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| **Committee:** | Southern HDEC |
| **Meeting date:** | 12 July 2022 |
| **Zoom details:** | 965 0758 9841 |

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| **Time** | **Review Reference** | **Project Title** | **Coordinating Investigator** | **Lead Reviewers** |
| 10.30 - 11 AM | 2022 FULL 12683 | Counting Ourselves 2022 | Dr Jaimie Veale | Mr Anthony Fallon & Assoc Prof Mira Harrison-Woolrych |
| 11 - 11.30 AM | 2022 FULL 12988 | A comparison of the safety and efficacy of bimagrumab with semaglutide in adults who are overweight or obese | Dr Penny Montgomery | Mr Dominic Fitchett & Ms Amy Henry |
| 11.30 – 12.00 PM | 2022 FULL 12612 | Understanding how changes in genetic material affect hearing and balance | Dr Rachael Taylor | Associate Professor Nicola Swain & Mr Anthony Fallon |
| 12.00 – 12.30 PM | 2022 FULL 13074 | A feasibility study of Psychedelic Microdosing-Assisted Meaning Centred Psychotherapy in advanced stage cancer patients (PAM Trial) | Dr Lisa Reynolds | Ms Amy Henry & Mr Dominic Fitchett |
|  |  | BREAK 30 MINUTES |  |  |
| 1.00 – 1.30 PM | 2022 FULL 12282 | XL092-002 / STELLAR 002- Expansion Study of the Safety and Efficacy of XL092 in Combination with Immuno-Oncology Agents | Dr Simon Fu | Associate Professor Nicola Swain & Mr Anthony Fallon |
| 1.30 – 2.00 PM | 2022 EXP 13112 | A pathway to care for NZ veterans revision 2 | Associate Professor David McBride | Associate Professor Nicola Swain & Mr Anthony Fallon |
| 2.00 – 2.30 PM | 2022 FULL 11306 | Selinexor and Lenalidomide post ASCT for Newly Diagnosed Myeloma (SeaLAND) | Dr Lauren Child | Mr Dominic Fitchett & Ms Amy Henry |
| 2.30 – 3.00 PM | 2022 FULL 13034 | Evaluation of the GORE® VIAFORT Vascular Stent for Treatment of Symptomatic Inferior Vena Cava Obstruction with or without Combined Iliofemoral Obstruction | Associate Professor Andrew Holden | Associate Professor Nicola Swain & Mr Dominic Fitchett |

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| **Member Name** | **Member Category** | **Appointed** | **Term Expires** | **Apologies?** |
| Dr Devonie Waaka | Non-lay (Intervention studies) | 18/07/2016 | 18/07/2019 | Apologies |
| Assc Prof Mira Harrison-Woolrych | Non-lay Intervention/Observational studies) | 28/06/2019 | 28/06/2020 | Present |
| Mr Anthony Fallon | Lay (Consumer/Community perspectives) (Chair) | 13/08/2021 | 13/08/2024 | Present |
| Mr Dominic Fitchett | Lay (the Law) | 05/07/2019 | 05/07/2022 | Present |
| Ms Amy Henry | Non-lay (Observational studies) | 13/08/2021 | 13/08/2024 | Present |
| Ascc. Prof Nicola Swain | Non-lay Intervention/Observational studies) | 22/12/2021 | 22/12/2024 | Present |

## Welcome

The Chair opened the meeting at 10am and welcomed Committee members, noting that apologies had been received from Dr Devonie Waaka

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 14 June 2022 were confirmed.

## New applications

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| **1** | **Ethics ref:** | **2022 FULL 12683** |
|  | Title: | Counting Ourselves 2022 |
|  | Principal Investigator: | Dr Jaimie Veale |
|  | Sponsor: |  |
|  | Clock Start Date: | 29 June 2022 |

Dr Jaimie Veale and Dr Jack Byrne 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 Researcher clarified that recruitment would be through self-referral and that the information sheet and questionnaires would be carried out online.
2. The Researcher clarified that there would be contact details provided from the research team to add another level of protection for participants in the event of significant mental distress.
3. The Committee queried if the anonymity of the study was necessary to which the Researcher clarified that this was to add protection to the participants in the event they do not wish to be exposed or feel like that could be exposed in their gender expression and journey. The Committee and Researcher decided that there would be an option given for individuals to leave identifiers in the event forwarding to clinicians would be required.

