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| **Committee:** | Southern Health and Disability Ethics Committee |
| **Meeting date:** | 08 September 2020 |
| **Meeting venue:** | Zoom Video Conference |

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| **Time** | **Item of business** |
| 11:00am | Welcome |
|  | Confirmation of minutes of meeting of 11 August 2020 |
| 11:30am | New applications (see over for details) |
|  | i 20/STH/144  ii 20/STH/140  iii 20/STH/135  iv 20/STH/136  v 20/STH/137  vi 20/STH/138  vii 20/STH/134  viii 20/STH/139  xi 20/STH/130  x 20/STH/141  xi 20/STH/142  xii 20/STH/72 |
| 4:45pm | General business:  Noting section of agenda |
| 5:00pm | Meeting ends |

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| **Member Name** | **Member Category** | **Appointed** | **Term Expires** | **Apologies?** |
| Dr Sarah Gunningham | Lay (other) | 05/07/2016 | 05/07/2019 | Present |
| Dr Devonie Waaka | Non-lay (intervention studies) | 18/07/2016 | 18/07/2019 | Present |
| Assc Prof Mira Harrison-Woolrych | Non-lay (intervention studies) | 28/06/2019 | 28/06/2020 | Present |
| Dr Paul Chin | Non-lay (intervention studies) | 27/10/2018 | 27/10/2021 | Present |
| Professor Jean Hay-Smith | Non-lay (health/disability service provision) | 31/10/2018 | 31/10/2021 | Apologies |
| Mrs Helen Walker | Lay (consumer/community perspectives) |  |  | Present |
| Mr Dominic Fitchett | Lay (the law) | 05/07/2019 | 05/07/2022 | Present |
| Dr Pauline Boyles | Lay (consumer/community perspectives) | 05/07/2019 | 05/07/2022 | Present |

## Welcome

The Chair opened the meeting at 11:00am and welcomed Committee members, noting that apologies had been received from Professor Jean Hay-Smith.

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 11 August 2020 were confirmed.

## New applications

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| **1** | **Ethics ref:** | **20/STH/144** |
|  | Title: | Clinical Evaluation of the Aatru npSIMS System |
|  | Principal Investigator: | Assoc Prof Jon Mathy |
|  | Sponsor: | Avania Clinical |
|  | Clock Start Date: | 27 August 2020 |

Jon Mathy, Robin Martin and Audra Wilson 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 Study

1. The purpose of the proposed study is to assess the suitability, safety and effectiveness of the non-electric NPWT device npSIMS (negative pressure Surgical Incision Management System) developed by Aatru Medical, for the management of closed surgical wounds.
2. Surgical procedures will be performed in the same way that any patient would have their surgery; there will be no difference in this procedure whether participants are on the study or not. Small, single use disposable electromechanical NPWT systems allow the patients to move around and have been used for treating these closed incision wounds, however due to the cost of these electromechanical devices, they are only used on high risk wounds.
3. The npSIMS is non-electric and uses a chemical reaction pump to have a similar effect to the electromechanical devices but is approximately 10-20% of the cost of these other devices. This study device may promote wound healing through the removal of excess fluid, infectious material and tissue debris.
4. The study will include up to 30 study participants who will participate for approximately 30 days during post-surgery follow-up. Eligible participants will have a surgical incision between 5 and 13 cm long, that will be closed with sutures or staples.
5. The surgical incision will be closed and treated post-operatively with the study device.
6. The participant will be asked to complete several study evaluations and complete a questionnaire (POSAS)related to their wound and the use of the npSIMS device and asked to rate their pain out of 10 (NRS).
7. The participants will have a phone/video follow up contact at Days 1,2,3,4,5 & 6 post surgery. At Day 7 a clinic visit will be performed and at Day 14 and 30 a telephone/video follow up will occur.

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 recruitment would occur. The Researchers stated that the investigator will introduce the study to potential participants. The Committee requested greater separation between recruitment and lead investigators to minimise risk of undue influence over participants. The Researchers stated that they will do so by having the clinic receptionist introduce the study to potential participants.
2. The Committee queried whether any animal or skin models had been tested for the study product. The Researchers stated that negative pressure therapy is well researched, however the study device delivers the therapy via chemical reaction rather than any mechanical movement that requires electricity.
3. The Committee queried how the study intervention differs from standard of care. The Researchers stated that the procedure itself is standard of care and the experimental aspect of the procedure is the new delivery system only.
4. The Committee queried whether there was any additional benefit from participating in the study. The Researchers stated that all who receive negative pressure therapy will experience benefits such as lower risk of surgical site infection, but there are no expected additional benefits to participants from using the study device instead of the standard care device.
5. The Committee queried who will manage clinical care of participants once the dressing has been applied. The Researchers stated that a research nurse follows up with the participant via phone, then the participant will visit the clinic on day 7; additionally the CI can be contacted at any time.
6. The Committee queried the role of the Sponsor in this study. The Researchers stated that Avania Clinical is the research organisation, Atrua Medical is Sponsor.
7. The Committee queried whether a formal internal DSMC or routine monitoring will be utilised. The Researchers stated that for suspected or confirmed adverse events, the primary contact person is the medical director of the Sponsor company, who is a medical monitor only.

Summary of outstanding ethical issues

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

1. Please review the study protocol and omit any sections (including literature references) that do not apply to the study described in the current HDEC application (please retain references relevant to this study)..
2. Please amend the protocol to remove any study procedures that are not planned for the study described in this HDEC application.
3. Please clarify the details of the Sponsor on study documentation.
4. Please clarify whether Avania Clinical is covered by Atrua Medical’s insurance policy for this study.
5. Please clarify that locality approval is from Counties Manukau DHB and not a primary health centre.
6. Please ensure that a formal data safety monitoring committee is convened to review safety and other applicable data during the pause in recruitment, as per any first-in-humans trial.

