher explained it presents a stimulus and can measure involuntary eye reactions to measure a child's vision without relying on a response from them. The Committee queried what data it would record. The Researcher explained the device would track eye position and space as a sequence of numbers and confirmed no identifiable information would be taken. The Committee requested information explaining the device is added to the participant information sheet. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17).*
2. The Committee requested an update to the data management plan to incorporate the non-identifiable / coded data from the novel device. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15 - 12.15a).*
3. The Committee requested an update to the data management plan to state health data will be stored for 10 years from when the participant turns 16. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.13).*

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

1. The Committee noted some of the language in the assent form may be too complex for a 7-year-old to understand and requested a revision to simplify the content.
2. The Committee requested a statement in the parent information sheet to advise them they can attend the vision screening if they wish to support their child.
The Committee requested additional space in the form for the ethnicity question in case a participant identifies with more than one ethnic group.
3. The Committee suggested inserting the word 'survey' into the information on social-emotional learning to clarify what the assessment is.

**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 - 12.15a).*

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

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| **4** | **Ethics ref:**   | 2023 FULL 13189 |
|   | Title:  | Follow up of early medical abortion: a multicentre randomised controlled trial |
|   | Principal Investigator:  | Associate Professor Michelle Wise |
|   | Sponsor:  | The University of Auckland |
|   | Clock Start Date:  | 25 May 2023 |

Dr Jane MacDonald and Mrs Ashleigh O'Mara-Baker 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 whether Māori would be specifically targeted for recruitment. The Researcher stated there would not be a specific focus and everyone would be randomised as they came to clinic. The Researcher noted existing data shows Māori tend to prefer a surgical option over an EMA. The Committee noted wāhine Māori are frequently lost to follow up and suggested the study could investigate why there was a preference for the surgical option. The Researcher stated they were involved with a separate study of anonymous surveys that may be able to provide data on this question. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 3.1).*

**Summary of outstanding ethical issues**

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

1. The Committee queried whether Pasifika would be specifically targeted for recruitment. The Researcher stated there would not be a specific focus and again anyone eligible to participate would be recruited into the study. The Committee noted the answer to C10 in the application indicated the researchers did not expect cultural issues for Pacific women and requested the researchers reconsider this. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 4.3).*
2. The Committee requested the researcher obtain authorisation from the University of Auckland's research office in the EthicsRM system. (*HDEC Standard Operating Procedure*, para 175).

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

1. The Committee advised that as EMA itself is not under study the associated risks can be removed from the information sheet as these will be explained as part of standard of care.
2. The Committee requested a proof-read of te reo Māori words used in the sheets, specifically to check for correct macron use.
3. The Committee noted the consent form does not mention accessing medical records, but this is described in the protocol. Please include a clause in the consent form so participants consent to this.
4. The Committee requested more detail about how urine tests will be delivered to participants who consented via telehealth (e.g. sent via courier or collected from a pharmacy) in the information sheet.
5. Please include a comment regarding discretion e.g. if participants do not want members of their whānau/family to be informed or involved it is their choice and any study communications will be sent discreetly.
6. Please insert headers and appropriate logos into the PIS.

**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 13624 |
|   | Title:  | FEISTY II: Fibrinogen Early In Severe Trauma studY II |
|   | Principal Investigator:  | Dr James Moore |
|   | Sponsor:  | Monash University |
|   | Clock Start Date:  | 25 May 2023 |