Summary of outstanding ethical issues

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

1. The Committee requested a formal independent peer review be provided. This can either be through the funding body or through an expert in the field unrelated to the study. Please refer to the [HDEC template for peer review](https://ethics.health.govt.nz/assets/Uploads/HDEC/hdec-peer-review-template-june-2021.docx) for guidance to this effect.
2. In the Data and Tissue Management Plan, please include a privacy statement concerning the potential for breaches of privacy and addressing the potential for privacy to be breached for the sake of identifying for safety and referral to external services.

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

1. Please use the [HDEC template](https://ethics.health.govt.nz/guides-templates-and-forms/participant-information-sheet-templates/) or refer to this document in the writing of the PIS to ensure inclusion of critical sections.
2. Please include a lay title for the research and consider abbreviating the section listing all the researchers included in the study and potentially place it at the end of the forms.
3. Please include the risks that people may suffer some mental distress during participation and use this to reassure participants.
4. Please number the pages.
5. Please amend the statement concerning the benefit of the study to trans communities as this is not a definite benefit. This can be stated as a potential benefit.
6. Please ensure that the Committee noted in the application is Southern HDEC.
7. Please include cultural contact details.
8. Please consider using pictures or a table of the questions.
9. Please include the standard statement concerning privacy and confidentiality as is in the [HDEC template](https://ethics.health.govt.nz/guides-templates-and-forms/participant-information-sheet-templates/).

**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 Mr Anthony Fallon and Dr Mira Harrison-Woolrych.

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| **2** | **Ethics ref:** | **2022 FULL 12988** |
|  | Title: | A comparison of the safety and efficacy of bimagrumab with semaglutide in adults who are overweight or obese |
|  | Principal Investigator: | Dr Penny Montgomery |
|  | Sponsor: | Versanis Bio, Inc. |
|  | Clock Start Date: | 29 June 2022 |

Dr Penny Montgomery, Kiran Dole and Dr Lloyd Klickstein & Fayez Jawed & Stephanie Trinh & Andrea Brown 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 Researcher clarified women under the age of 40 would not be recruited due to the teratogenic properties of the study drug. Please include this exclusion in any advertisements.
2. The Committee noted that a therapeutic study cannot be terminated solely for commercial reasons in New Zealand.
3. The Committee noted that ACC-equivalent compensation will need to be provided contrary to the answer given at E8 of the application form. The Researcher clarified that their insurer has indicated any compensation would be paid in a lump sum as opposed to weekly compensation (as specified in the application form) and they weren’t sure if this constituted ACC-equivalent compensation. The Committee confirmed that, so long as the overall level of compensation is equivalent, the mode of payment (weekly or lump sum) is irrelevant.

Summary of outstanding ethical issues

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

1. The Committee requested that any advertisements that would be used for recruitment be provided to the Committee for approval.
2. The Committee noted that there was mention of obesity in Māori and Pasifika peoples but no targeting to this population given the epidemic of obesity in these populations. The Committee requested that some thought be given to proactive recruitment to those populations.

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

1. Please include a plan for the management of mental health in the event of notice of significant mental distress.
2. Please reword the description of randomisation into the treatment arms of the research.
3. Please include a statement as to why there are no women recruited below the age of 40.
4. Please use the [HDEC template](https://ethics.health.govt.nz/guides-templates-and-forms/participant-information-sheet-templates/) regarding contraception for the people in the study of potential child-bearing age.
5. Please state the city, country and any other pertinent information as to the storage of samples sent overseas.

**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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| **3** | **Ethics ref:** | **2022 FULL 12612** |
|  | Title: | Understanding how changes in genetic material affect hearing and balance |
|  | Principal Investigator: | Dr Rachael Taylor |
|  | Sponsor: | The University of Auckland |
|  | Clock Start Date: | 29 June 2022 |

Dr Rachael Taylor & Dr Miriam Rodrigues 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 Researcher clarified there would be inclusion of healthy controls in part 3 of the study and how the data collection would be aged matched.
2. The Researcher queried the numbers involved in the study, how they would be recruited, the controls involved and the inclusion of the non-consenting individual. The researcher clarified that this study was to be conducted on a single extended family that are all affected by this gene variant that had not previously been characterized. The Researcher anticipates 10-15 hearing loss/affected participants and another set of unaffected people (younger family members) who would then serve as controls and may or may not be aware of their genetic status.
3. The Researcher clarified that there was tissue in the Brain Bank that has been consented and data collected with respect to the operation and governance of the tissue bank. The use of this is beyond the scope of this committee.
4. The Researcher clarified the application for part 2 would be regarding the retrospective section of the study and that the tissue would be sent overseas, and that the latter aspect would be consented formally.
5. The Committee noted that there were no issues as per the deceased data usage and the planned proxy consent of the individual who is currently unable to be consented.
6. Please consider reimbursement greater than a $20 koha as this seems to be quite low for the part 3 participants.