The Committee requested the following changes to the Participant Information Sheet and Consent Form:

1. Please amend the PIS to ensure that the participant’s GP will routinely be informed of their patient’s participation.
2. Please replace technical language with lay-friendly language where possible.
3. Please include a graphic demonstrating the approximate mechanism of action for the study device.
4. Please ensure that wording is specific to this study and not generic.
5. Please remove any study procedures that are not planned for the study described in this HDEC application.
6. Please amend the start of the PIS to include that the proposed study is first in humans and a small feasibility study.
7. Please clarify that there may be no benefit to participants for joining the study.
8. Please include brief information from previous studies.
9. Please update the contact details for adverse events.
10. Please amend the Risks section of the PIS to more accurately reflect the risks as described in the study protocol.
11. Please clarify in the PIS whether photographs will be discarded or kept with other study data and whether photos will be potentially identifiable (i.e. will contain the participants face or other distinguishable features).

Decision

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

* Please review the study protocol and omit any sections (including literature references) that do not apply to the study described in the current HDEC application (please retain references relevant to this study).
* Please amend the protocol to remove any study procedures that are not planned for the study described in this HDEC application.
* Please clarify the details of the Sponsor on study documentation.
* Please clarify whether Avania Clinical is covered by Atrua Medical’s insurance policy for this study.
* Please clarify that locality approval is from Counties Manukau DHB and not a primary health centre.
* Please ensure that a formal DMSC conducts the review during the pause in recruitment as per any first-in-humans trial.
* Please amend the Participant Information Sheets and Consent forms, taking into account feedback provided by the Committee (above)

After receipt of the information requested by the Committee, a final decision on the application will be made by Mr Dominic Fitchett and A/Prof Mira Harrison-Woolrych.

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| **2** | **Ethics ref:** | **20/STH/140** |
|  | Title: | Physiological pain regulation and the buffering effect of social support in patients with chronic pain |
|  | Principal Investigator: | Dr Maria Kleinstaeuber |
|  | Sponsor: | University of Otago |
|  | Clock Start Date: | 27 August 2020 |

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 Study

1. Chronic pain leads to alterations in the cardiac system, associated with prolonging chronic pain distress, further medical conditions and maladaptive pain management. A better understanding of the underlying mechanisms and moderating factors could help optimise patients’ treatment and consequently improve their pain coping and general health status.
2. The proposed study seeks to investigate cardiovascular changes in patients with chronic pain compared to healthy controls, using an experimental approach with acute pain stimulation.
3. In particular, the Researchers are interested in the buffering effect of social support on pain perception and stress reactivity in patients with chronic pain compared with healthy controls. Social support will be therefore manipulated during the experimental procedure.

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 stated that there was insufficient justification as to why deception of participants is necessary to answer the study question, e.g. participants could be informed that a research assistant will be present without necessarily stating why they were present.
2. The Committee stated that the application describes social support while the peer review suggests verbal support may be a more appropriate descriptor. Please reconcile these.
3. Please address the suggestions made in the peer review.
4. Please reframe the proposed study as an intervention design (application form indicated observational design).
5. Please amend the Risks section of the PIS to clarify that there is a small risk of vasovagal reaction to the intervention.
6. Please amend the Participant Information Sheet (PIS) using the template PIS found on the HDEC website, and ensure that the study protocol aligns with the information in the updated PIS.
7. Please consider resubmitting this application to the Southern HDEC, as they are familiar with the study proposal.

Decision

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

* Where deception and/or concealment are part od the research design, researchers must justify this choice to an ethics committee, according to the following critera… (Standard 7.32; see also Standards 7.33 – 7.37, National Ethical Standards for Health Research and Quality Improvement, 2019 - https://ethics.health.govt.nz/home under Quick Links section )

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| **3** | **Ethics ref:** | **20/STH/135** |
|  | Title: | GWAS of asthma in Niue Islanders |
|  | Principal Investigator: | Dr. William Abbott |
|  | Sponsor: |  |
|  | Clock Start Date: | 20 August 2020 |

Dr William Abbott 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 Study

1. A collection of 492 DNA samples from people of Niue Island ethnicity was obtained between 1997 and 1999. The purpose of the collection was to identify asthma susceptibility genes in the Niue Island population. 184 subjects had atopic asthma, 29 had non-atopic asthma, 220 subjects have never had asthma and there were 59 subjects in whom it was not possible to assign an asthma phenotype.
2. There were 100 control subjects aged > 40 years who have never had either childhood-onset or adult-onset asthma.
3. An aliquot of 3ug of this genomic DNA from each subject will be sent to the QIMR Berghofer Medical Research Institute who have expertise in whole genome screening.
4. Researchers will use a GSA array to type 749,000 SNP loci.
5. Statistical analyses of the genetic data will be performed by a co-investigator (Dr. David Duffy) who is an internationally recognised expert on asthma genetics.