Dr James Moore and Ms Shaanti Olatunji 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 which trauma patients would be eligible for the study. The Researcher stated the population would involve patients with severe bleeding, commonly caused by high energy impacts such as car crashes or high falls. The Researcher confirmed patients with mild degrees of trauma would not be eligible. The Researcher stated all participants would be those with life-threatening bleeding and would not have capacity to provide informed consent. All participants in the trial would be enrolled under [Right 7(4) of the Code of Health and Disability Services Consumers' Rights](https://www.hdc.org.nz/your-rights/about-the-code/code-of-health-and-disability-services-consumers-rights/).
2. The Committee queried how many participants the Researcher expected to survive and could provide consent at a later time. The Researcher stated the overall mortality rate for severe trauma in New Zealand was approximately 9% and the majority of patients would be expected to survive, though it is likely some will not.
3. The Committee queried whether the fibrinogen clotting agent is administered in ambulances. The Researcher stated it is not currently and one of the reasons for doing the trial is to determine if it would be appropriate for use in ambulances and rural hospitals without blood banks as this causes an equity issue with rural patients.
4. The Committee requested an explanation of the study's randomisation. The Researcher explained that participants would be randomised to one of the two agents used routinely. The Committee queried how clinicians can determine whether a patient requires fibrinogen or not. The Researcher stated it would be based in clinical judgement at the time that the patient has severe bleeding and requires treatment. The Researcher explained most of the treatments are protocolised and there is a range of different blood products to approximately replace the volume lost. The Committee queried whether there was an empirical test to establish this. The Researcher confirmed there were both lab and point of care tests to detect low fibrinogen levels and these are the patients this trial is aimed toward.

**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 in order to approve the study under Right 7(4) the best interests test would need to be met and queried how involvement in the study would be in each individual's best interest compared to standard of care. The Committee noted that receiving one of the two approved products in the trial in itself does not establish grounds for waiver of consent and an individual best interest to meet the requirements of Right 7(4) of the Code. The Researcher acknowledged that the access to the study products itself is not a “best interest” benefit. However, the trial will provide ICU research nurses for additional acute care and monitoring for clotting which, in a resource-constrained environment, will constitute a benefit for study participants. Additionally, the study will assess participants at follow-up for mental health conditions like PTSD and will provide a pathway to ongoing care with an escalation protocol if needed. The Committee determined that these additional study components meet the “best interest” test. The Committee requested information regarding these benefits is written into the protocol and requested the escalation protocol for follow-up. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.70).*
2. The Committee noted the brochure and information sheet state there is no guarantee of benefits but the study may help others. As the study is intending to enrol participants under Right 7(4) of the Code a benefit needs to be guaranteed. The Committee requested a revision to incorporate the benefits of participation. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17).*
3. The Committee noted the whānau brochure is opt-out (as it states if participants do not want to be involved to sign the form) and requested it be changed to opt-in (so participants that do want to be involved sign). The Committee appreciates that this research is done in an emergency setting, and enrolment into the trial is likely to occur before whānau are approached for a research discussion. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.69).*

**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 study brochure for whānau *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.69).*
5. Please supply the escalation / follow up protocol. (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 Ms Joan Petit

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| **6**   | **Ethics ref:**   | 2023 FULL 17969 |
|   | Title:  | An open-label, Phase 2 study to assess the safety and efficacy of EQ101 in adult subjects with moderate to severe alopecia areata |
|   | Principal Investigator:  | Dr Penny Montgomery |
|   | Sponsor:  | Equillium AUS Pty Ltd |
|   | Clock Start Date:  | 25 May 2023 |

Dr Penny Montgomery, Dr Sharin Asadi, Dr Claudette Bethune and Mr Joel Rothman 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 how potential participants would be recruited. The Researcher explained most would come from dermatologist waitlists for trials and advertisements and expected less from the study team's database.
2. The Committee queried whether the full body photos would be taken in New Zealand. The Researcher confirmed this would only occur in Australia with a specialised camera and would not be part of the New Zealand study.
3. The Committee advised that terminating a trial for purely commercial reasons is not permissible in New Zealand.

**Summary of outstanding ethical issues**

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

1. The Committee noted the coordinating investigator's Medical Protection Society certificate has expired and requested an updated version. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 17.6).*

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

1. Please include a statement advising that reimbursement will cover travel/parking expenses so participants understand what is covered and what is not.
2. Please include information explaining that the physical body hair checks include pubic hair. Please include a statement advising that draping or a chaperone will be offered.
3. The Committee requested a proof-read of te reo Māori words used in the sheets, specifically to check for correct macron use.
4. The Committee requested the Researcher adapt the information in the [HDEC contraceptive template.](https://ethics.health.govt.nz/assets/Uploads/HDEC/templates/participant-information-sheet-consent-form-template-reproductive-risks-v.4.0-april2023.docx)
5. Please change 'may' to 'will' in the sentence on notifying the participant's GP after obtaining consent.