Summary of outstanding ethical issues

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

1. The Committee requested a peer review be provided as per the independent [peer review template.](https://ethics.health.govt.nz/assets/Uploads/HDEC/hdec-peer-review-template-june-2021.docx)
2. The Committee requested the following changes to the Protocol:
   1. Please include more detail around the family and relationships therein, potentially consider including a pedigree chart or family tree with some colour coding to help visualise the contact and effected individuals.
   2. Please include more information about the control groups and the details of their testing expectations.

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

1. Please refer to the [HDEC PIS template](https://ethics.health.govt.nz/guides-templates-and-forms/participant-information-sheet-templates/) for the section on genetic testing to ensure that participants are informed of the potential risks of genetic testing.
2. Please include the Māori cultural statement as per the use of tissue as in the [HDEC template](https://ethics.health.govt.nz/guides-templates-and-forms/participant-information-sheet-templates/).

**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 Mr Anthony Fallon and Associate Professor Nicola Swain.

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| **4** | **Ethics ref:** | **2022 FULL 13074** |
|  | Title: | A feasibility study of Psychedelic Microdosing-Assisted Meaning Centred Psychotherapy in advanced stage cancer patients (PAM Trial) |
|  | Principal Investigator: | Dr Lisa Reynolds |
|  | Sponsor: | The University of Auckland |
|  | Clock Start Date: | 29 June 2022 |

Dr Lisa Reynolds, Dr Will Evans, Dr Suresh Muthukumaraswamy, Eva Morunga and Alesha Wells were present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of resolved ethical issues

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

1. The Researcher clarified the sponsor had no role in the research design, funding or licensing of any products. The data and storage of data would be governed by the University of Auckland.
2. The Researcher clarified that SCOTT approval was gained for the phase 1 trial and that this application would be submitted once further manufacturing information had been obtained.
3. The Researcher clarified that the phase 1 trial informed the blinding procedure and efficacy of this phase and the researchers clarified that the mild deception they would be using would remove the unnecessary use of an active placebo given the vulnerability of the study population. The Researcher deemed this a better blinding procedure.
4. The Researcher clarified that the questionnaires surrounding depression and suicide would be used as markers at the start and end of the study, but would not all be used at the same visit as there are a great deal of them. The researchers noted that they would be careful to not overburden the participants.
5. The Researcher clarified the need for the population dosage to be sent home with them as there is a lot of uncertainty for this population in coming to the clinic repeatedly over short periods of time.

Summary of outstanding ethical issues

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

1. Please review carefully for any suggestion/implication that this might be a potential cure for the cancer or other physical ailments and ensure this treatment is purely for the relief of grief or depression related to the participants’ care. Please consider removing the black box warning as this makes it seem more like a treatment for cancer.
2. The Committee requested that the wording around the deception be changed to reduce the degree of deception with the use of some additional punctuation.
3. Please include a statement concerning karakia of samples and whether this will be available.
4. Please include information around the questionnaires for suicide and depression in the risk section.
5. Please remove slang such as “trip” , when describing the effects of the drug .
6. Please give a lay definition to the term “micro-dose” the first time the term is used.
7. Please include the information that there may be a lockbox provided for the study drug if required.

**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:** | **2022 FULL 12282** |
|  | Title: | XL092-002 / STELLAR 002- Expansion Study of the Safety and Efficacy of XL092 in Combination with Immuno-Oncology Agents |
|  | Principal Investigator: | Dr Simon Fu |
|  | Sponsor: | Exelixis Inc. |
|  | Clock Start Date: | 29 June 2022 |

Dr Simon Fu, Daphne Mason, Mary Tilson and Maree Ward 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 the recruitment process, and whether there will be a separation between clinician and participant. The researchers explained that they have a team approach the participant for recruitment and someone else consenting the patient, alongside the nursing staff phoning and talking to the participant, not just doctors – multidisciplinary team that contacts the participants.
2. The Committee queried the nature of the drug itself. The Researcher explained that the drug is a new drug, however it is very similar to existing drugs and the research team has experience using these type of drugs
3. The Committee queried the level of reimbursement and how much New Zealand participants will receive. The researcher explained it depends on how far the participant is travelling. If the travel is local, reimbursement can be up to $100 on an individual basis.
4. The Committee queried the storage of tissue for 25 years which is longer than the usual. The Researcher explained it was a sponsor’s recommendation. The Committee noted this is acceptable so long as this is explained in the participant information sheet (PIS).