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 the proposed secondary use of human tissue aligns with the original consent that they were attached to. The Researcher stated that financial and technological factors limited analysis when the samples were initially analysed, however now that resources are available the Researcher would like to conduct further analysis.
2. The Committee queried whether an additional member of the Research team could be sought to engage in reconsenting participants. The researcher stated that funds were not available for this.
3. The Committee queried whether the overseas laboratory would be retaining any data. The Researcher confirmed that they would not.
4. The Committee queried what further analysis prior to the destruction of samples would entail. The Researcher stated that they would perform any further analysis 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 stated that the original consent explicitly stated that samples will not be sent overseas, therefore they cannot approve the proposed study in its current form.
2. The Committee stated that many of the original tissue donors were children who are now over the age of consent, should be reconsented for continued storage of their tissue samples, and should be reconsented for having tissue samples sent overseas for analysis.

Decision

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

* Please provide justification for the Committee to grant a waiver of consent for secondary use (re-use) of human tissue (Standards 7.49 – 7.56)

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| **4** | **Ethics ref:** | **20/STH/136** |
|  | Title: | CVBT |
|  | Principal Investigator: | Mr. Haemish Crawford |
|  | Sponsor: | UIHC |
|  | Clock Start Date: | 20 August 2020 |

Haemish Crawford 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 Study

1. Infantile (early-onset) idiopathic scoliosis (IIEOS) is a relatively rare disease affecting 40 of 100,000 children. Defined as an idiopathic curve measuring >20 degrees in those less than 3 years of age, the natural history of IIEOS is variable with some curves resolving spontaneously and others quickly progressing to such a degree that severe pulmonary disease, and shortened life span may occur.
2. Casting, and less frequently bracing, have been used to treat this condition in hopes of resolving the curve or at least delaying surgical interventions. Growth-sparing surgery can minimize the deformity while maximizing thoracic volume and pulmonary function, however treatment typically spans several years, complications are not uncommon, and most patients still require definitive spinal fusion when they approach skeletal maturity. Hence, the need for effective early treatment.
3. Multiple retrospective evaluations of casting for EOS have been published but the quality of these studies, and the resultant body of evidence is limited by use of retrospective designs and the inclusion of scoliosis of mixed etiology, varying treatment protocols, length of follow-up and varying definitions of success and failure.
4. When resolution is not achieved, palliation (delay in the need for surgery) is frequently achieved, leading to the now widespread use of casting in this population.
5. Although casts are non-invasive, the serial application of casts is not without risks. These concerns have led to increased interest in the use of bracing as an alternative to casting for EOS.
6. Both full- and night-time bracing are being prescribed, but to date only four small case series evaluating modern bracing techniques exist. There is a need for stronger evidence regarding the comparative effectiveness of these two approaches.

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 taking patient preference into account will result in bias and therefore mean that this study is not randomised. The Researcher stated that there is often difficulty in randomisation with children because the parents often introduce bias; many parents would prefer to choose rather than enrol in a RCT.
2. The Committee queried whether participants could continue for longer than the two-year follow-up if they wanted to. The Researcher stated that by then they will know which treatment is better, therefore it would not be ethical for the Researchers to let the participants continue on the inferior treatment.
3. The Committee stated that, should any participant stay in the study until they turn 16 years old, the Researchers should submit an amendment to reconsent them at that time.
4. The Committee queried whether the bracing is standard of care in New Zealand. The Researchers stated that a brace is offered if plaster is declined; one of the aims of the proposed study is to determine which is better.
5. The Committee queried whether the risk of undue influence on potential participants from the dual role of researcher and clinician could be mitigated by using a research officer or research nurse. The researcher stated that usually this elicits lower study numbers, due to the onus of extra work on staff who are not as invested in the project.
6. The Committee queried whether there is support for participants having trouble coping. The Researcher stated that participants fill out questionnaires in the clinic so that any issues can be followed up with them.

Summary of outstanding ethical issues

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

1. Please provide a fulsome independent expert peer review, either from the funding application process or using the HDEC peer review template.
2. Please amend the data management plan so that data from people who do not want to participate is excluded.
3. Please ensure Māori consultation is undertaken.

The Committee requested the following changes to the Participant Information Sheet and Consent Form:

1. Please amend the PISCFs to replace the term “subjects” with “participants”.
2. Please amend the PIS to state that photographs will be taken as part of the research, how they will be deidentified and whether they are uploaded to the study database or registry.
3. Please review the data storage plan in the PIS and make language more lay-friendly where possible.
4. Please amend the PIS to clarify who may be given access to study information post-withdrawal.
5. Please amend the risks of data collection as per the new data management section of the HDEC PIS template.
6. Please amend the PIS to state that the spine registry is based overseas, including where it is based.

Decision

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

* Please provide a fulsome independent expert peer review, either from the funding application process or using the HDEC peer review template.
* Please amend the data management plan so that data from people who do not want to participate is excluded.
* Please provide evidence of Māori consultation.
* Please amend the Participant Information Sheets and Consent Forms, taking into account feedback provided by the Committee (above)

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| **5** | **Ethics ref:** | **20/STH/137** |
|  | Title: | LIFE -BTK |
|  | Principal Investigator: | Associate Professor Andrew Holden |
|  | Sponsor: | Abbott Australia Pty Ltd |
|  | Clock Start Date: | 20 August 2020 |