**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)*
* please provide evidence of current professional indemnity for the coordinating investigator *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 17.6).*

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| **7**  | **Ethics ref:**   | 2023 FULL 15583 |
|   | Title:  | Characteristics of Spontaneous Venous Pulsation (SVP) and its relationship to other physiological parameters. |
|   | Principal Investigator:  | Dr Kelechi Ogbuehi |
|   | Sponsor:  | ODocs Eye Care through The University of Otago |
|   | Clock Start Date:  | 25 May 2023 |

Dr Kelechi Ogbuehi 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.

Mr Ewe Leong Lim declared a potential conflict of interest. Mr Lim relinquished voting rights and did not participate in the discussion of the application. Quorum was maintained for the duration of the discussion.

**Summary of resolved ethical issues**

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

1. The Committee queried the involvement of the manufacturer in the data analysis. The Researcher stated the company would not be involved in the analysis and would not have veto power or control over publication.
2. The Committee noted an overseas collaborator would repeat the study in Australia. The Committee requested confirmation that identified data from the study would not be sent. The Researcher confirmed the only access to identified data would be for staff working in the coordinating investigators office and oDocs would receive coded data only.
3. The Committee recommended the study be revised to only include adults unless data from children is genuinely needed.

**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 who owned the investigational product. The Researcher stated it belonged to oDocs Eye Care and is contracted for use through the University of Otago. The Committee requested the researcher obtain local sponsor authorisation from the University of Otago in the application form for the resubmission. (*HDEC Standard Operating Procedure*, para 175).
2. The Committee noted this is a commercially sponsored study and evidence of ACC-equivalent insurance would be required from the sponsor. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 17.1).*
3. The Committee requested the Researcher adapt the [HDEC Data Management Plan template](https://ethics.health.govt.nz/assets/Uploads/HDEC/templates/HDEC-data-only-management-template-Nov2022.docx) as this contains all the information required to comply with Chapter 12 of the National Ethical Standards. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15 – 12.15a).*
4. The Committee requested the board of the company sign off as global sponsor. The Researcher stated it was a small company with only a few employees but could find someone other than the company founder to sign the authorisation.
5. The Committee requested the Researcher provide additional information on the statistical prevalence in Māori when completing the cultural section in the resubmission. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 3.1).*
6. Please detail the recruitment strategy, noting that preference should be given to those receiving a forthcoming appointment for lumbar puncture, rather than those being diverted to neurology in a medical emergency. This will ensure that participants have sufficient time to reflect on participation and discuss with others. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.4).*

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. The Committee requested the Researcher adapt the [HDEC Information Sheet template](https://ethics.health.govt.nz/assets/Uploads/HDEC/templates/participant-information-sheet-consent-form-template-v5.0april2023.doc) as this contains all the information required to comply with Chapter 7 of the National Ethical Standards. The Committee requested information differentiating between what is standard of care for a lumbar puncture and what is additional for the research.
2. Please undertake a review for repetition.
3. Please include a lay-friendly title for the study.
4. Please include a clear description of the investigational procedure being studied and distinguish those procedures clearly from the standard of care procedures that the participant would receive outside of the study.
5. Please include lay-friendly descriptions for clinical and technical terms which may not be readily understood by a lay reader (e.g. intra ocular pressure, intracranial pressure, clinical parameters, retinal fundus image, OCT scan).
6. Please include information on what AI technology will be used in the study.
7. Please state what health data the study will collect.
8. Please state whether video or image of the retinal fundus will identify the participant. Please include a description of what will be recorded.
9. Please include a description of the commercial relationship between the study coordinator and the study.
10. Please revise the statement on withdrawal as participants in New Zealand may withdraw verbally and it is not required to be written.
11. Please incorporate the ACC compensation section from the HDEC template.
12. Please state what eyedrops will be used and include any potential risks associated with their use.
13. Please elaborate on what additional research tests may be done with participant data on page 4.
14. Please separate information discussing compensation from the sentence describing voluntary participation.
15. Please include a statement advising that once the data analysis has begun participant data cannot be withdrawn.
16. Please include contact details for study staff as per the HDEC template.
17. Please clarify whether data will be de-identified or anonymised as both terms are used.