Summary of outstanding ethical issues

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

1. Please use a lay title.
2. Please double check for general grammar and include more lay language if possible.

**Decision**

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

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

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| **6** | **Ethics ref:** | **2022 FULL 11306** |
|  | Title: | Selinexor and Lenalidomide post ASCT for Newly Diagnosed Myeloma (SeaLAND) |
|  | Principal Investigator: | Dr Lauren Child |
|  | Sponsor: | Australasian Leukaemia and Lymphoma Group |
|  | Clock Start Date: | 29 June 2022 |

Dr Lauren Child, Fadiya Al-Abuwsi and Gloria Nkhoma 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 the role of the pharmaceutical company in the study. The Researcher explained they are supplying the study drug; however, they are not supplying any additional financial support and do not have access to the study data (other than reports of SAE)
2. The committee asked how the potential researcher/clinician conflict will be dealt with and what is put in place to reduce this. The Researcher explained the coordinators go through the screening and make sure it is all correct, that the screening process does go through multiple people & that each participant's haematologist will approach the potential participant in the first instance.
3. The Committee asked about reimbursement of travel costs. The Researcher explained that the participants would be reimbursed for travel outside of standard of care appointments. However, efforts would be made to ensure research visits coincided with standard of care visits.
4. The committee asked about the reproductive risks for participants and how many women of reproductive age are going to be recruited. The Researchers explained that it is unlikely due to the age that these women would be recruited.
5. Application form states that, if well tolerated, Selinexor can be increased to 60mg weekly from cycle 2, but the participant information sheet (PIS) (p5) and Protocol both state dose will be maintained at 40mg weekly. Researcher clarified the PIS, and Protocol are correct, and the application form was incorrect.

Summary of outstanding ethical issues

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

1. The Committee requested that the researcher submit evidence of the CI’s indemnity.

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

1. Please include a mention that no method of contraception is 100% effective and participants need to take caution when on this medicine. Include a black box somewhere on the participant information sheet and add statement consent form page 12.
2. Please simplify the lay title.
3. Please proofread and check for formatting errors throughout.
4. Please remove the yes/no tick boxes in the ‘future unspecified research' consent form.

**Decision**

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

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

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| **7** | **Ethics ref:** | **2022 FULL 13034** |
|  | Title: | Evaluation of the GORE® VIAFORT Vascular Stent for Treatment of Symptomatic Inferior Vena Cava Obstruction with or without Combined Iliofemoral Obstruction |
|  | Principal Investigator: | Associate Professor Andrew Holden |
|  | Sponsor: | W. L. Fore & Associates, Inc. |
|  | Clock Start Date: | 29 June 2022 |

Associate Professor Andrew Holden, Elleni Takele and Helen Knight 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 asked about the process of recruitment and asked the researcher to explain in more detail what steps are being taken when approaching a potential participant. The Researcher explained that they do a high-level screen before approaching a participant and which reduces approaches to ineligible participants. While the committee prefers participants be approached by their primary clinician in the first instance, this was deemed acceptable as researchers are integrated into the clinical team and based in the same treatment unit.
2. The Committee queried how many participants are involved in this study. The Researcher explained that they plan to recruit 5 participants.
3. The Committee queried section B8 and continued access to the intervention for the participant. The Researchers explained that the stent will not be removed from the participants once it has been implanted.
4. The Committee asked about the contraceptive advice in the participant information sheet. The Researchers explained pregnant women or women who plan to become pregnant are excluded because it is a first in human study & safety is essential. They clarified that the risk to a pregnancy is because of radiation used in monitoring the stent (CT scan, etc).

Summary of outstanding ethical issues

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

1. Please delete the male contraceptive advice and note what the reproductive risk is for people who are of reproductive age. Consider clarifying when pregnancy might be possible.
2. Please include a statement of the risk of radiation as per D20.1/d20.2.
3. Please use a lay title (page 1).
4. Please put FIRST IN HUMAN in black box at top of page (page 1).
5. Please use plain language wherever possible, i.e., ‘blockage’ instead of ‘occlusion’ (page 3).
6. Please consider using ‘sponsor’ instead of full company name wherever possible (i.e., page 4-5)

**Decision**

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

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

## General business

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

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| **Meeting date:** | 09 August 2022. |
| **Zoom details:** | To be determined |

1. **Review of Last Minutes**

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

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

The meeting closed at 2.30pm.