Elleni Takele 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 Study

1. Peripheral vascular disease (PVD) is a narrowing of the arteries that carry blood to the leg, which can result in pain or discomfort when walking, exercising, or at rest.
2. The most common cause of PAD is a build-up of plaque in the walls of the leg arteries restricting oxygen rich blood flow to the legs. These narrowings can occur in different arteries such as the thigh, calf and foot arteries.
3. Angioplasty is most commonly used to treat PAD, which involves inflating a balloon to stretch open the area of narrowing in the blood vessel to increase blood flow. The arteries in the calf can be quite difficult to treat as they are quite small arteries. Although angioplasty provides immediate success it has not shown the best long term results in the calf arteries.
4. If required, a stent (small metal tube) can be permanently placed into the artery. The stent pushes on the artery walls like scaffolding, holding it open so blood can flow through. This is not preferred as the permanent nature of stents can contribute to problems such as blood clots, restriction of the artery moving naturally, and complications if the artery re-narrows with the stent inside.
5. The study device is ESPRIT BTK Everolimus Eluting Bioresorbable Scaffold System (ESPIRIT BTK). ESPIRIT BTK is intended to resorb into the body after a period of time, thereby providing the necessary support to the artery after angioplasty and eliminating some of the problems associated with permanent stenting.
6. The ESPIRIT BTK is coated with the drug Everolimus, which has been proven to slow the growth of cells in the artery wall and prevent or slow down artery re-narrowing. This study will evaluate the safety and performance of the ESPIRIT BTK in patients with PAD in the calf arteries.
7. Participants will be randomly assigned to either angioplasty with a balloon or the ESPIRIT BTK. They will be followed up for 5 years post procedure. The study will enrol up to 225 participants across 50 sites worldwide.

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 the proposed study was first-in-humans. The Researcher stated that it is not for the device, but it is for the application of the stent below the knee.
2. The Committee queried whether an extra blood test (in addition to standard of care) would be needed from participants. The Researcher stated that generally this would not be necessary, and if it is a protocol deviation would be submitted.
3. The Committee queried what safety protocols are in place for participants when answering questions on wellbeing. The Researcher stated that standard referral procedures would be used as per any acute medical problem; responses of concern will be detected as a Researcher will be present for the completion of the questionnaires and will be in discussion with the participant at the same time.
4. The Committee queried whether any clinicians are approaching potential participants. The Researcher stated that a coinvestigator will introduce the idea of the study to potential participants then follow up with them, so no cold calling of potential participant will occur.
5. The Committee queried the circumstances of live-streaming the procedure to the sponsor. The Researcher stated that this would not be recorded, and if the sponsor wants to record then an amendment will be submitted to the HDEC; additionally, the participant can choose not to have the Sponsor watching, however the Sponsor will make the final decision whether to enrol participants who do not agree to remote observation..
6. The Committee queried a comment in the application that a stent currently has CE approval for use in arteries below the knee, and whether that is the study stent. The Researcher confirmed that it is, however the stent is used in this study for a different application (i.e. with a different drug).

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 stated that the Researcher should confirm with SCOTT as to whether the study should be reviewed by SCOTT, as the device contains a medication.
2. The Committee stated that the Researchers should clarify whether the insertion of the study stent and the measurement of participant reaction will extend the procedure time.
3. Please clarify and align what Class the study device is across all study documentation.
4. Please provide response to peer review comments regarding the estimated 10% drop-out rate, and whether this is realistic.
5. Please amend the protocol to include the data management plan, as per the application form.
6. Please amend the insurance certificate to include a definition of the policy territory.

The Committee requested the following changes to the Participant Information Sheet and Consent Form:

1. Please amend the PIS to remove the section stating that the sponsor can terminate the study at any stage, as health research cannot be terminated for commercial reasons in New Zealand.
2. Please amend the PIS to include a lay- friendly title.
3. Please amend the PIS to clarify that screen failure information will be deidentified and sent to the sponsor.
4. Please clarify the language regarding exclusion criteria for drugs that participants are already taking.
5. Please amend the table on page five of the PIS to clarify that questions will also cover depression and anxiety.
6. Please amend the PIS to include assurance of the privacy of the participant with regards to the sponsor watching the live stream of the procedure.
7. Please amend the risks section of the PIS to state that there is a greater risk compared with the existing procedure, as the study procedure involves more time in surgery.
8. Please amend the risks section to use risk frequencies where appropriate, and remove repeated risks.
9. Please review the PIS to ensure that study device acronyms are consistent.
10. Please amend the PIS to explain the term “platinum radio opaque marker” in lay-friendly language.
11. Please amend page 8 of the PIS to state that the barrier method of contraception should be used in addition to other methods.
12. Please amend pages 8-10 of the PIS to refer to Southern HDEC, rather than Northern B HDEC.
13. Please amend the PIS to include a data management section as per the HDEC template PIS (.https://ethics.health.govt.nz/guides-templates-forms-0 ).

Decision

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

* Please confirm with SCOTT as to whether the study should be reviewed by SCOTT.
* Please clarify whether the insertion of the study stent and the measurement of participant reaction will extend the procedure time.
* Please clarify and align the study device Class across all study documentation.
* Please provide response to peer review comments on the sample size allowance for a 10% drop-out rate.
* Please amend the protocol to include a data management plan, as per the application form.
* Please amend the insurance certificate to include a definition of the policy territory.
* Please amend the Participant Information Sheets and Consent Forms, taking into account feedback provided by the Committee (above)

After receipt of the information requested by the Committee, a final decision on the application will be made by Mr Dominic Fitchett and Dr Paul Chin.