**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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| **8**   | **Ethics ref:**   | 2023 FULL 17999 |
|   | Title:  | EVOLUTION (EValuating glucose contrOL Using a next generaTION automated insulin delivery algorithm in patients with type 1 and type 2 diabetes) |
|   | Principal Investigator:  | A/Prof. Martin de Bock |
|   | Sponsor:  | Insulet Corporation |
|   | Clock Start Date:  | 25 May 2023 |

Dr Tom Wilkinson and Dr Trang Ly 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 why the confinement phase of the study would take place in a hotel instead of a clinical trial unit. The Researcher explained most diabetes patients can manage episodes of hypoglycaemia themselves and would be wearing continuous glucose monitors so a hospital setting would not be required. The Researcher confirmed they would be on-site and as a low glucose event develops over time the monitoring system would send an alert to the study team. The Researcher confirmed the device would operate for 24 hours a day and could respond to alerts in the 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 device would be returned at the end of the study, and this is a recurring problem with diabetes device research. The Researcher acknowledged this issue and explained continuous monitoring devices are not funded in New Zealand and the study device is not commercially available yet. The Researcher stated the importance of studies such as this in working toward getting these devices funded. The Committee queried whether the study could provide a device that is available on the market to participants at the end of the study. The Researcher stated they were exploring this option but as the company does not have a commercial footprint in New Zealand this cannot be guaranteed. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 10.15-10.17).*
2. The Committee queried whether a specific hotel had been selected and what implications this would have for the hotel (e.g. whether it is a valid locality for a medical experiment and if its insurance would cover this). The Researcher stated the hotel design has been used overseas and while they have a preferred hotel in mind they have not made the booking yet. The Committee requested the Researcher develop a document to detail contingencies of adverse events and how the study team will respond. The Committee requested this include a detailed safety protocol on how the hotel would operate as a site (including hazards such as fire or earthquake). The Committee requested the hotel review this document to ensure it is an appropriate location to conduct the trial. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 11.25).*

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

1. Please correct page numbers throughout the document (as they currently reset to page 1 at each section).
2. Please remove the sentence stating "Representatives of the sponsor may attend the hotel study (phase 3).
3. Please state whether participants may invite a support person to join them for their stay in the hotel.
4. Please remove NuvaRing from the contraception section as this is no longer available in New Zealand.

**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 submit a safety plan for conducting the trial on-site at a hotel *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 11.25).*
5. Please obtain authorisation from the chosen hotel to confirm the site is suitable to conduct the study (*HDEC Standard Operating Procedure*, para 175).

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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| **9**  | **Ethics ref:**   | 2023 FULL 16663 |
|   | Title:  | PARAGON-2: A phase 2 study of the combination of letrozole plus alpelisib and letrozole plus ribociclib as treatment for hormone resistant or metastatic gynaecological cancers |
|   | Principal Investigator:  | Dr Michelle Wilson |
|   | Sponsor:  | University of Sydney |
|   | Clock Start Date:  | 25 May 2023 |

Dr Michelle Wilson, Ms Sophie Goodger and Ms Azmeena Sajid 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 noted the primary purpose of the study was not for the principal benefit of the manufacturer and was satisfied the study was investigator-initiated.
2. The Committee queried whether continued access would be provided to participants who benefitted from the study treatment. The Researcher stated their understanding was participants could remain on treatment for as long as it was providing a benefit.
3. The Committee queried whether this would be framed as an open-label extension study or simply provide extended access. The Researcher stated they were uncertain at this stage. The Committee noted if it develops into an open-label extension study information regarding this can be submitted via the amendment pathway.