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| **6** | **Ethics ref:** | **20/STH/138** |
|  | Title: | Dignified Dying, Reality of Human Mortality- the New Zealand context |
|  | Principal Investigator: | Mrs Inderpreet Kaur |
|  | Sponsor: | Massey University |
|  | Clock Start Date: | 20 August 2020 |

Inderpreet Kaur and Iain Laird 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 Study

1. This research will be a specific component of a large international cohort study (iLive) that is currently being pursued by ten European Union countries and led by Erasmus MC in The Netherlands.
2. The project aims to gain a comprehensive insight into the concerns, expectations and preferences of terminally ill patients and their wider whanau; and to understand the cultural, socio-economic, gender and age-related variants that underpin these concerns, expectations and preferences. The aim is to study a cohort of 100 patients from the time of expected prognosis of 6 months or less and follow them through until they die and beyond. Data will be analysed against uniquely New Zealand concerns including a focus on Maori and Pacific island participants.
3. The data gained from this research will be aimed at: (a) Providing in-depth understanding of the concerns, expectations and preferences of dying patients and their formal and informal caregivers and; (b) Understanding the cultural, gender, age and socio-economic variance in these concerns, expectations and preferences.
4. The study population includes patients, their relatives and their attending physicians. Competent adult patients with an estimated life expectancy of six months or less are eligible, regardless of their diagnosis, gender, age, or place of residence or care. Relatives of participating patients are eligible to participate in the study if they are 18 years or older and provide informed consent to participate, and if the patient agrees. Relatives can be a family member, friend or other close relative. They must be aware that the patient is unlikely to recover from his/her disease. Attending physicians who recruit patients are participating by filling in a brief questionnaire about the medical characteristics of each patient who consents to participate.

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’ varying ability to consent will be managed. The Researcher stated that they are experience in aged care and will also encourage potential participants to pause and reschedule at any point in the interview process.
2. The Committee queried the relationship between the proposed project and the wider Sponsor project. The Researcher stated that the data collected in the proposed project will be used for a wider international study, but the analysis performed for this project will be separate from that analysis.
3. The Committee queried the draft protocol submitted for review. The Research stated that the protocol was still in draft due to numerous changes made by the Sponsor; the current version is the latest draft and any subsequent changes are expected to be minor.
4. The Committee stated that the questionnaires could be quite onerous to participants. The Researcher agreed and added that they are a requirement of the study sponsor, however the data can be collected over multiple sessions.

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 stated that several sections of the protocol must be completed, including the section on qualitative interviews. A final New Zealand protocol should be submitted for HDEC review.
2. The bereavement and physician questionnaires should be provided to HDEC for review.
3. Please clarify whether the Māori palliative care nurse recommends translated versions of study documents for participants.
4. Please add the HDEC template data management plan (found on the HDEC website) to the protocol.
5. Please amend study documents to reflect that health information will be stored for ten years.
6. Please clarify whether physicians will be participants, as referenced in the protocol.

The Committee requested the following changes to the Participant Information Sheet and Consent Form:

1. Please fully adapt the PIS to the New Zealand research setting.
2. Please amend the PIS to be more specific about why the potential participant is being approached about this study (i.e. more specific about the study topic of end of life).
3. Please provide information about any planned qualitative interviews in the PIS.
4. Please amend the PIS to include information about family members providing data.
5. Please provide a separate PIS for the relatives.
6. Please ensure the Relative PIS explicitly state that relatives will be asked to complete a bereavement questionnaire, following the primary participant’s death.
7. If physicians are confirmed to be participants in the research, please provide a separate PIS for physicians.

The Committee suggested that the Researcher resubmit their application to the Southern HDEC, as they are familiar with the project and will be able to take into account the application history when reviewing.

Decision

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

* Please submit a fulsome and complete study protocol (Standards 9.7 & 9.8, National Ethics Standards for Health and Disability Research and Quality Improvement, 2019).

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| **7** | **Ethics ref:** | **20/STH/134** |
|  | Title: | EmQuest |
|  | Principal Investigator: | Dr Michelle Wilson |
|  | Sponsor: |  |
|  | Clock Start Date: | 27 August 2020 |

Michelle Wilson 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 Study

1. Endometrial cancer is the most common gynaecological cancer in developed countries. Women who receive treatment in earlier stages of the disease may be cured, but live with the long-term sequelae of their treatment. Similarly, there are women with more advanced disease who will live with their cancer, as well as the associated treatment toxicities, for many years. Despite the large numbers of women affected, the impact of diagnosis and treatment on their ongoing health remains relatively undefined.
2. Previous studies indicate that the impact on quality of life varies widely. Many women suffer specific symptoms after treatment, including diarrhoea, urinary incontinence, lymphoedema, insomnia and problems with sexual intercourse.
3. There is little known currently about the symptom burden, and specific predictors of toxicity in this group of patients. We intend to address this lack of information by comprehensive collection of self-reported demographic, disease and treatment data and patient-reported outcome measures in an on-line survey across two domains – specific symptoms and quality of life. We will then aim to look for specific factors that predict for poor outcomes for women.
4. The proposed study is part of an international cross-sectional electronic survey, distributed by Gynaecologic Oncology professional societies and consumer groups.
5. The survey will collect data on baseline characteristics, including current health, treatment received, and time lapsed since treatment. It will then collect data using patient-reported outcome tools, over two domains: health-related quality of life and specific symptoms.
6. The survey has been reviewed by a consumer research panel through ANZGOG, for readability and any concerns the participants may have. No major concerns were raised, but minor changes have been made in response to their comments for clarity.
7. The questionnaire will be available for women to complete online for a minimum of six months.

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 there were other sites for this study. The Researcher stated that the study is already underway in Australia, while other sites have been delayed so far.

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 stated that cold calling potential participants may not be appropriate, and the Researcher should consider sending out letters or advertising by poster to let potential participants come to them. The Researcher stated that some support group websites have already posted about it; the Committee stated that this may be a useful forum to determine the best way to approach participants.
2. Please amend the protocol to ensure greater support is available to participants, who may become distressed as a result of their participation.
3. Please provide a copy of the peer review that led to the grant approval, or a peer review using the HDEC template.
4. Please amend the wellbeing questionnaire as it currently stated that answers will help the clinician know how the participant feels; this is not possible due to the anonymity of the survey.
5. Please clarify whether Māori support persons will include trained counsellors and adjust study documentation accordingly.

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

1. All the information that would be available in a PIS should also be available at the beginning of the anonymous online survey.
2. If the researcher is not able to link the PIS electronically to the start of the online survey, A PIS could be emailed to participants; if email address are not available, then a phone call should be made to obtain an email address to send the PIS to.
3. Please ensure that the PIS clearly states that answers cannot be withdrawn by the participant, as they are anonymous.
4. Please clarify in the PIS whether withdrawal from the survey when it is partially completed will result in retention of deletion of answers up to that point.
5. Please ensure that the PIS clearly states that support is available to participants and include New Zealand contact details for support.
6. Please ensure that it is stated at the beginning of the PIS that the survey is anonymous.

Decision

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

* Please submit a fulsome and complete study protocol (Standards 9.7 & 9.8, National Ethics Standards for Health and Disability Research and Quality Improvement, 2019).
* Please provide peer review of this study (Standards 9.25 – 9.32, National Ethics Standards for Health and Disability Research and Quality Improvement, 2019).

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| **8** | **Ethics ref:** | **20/STH/139** |
|  | Title: | Perispinal Entanercept in post stroke patients with moderate to severe disability |
|  | Principal Investigator: | Dr Nigel Gilchrist |
|  | Sponsor: | Florey Institute of Neuroscience and Mental Health |
|  | Clock Start Date: | 27 August 2020 |

Nigel Gilchrist and Deirdre Thompson 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.

A potential conflict of interest was raised by Dr Paul Chin, however upon further discussion no significant conflict was present with regards to this ethics application.

Summary of Study

1. The objective of this randomized clinical trial (n=170) is to test the safety and efficacy of administration of 25 mg perispinal Etanercept in improving patient reported outcomes at 28 days after treatment.
2. The Primary Hypothesis is that treatment with 25 mg perispinal Etanercept improves quality of life in stroke survivors.
3. The Secondary Hypothesis is that repeated administration of perispinal Etanercept 25mg leads to improved quality of life compared to a single administration.
4. This randomized clinical trial will include the following patients:
5. Patients with a history of acute ischemic or haemorrhagic stroke confirmed on imaging
6. Age ≥18 years-65 years at time of stroke
7. Moderate-to-severe disability resulting from stroke as defined by a modified Rankin scale of 3-5
8. Stroke occurred between 1 and 5 years before enrolment.
9. SF-36 score <95
10. Patient is able to complete the SF-36 questionnaire independently or availability of a relative or carer who is able to complete the SF-36 questionnaire on behalf of the patient
11. Consent can be obtained from the participant

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 it is possible for a participant to be randomised to placebo twice. The Researcher stated that this is possible.
2. The Committee queried whether, if there is a clear benefit towards the end of the study, the placebo group would be offered the active treatment once the study is completed. The Researcher stated that this will be offered, however it is not yet addressed in study documentation due to insufficient evidence.
3. The Committee queried whether anyone who cannot consent themselves will be included in the study. The Researcher stated that only those who are competent to consent will be included.
4. The Committee queried whether the target age range for the study may be too young. The Researcher stated that, as the study will also recruit individuals up to five years post-stroke with ongoing disability, that participants will be up to 70 years old when the study commences. Additionally, younger participants are preferred as advanced age tends to introduce a greater number of confounding variables.
5. The Committee queried why a subcutaneous injection into the neck is necessary for the administration of the study drug. The Researcher stated that this is a replication of the original study and clarified that there will be no direct injection into cerebral spinal fluid.
6. The Committee queried whether any tissue was being sent overseas. The Researcher confirmed that no tissue would be sent overseas.
7. The Committee queried whether doing nothing as control would be valid for the study versus administering a placebo injection. The Researcher stated that the injection was an important part of determining a placebo effect.
8. The Committee queried whether there was a risk to participants on coagulants. The Researcher stated that if a risk is identified in an individual participant, they will not receive an injection.

Summary of outstanding ethical issues

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

1. Please amend the protocol to remove the statement that consent can come from a responsible person, as proxy consent is not permitted in New Zealand.
2. Please provide information as to what health information will be accessed for the study.
3. Please provide HDEC with the full review that led to the study grant, or use the HDEC peer review template. Please ensure that justification for the use of a saline injection as placebo is included.
4. Please provide an updated insurance certificate that is New Zealand/site specific.

The Committee requested the following changes to the Participant Information Sheet and Consent Form:

1. Please include Hepatitis B and C as possible unexpected findings, as these will be screened for, and that these infections are notifiable diseases.
2. Please amend the PIS to ensure that it is specific to New Zealand participants, please refer to the HDEC PIS template for guidance.
3. Please state whether the study drug is approved in New Zealand for any indication.
4. Please explain what do to if participants become distressed while completing the study questionnaires.
5. Please provide information on the confidentiality of video recordings.
6. Please amend the contraceptive language to reflect the the contraception template found in the HDEC template PIS.
7. Please explain why researchers may contact participants after the study has ended.
8. Please include data management information, as found in the HDEC PIS template.
9. Please ensure the HDEC Consent Form template is used.
10. Please make it clear that withdrawal of consent does not need to be given in writing.