**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 an update to the protocol and participant information sheet to include a description of what will happen with samples and information taken from individuals who fail screening (e.g. whether they will be destroyed or used in the analysis). *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17).*
2. The Committee requested the Researcher obtain locality approval from the University of Auckland in the EthicsRM system. (*HDEC Standard Operating Procedure*, para 175).
3. The Committee queried whether participants would be reimbursed for any transport or parking costs. The Researcher stated they would intend to but would need to explore whether the budget would allow it. The Researcher agreed to investigate alternative funding sources to secure petrol vouchers. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 11.20a).*

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

1. The Committee noted two paragraphs on page 6 discussing future extended research on samples are repetitive and can be simplified. The Committee noted advice further in the sheet on tumour testing risks. Please include a statement on page 6 advising that any future research on samples is optional and will be subject to a separate consent.
2. Please revise the statement on SCOTT approval to clarify that the drug has previously received approval.
3. Please remove the reference to blood volume in teaspoons and provide a value in millilitres.
4. Please insert a statement advising there will be a questionnaire that contains questions that may cause distress.
5. Please clarify the exceptional circumstances in which participants in the Canterbury region would need to travel to the Christchurch site on page 5.
6. Please clarify in the table on page 3 which procedures are standard of care and which are for the research study only. The type of procedure and the order in which they are performed could affect decision-making on part of the potential participant.
7. Please clarify if existing recent biopsies (as opposed to new biopsies) may be used for screening purposes and/or main study procedures.

**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).*
* please obtain locality authorisation. (*HDEC Standard Operating Procedure*, para 175).
* please investigate whether reimbursement is feasible. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 11.20a).*

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| **10**   | **Ethics ref:**   | 2023 FULL 15319 |
|   | Title:  | GO44010: A study to evaluate the safety and activity of RO7496353 in combination with Atezolizumab or Nivolumab with or without SOC chemotherapy in solid tumours. |
|   | Principal Investigator:  | Dr Peter Fong |
|   | Sponsor:  | PPD Part of Thermo Fisher |
|   | Clock Start Date:  | 25 May 2023 |

Dr Peter Fong and Ms 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 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 screening process was extensive and queried what happens to screen failures. The Committee queried whether a sequence to limit the burden and exclude participants who fail the screen early is possible. The Committee noted the study documentation does not allow participants who fail the screen to consent to the use of their information and samples. The Researcher stated the consent form presumes the participant will enter into the main study. The Researcher explained the purpose of the screening phase was to determine whether it would be safe for the participant to enter the trial or not. The Researcher stated the data obtained in the screening phase would not be used in the study analysis, but they may look at reasons for failure to identify common themes. The Committee requested additional information be added to the participant information sheet to advise participants who fail the screening that their data will be kept unless they request its removal. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15).*
2. The Committee queried whether the screening biopsy is mandatory or optional as some participants may have archived biopsy tissue and some may not. The Researcher stated if archival tissue is available, they would seek consent to use it and if not would make a clinical determination whether a biopsy is necessary. The Researcher agreed to update the information sheet to make this process clear for participants. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15).*
3. The Committee queried whether samples could be returned to the participant. The Researcher stated if a biopsy was taken, and the participant requested this be returned it would be. The Committee requested information explaining this is added to the participant information sheet. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15).*
4. The Committee noted page 77 of the protocol stated screen failure samples may be used and queried what tests they may be used for. The Researcher stated they would need to clarify this with the Sponsor. The Committee requested information regarding any possible uses be added to the information sheet. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15; 14.16-14.17).*
5. The Committee noted the section on genome analysis on page 6 of the PIS states that heritable studies will not be undertaken but the section on handling on page 13 states there will be. The Committee requested a clarification on whether whole genome sequencing is mandatory or if only circulating tumour DNA will be analysed and to update the information sheet accordingly. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15).*

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

1. The Committee noted is it not clear which of the procedures are standard of care and which are additional research elements in the table of procedures and requested a revision to make this clear.
2. The Committee requested the Researcher check whether the sheet includes the latest cultural statement from Auckland City Hospital.
3. Please state how many humans have received the investigational product in previous trials on page 2.
4. Please change the reference to 'research study' on page 3 to 'clinical trial'.
5. Please revise the phrase on page 6 'cancer and other diseases and possible links among diseases' which edges toward future unspecified research. The Committee requested this be limited to specifically defined purposes (e.g. 'this type of cancer").
6. Please remove NuvaRing from the contraception section as this is no longer available in New Zealand.