Decision

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

* Please amend the protocol to remove the statement that consent can come from a responsible person, as proxy consent is not permitted in New Zealand.
* Please provide information as to what health information will be accessed for the study.
* Please provide HDEC with the full peer review that led to the study grant, or use the HDEC peer review template. Please ensure that justification for the use of a saline injection as placebo is included.
* Please provide an updated insurance certificate that is New Zealand/site specific.
* Please amend the Participant Information Sheets and Consent Form, taking into account feedback provided by the Committee (above).

After receipt of the information requested by the Committee, a final decision on the application will be made by Dr Sarah Gunningham and Dr Paul Chin.

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| **9** | **Ethics ref:** | **20/STH/130** |
|  | Title: | Younger onset dementia diagnosis |
|  | Principal Investigator: | Dr Brigid Ryan |
|  | Sponsor: | University of Auckland |
|  | Clock Start Date: | 27 August 2020 |

Brigid Ryan and Maurice Curtis 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 Study

1. Younger onset dementia is defined as dementia with symptom onset before the age of 65. As a direct result of patients’ relative youth, younger onset dementia takes longer to diagnose than late onset dementia. Diagnosis of younger onset dementia often takes five years or longer and delayed diagnosis is widely accepted to be a major burden on patients, families, and caregivers.
2. Timely diagnosis is critical for access to dementia-specific services, successful clinical management, and patient and family wellbeing. It is therefore important to understand why diagnosis is delayed, and how it might be hastened.
3. In the proposed study, Researchers aim to identify factors determining the time to diagnosis for younger onset dementia in a New Zealand cohort. To this end, the diagnostic pathway will be mapped by collecting data from people with younger onset dementia and their care partners, and health professionals. Data will be collected via questionnaire and by reviewing medical records.
4. This research aims to identify modifiable factors that delay diagnosis in NZ and provide a starting point to facilitate timelier diagnosis of younger onset dementia.
5. The main objective of this study is to identify factors that increase the time to diagnosis of younger onset dementia in New Zealand.

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 competency to provide consent will be assessed. The Researchers stated that the individual’s care partner will be involved in supported decision making.
2. The Committee stated that the protocol implies that a support person is essential to participate and queried whether this was accurate. The Researcher stated that for early stage dementia patients they will be able to consent for themselves without support and any inaccuracies in their accounts can be verified through records; carer participation is not a requirement.
3. The Committee queried how deceased persons will be recruited into the study. The Researchers stated that only the care partner will participate in the study in these instances; they will also be the ones to give permission to access medical records, and will receive an extra questionnaire to complete.
4. The Committee queried whether someone trained in supported decision making is involved in the study. The researchers stated that there is not, however they are following the National Ethical Standards for Health and Disability Research and Quality Improvement, which state that limited risk scenarios do not always require clinical oversight.
5. The Committee queried whether identifiable data should be destroyed rather than stored for ten years with study data. The Researchers stated that the identifiable data held by Researchers are copies only, so data will not be lost if destroyed.

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 stated that a separate advertising poster should be created for the care partners of deceased dementia patients, to help ensure appropriate sensitivity to those individuals.

The Committee requested the following changes to the Participant Information Sheet and Consent Form:

1. Please amend the PIS to include more visual aids that may help the supported decision-making process.
2. Please amend the PIS to include the ACC statement found in the HDEC PIS template.
3. Please amend the PIS to include information on whether study data will be used for future research.
4. Please amend the PIS to include greater detail on what kind of information will be collected from loved ones and what records will be examined by the Researchers.
5. Please amend the PISCF for care partners with regards to withdrawal from the study, so that it reads that information about “me and the dementia patient” collected up until that point will still be processed.

Decision

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

* Please produce a separate advertising poster for the care partners of deceased dementia patients.
* Please amend the Participant Information Sheets and Consent Forms, taking into account feedback provided by the Committee (above)

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| **10** | **Ethics ref:** | **20/STH/141** |
|  | Title: | The Interface Between Dialysis and Psychiatry - A Case Report |
|  | Principal Investigator: | Dr Luke Sutherland Registrar |
|  | Sponsor: |  |
|  | Clock Start Date: | 27 August 2020 |

Luke Sutherland 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 Study

1. The proposed study involves a haemodialysis patient with known schizophrenia, who developed acute psychosis resulting in several acute medical issues requiring an extensive period in hospital.
2. This research will describe this case and the complex ethical issues raised in the care for such patients, and broadly discuss the literature regarding the ethical conflicts that can occur at the interface of chronic medical conditions, specifically end-stage renal disease and psychiatric disease.

Summary of ethical issues

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

1. The Committee queried the participant’s capacity to provide informed consent, and whether capacity to consent may change in the future. The Researcher explained that the participant does not have insight into their condition and that this is unlikely to change at least in the next twelve months.
2. The Committee queried whether there are times when the participant has greater insight and may be able to consent. The Researcher stated that the participant is committed under the Mental Health Act, so is legally unable to consent for themselves.
3. The Committee queried whether the Researcher had support for the proposed project from supervisors and consultants. The Researcher stated that he does have support from them, provided the project can get ethics approval.
4. The Committee suggested that the Researcher could write generally about the issues raised by this case and other similar cases rather than writing about the specifics of this case, which could potentially identify the participant. The Researcher agreed to this and withdrew their application for this case report study.

This application was withdrawn by the Researcher.