**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 Ms Joan Petit.

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| **11**  | **Ethics ref:**   | 2023 FULL 17907 |
|   | Title:  | BRN-002 in Adult Participants with High-Risk Atherosclerotic Cardiovascular Disease or Homozygous Familial Hypercholesterolemia |
|   | Principal Investigator:  | Mr Andrew Edwards |
|   | Sponsor:  | PPD Ltd, part of Thermo Fisher |
|   | Clock Start Date:  | 25 May 2023 |

Mr Andrew Edwards, Professor Richard Stubbs and Ms Katelyn Diffin 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 noted questionnaires participants would complete may indicate distress and a referral would be made. The Committee queried whether the questionnaires would be reviewed in a timely manner to respond to participant distress. The Researcher confirmed participants would be seen regularly and on each occasion the information would be reviewed.

**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 11 of the information sheet indicated participants were responsible for their own tax. The Committee queried whether the site could withhold tax so the burden is not on participants. The Researcher stated they were in discussion with Inland Revenue on this issue as participants are neither contractors nor employees. The Committee requested an update on this process. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 11.20a).*
2. The Committee noted page 4 advised that alcohol breath testing may occur at any time. The Committee queried whether alcohol consumption was prohibited. The Researcher stated it was not prohibited but cannot be consumed within eight hours preceding a dose. The Researcher agreed to revise the statement to clarify. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15).*
3. The Committee queried the identifiability of photos of the eyes. The Researcher stated the photographs would be cropped in such a way to only show the eye area and not the whole face. The Committee requested information regarding this is added to the data management plan. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15).*

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

1. The Committee noted the information about Scout Clinical having access to identifiers was under the 'Māori sovereignty' section and should be moved.
2. Please update the table on page 7 to make clear what is mandatory and what are optional extras.
3. Please include text on the history of BRN002 as being part of other drugs and having a known safety profile to reassure participants on page 2.
4. Please include the number of New Zealand participants to the worldwide value on page 2.
5. Please remove the clause stating participants cannot discuss the trial or post about it online and instead state this is discouraged.
6. Please advise participants that if they are in receipt of benefit or allowance, their usual payments may be affected by the study payment. Please also clarify if participants must be eligible to work in New Zealand in order to participate.

**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 Kate O'Connor and Dr Amber Parry-Strong.

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| **12**   | **Ethics ref:**   | 2023 FULL 17878 |
|   | Title:  | R7544-HV-22109: A study to evaluate REGN7544 in healthy participants for the potential treatment of hypotension, hypovolemia and other related disorders |
|   | Principal Investigator:  | Dr Chris Wynne |
|   | Sponsor:  | Regeneron Pharmaceuticals |
|   | Clock Start Date:  | 25 May 2023 |

Dr Chris Wynne and Ms Holly Thirlwall 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 noted the Covid vaccine is referenced in study documentation and queried whether this should be expanded to include others such as the flu vaccine. The Researcher confirmed there is a typical stand-down period for all medications which would include other vaccines.
2. The Committee queried whether participants would be given instruction if they became hypertensive. The Researcher confirmed full instructions regarding any management would be provided and a doctor would be on-call 24 hours a day.
3. The Committee noted participants cannot take any medication that may increase blood pressure and queried whether this included the contraceptive pill. The Researcher stated there is a requirement for the medication to be stable for a period of time and potential participants would need to meet the standard blood pressure criteria on the contraceptive.

**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 it is acceptable to state the study was reviewed and approved by HDEC in advertising material but requested the HDEC logo is not included.
2. The Committee cautioned against use of the word 'treatment' in the radio script and requested an alternative word is used in advertisement material.
3. The Committee noted a study codename is useful for administrative purposes and requested the Researcher notify the HDEC once a codename is available.

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

1. The Committee noted the consent form introduces the term 'personal data' but the information sheet refers to 'identifiable', 'deidentified' and 'coded' data. The Committee requested a revision for consistency.

**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).*
* please update the study advertisement *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 11.12).*

**General business**

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

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| **Meeting date:** | 04 July 2023 |
| **Zoom details:** | To be determined |

 No members tendered apologies for this meeting.

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.

The meeting closed at 6:00pm.