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| **11** | **Ethics ref:** | **20/STH/142** |
|  | Title: | Veganism by Proxy: A Novel Case of Elder Abuse |
|  | Principal Investigator: | Dr Luke Sutherland Registrar |
|  | Sponsor: |  |
|  | Clock Start Date: | 27 August 2020 |

Luke Sutherland 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 Study

1. The Researcher intends to write a case report about an elderly dialysis patient with severe weight loss and hospitalisation, in the context of a strict vegan diet enforced by a family member of the patient's, who is also the patient's main carer.
2. The proposed case study will then have a general discussion around the ethical issues raised by this case.

Summary of ethical issues

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

1. The Committee queried whether the potential participant is competent to provide consent for this research. The Researcher stated that the individual is competent, but is unlikely to provide consent to participate.
2. The Committee suggested that the Researcher could write generally about the issues raised by this case and other similar cases rather than writing about the specifics of this case, which could potentially identify the participant. The Researcher agreed to this and withdrew their application for this case report study.

This application was withdrawn by the Researcher.

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| **12** | **Ethics ref:** | **20/STH/72** |
|  | Title: | Enrichment of community health through SPI |
|  | Principal Investigator: | Professor Steven Ratuva |
|  | Sponsor: |  |
|  | Clock Start Date: | 30 April 2020 |

Steven Ratuva, Rosemarie Martin and Arindam Basu 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 Study

1. The goal of the proposed study is to develop an integrative understanding of social protection, then develop and validate a model of the association between social protection, and social determinants of health among Pacific communities within New Zealand. This goal will be achieved by first developing a model of social protection index for the New Zealand based Pacific Island population and then incorporating perceptions and aspirations of social protection of the Pacific communities. The updated social protection metric will then be validated in statistical models to test its association with social determinants of health among the Pacific communities within New Zealand.
2. The goal of this project is to investigate the socio-economic and cultural drivers of poor health amongst the Pacific population and to identify the shortcomings of existing traditional and formal social protection strategies to address such drivers. It will involve:
   * Field investigation of people’s economic, religious, social, professional and cultural situations, attitudes and beliefs at the individual and collective levels and how these contribute to unhealthy lifestyles.
   * A stocktake of existing social protection measures meant to address these and where they have gone wrong.
   * Construction of a Social Protection Index (SPI) database and formula that links social protection to social determinants of health for use by the communities as well as policy makers.
3. Finally, based on the analyses stated above, the researchers will identify the most appropriate intervention and social protection strategies to promote community empowerment and long-term health enrichment within the Pacific communities using community-friendly strategies.

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 the concept of social protection is being utilised in the context of this study. The Researcher stated that they are looking at whether someone’s lack of resources can be separated from their health outcomes and what protections disadvantaged people receive from the state in relation to health outcomes.
2. The Committee queried whether individuals with dual heritage will be included, e.g. someone who identifies as both Māori and Samoan. The Researchers stated that they will be included but the focus will be on their Pacific heritage.

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 many of the aspects of the protocol that need clarification are already discussed in the research proposal and can simply be transferred into the protocol.
2. Please amend the protocol to clarify that no individuals under the age of 16 will be included in this study.
3. Please amend study documentation to clarify that ‘freely accessible data’ only refers to the overall results of the study, not to the de-identified data.
4. Please ensure that the data management plan is fulsome and follows the requirements laid out in chapter 12 of the National Ethical Guidelines for Health and Disability Research and Quality Improvement (2019).
5. Please provide greater detail in the protocol on the interview process, e.g., where they will be conducted, who will be present (in terms of researchers and families).
6. If home visits are occurring, please include a safety plan for researchers in the protocol.
7. Please clarify whether interviews will be recorded and if so, who will transcribe them and how identifiable will the recordings be.
8. Please amend the duration of data storage to ten years.
9. Please provide evidence of Māori consultation.

The Committee requested the following changes to the Participant Information Sheet and Consent Form:

1. Please amend the PIS to include a succinct definition of “social protection” in the context of this study.
2. Please amend the PIS to include the section on data management found in the HDEC PIS template.
3. Please provide greater detail in the PIS on the interview process, e.g., where they will be conducted, who will be present (in terms of researchers and families).
4. Please amend the PIS to include examples of potentially sensitive questions that may be asked in the focus groups.

Decision

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

* The Committee noted that many of the aspects of the protocol that need clarification are already discussed in the research proposal and can simply be transferred into the protocol.
* Pleas amend the protocol to clarify that nobody under the age of 16 will be included in this study.
* Please amend study documentation to clarify that ‘freely accessible data’ only refers to the results of the study.
* Please ensure that the data management plan is fulsome and follows the requirements laid out in chapter 12 of the National Ethical Guidelines for Health and Disability Research and Quality Improvement (2019).
* Please provide greater detail in the protocol on the interview process, e.g., where they will be conducted, who will be present (in terms of researchers and families).
* If home visits are occurring, please include a safety plan for researchers in the protocol.
* Please clarify whether interviews will be recorded and if so, who will transcribe them and how identifiable will the recordings be.
* Please amend the duration of data storage to ten years.
* Please provide evidence of Māori consultation.
* Please amend the Participant Information Sheets and Consent Forms, taking into account feedback provided by the Committee (above)

After receipt of the information requested by the Committee, a final decision on the application will be made by Dr Sarah Gunningham and Dr Devonie Waaka.

## General business

1. The Committee noted the content of the “ noting section” of the agenda.
2. The Chair reminded the Committee of the date and time of its next scheduled meeting, namely:

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| **Meeting date:** | 13 October 2020, 11:45 AM |
| **Meeting venue:** | Zoom |

The following 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.

1. **Matters Arising**

The Committee requested that the Chairs discuss and reach consensus on whether all PIS changes must come to HDEC for review as a Substantial Amendment.

The meeting closed at 5:10pm.