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| **Committee:** | Southern Health and Disability Ethics Committee |
| **Meeting date:** | 08 December 2020 |
| **Meeting venue:** | Online Meeting |

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| **Time** | **Item of business** |
| 10:00am | Welcome |
| 10:05am | Confirmation of minutes of meeting of 10 November 2020 |
| 10:15am | New applications (see over for details) |
| 10:15 – 10:40  10:40 – 11:05  11:05 – 11:30  11:30 – 11:55  11:55 – 12:20  12:20 – 12:50  12:50 – 1:15  1:15 – 1:40  1:40 – 2:05  2:05 – 2:15  2:15 – 2:40  2:40 – 3:05  3:05 – 3:30  3:30 – 3:55 | i 20/STH/186  ii 20/STH/207  iii 20/STH/209  iv 20/STH/210  v 20/STH/211  **[Lunch break]**  vi 20/STH/212  vii 20/STH/213  viii 20/STH/214  **[10 min break]**  ix 20/STH/216  x 20/STH/218  xi 20/STH/219  xii 20/STH/220 |
| 3:55pm | General business |
| 4:00pm | 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 | Apologies |
| Dr Devonie Waaka | Non-lay (intervention studies) | 18/07/2016 | 18/07/2019 | Apologies |
| 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 | Present |
| Mrs Helen Walker | Lay (consumer/community perspectives) | 19/08/2020 | 19/08/2021 | 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 10:15am and welcomed Committee members, noting that apologies had been received from Dr Sarah Gunningham and 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 10 November 2020 were confirmed.

## New applications

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| **1** | **Ethics ref:** | **20/STH/186** |
|  | Title: | CaPTO study |
|  | Principal Investigator: | Dr. Ramya Nagarajan |
|  | Sponsor: | University of Auckland |
|  | Clock Start Date: | 29 October 2020 |

Dr. Ramya Nagarajan 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. This consists of two parts. The first part is an observational retrospective study looking at people who have been treated with prostate cancer. The most common treatment for this group is either radiotherapy or operation. This study will examine the electronic records in order to compare mortality and morbidity outcomes between those who received radiotherapy and those who underwent an operation.
2. The second part of the study is an observational study to look at the impact of the cancer on quality of life through the use of three standardised and novel questionnaires. These will be administered to a subset of those whose medical records will be used in part 1 (N=5,000).
3. The two parts described above will be used to develop a prediction tool

Summary of resolved ethical issues

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

1. The Committee stated that the New Zealand National Ethical Standards should have been referred to rather than the British guidelines. Nonetheless, the appropriate justifications for the use of identifiable health information without consent had been given.
2. The Committee asked who will be sending the questionnaires to participants, which the Researcher explained will be herself alone. The Researcher acknowledged that 5,000 participants is an optimistic number, and that fewer in practice may be contacted. However, ethnic groups will be stratified in order to capture patients at different stages of cancer development as well as equal numbers of different ethnic and treatment groups.

Summary of outstanding ethical issues

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

1. Further information requested: the Committee stated that a more detailed evidence of scientific peer review is needed, either from the same or from new peer reviewer(s). This should include the reviewers’ comments on the different scientific merits of the study. For guidance, see the HDEC peer-review template: <https://ethics.health.govt.nz/system/files/documents/pages/hdec-peer-review-template-june-2020.docx>.
2. The Committee asked how the participants will be contacted after the questionnaires are originally sent out. The Researcher stated that a packet of the questionnaires will originally be sent by mail, and then 3 weeks after the questionnaire and PIS package are sent out, the Researcher will call those who have not responded to check if they received it and if they have any questions.   
   The Committee noted that the questionnaires may raise issues for some men around how they were treated, their satisfaction with their support and so on. The Researcher stated that phone and email contact details are given on the PIS for participants to reach out to them if they wish to. The Researcher also noted that the purpose of the study is to look at participants’ satisfaction with their treatment. The Committee further noted that a face-to-face meeting is more likely to appeal to Māori and Pacifica men, and would lead to a more representative sample even if it is smaller.  
   Action requested: The Committee suggested conducting the study on a smaller number of participants, and conducting it in person in order to be able to hear their views more effectively and to provide support.
3. **Noting the methodological issues with the second part of the study** (the qualitative interviews), **the Committee suggested that the first part of the study could be approved within the current application and the second part to be submitted in a second application.**   
   Action requested: please amend the study protocol so as to make it specific for the first part of the project.

Decision

Part 1 of this application was *provisionally approved* by consensus, subject to the following information being received:

* Please address all outstanding ethical issues, providing the information requested by the Committee.

After receipt of the information requested by the Committee, a final decision on the application will be made by Professor Jean Hay-Smith and Mrs Helen Walker.

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| **2** | **Ethics ref:** | **20/STH/207** |
|  | Title: | TROG 18.01 - NINJA |
|  | Principal Investigator: | Dr Roger Yang-Chun Huang |
|  | Sponsor: | TROG Calvery Mater Newcastle |
|  | Clock Start Date: | 26 November 2020 |

Dr Roger Yang-Chun Huang and Jenny Boyd 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. NINJA is a randomised interventional clinical trial comparing two prostate radiotherapy schedules:
   1. Monotherapy (40 Gray {Gy} in 5 fractions {5 doses})
   2. Virtual High Dose Rate Brachytherapy Boost (20 Gy in 2 fractions followed by 36 Gy in 12 fractions).
2. NINJA is being conducted in radiation therapy treatment centres in Australia and New Zealand. The trial will evaluate the control of prostate cancer in both arms of the study, demonstrate the clinical impact of knowledge based planning and show the ability to fully transition centres from computed tomography (CT) to Magnetic Resonance Imaging based prostate radiotherapy planning.
3. The study design is a prospective randomised phase 2/3 trial. NINJA will initially be launched as a randomised phase 2 study for the first 150 men to demonstrate accrual feasibility as well as addressing the knowledge based planning and Magnetic Resonance Imaging planning aims, prior to proceeding to a phase 3 randomized controlled trial of 472 patients.

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 why the Researchers believed that there will be no cultural issues for Māori. The Researchers stated that no tissue (in addition to standard of care) will be taken or analysed during this study, and that Māori will have the same access to participation as people from other ethnic groups. The Committee stated that whakama may be a cultural issue for Māori in the study, due to the sensitive subject matter. The Researchers stated that although sensitive questions will be asked, previous experience in studies of prostate cancer rates has not shown this to be a significant issue.
2. The Committee asked what action the Researchers would take if the quality of life questionnaires indicated any risk to participants’ mental health or self-harm. The Researchers stated that in this would be alerted to the participants’ doctors, and that an oncology psychologist is also available on-site.
3. The Committee asked if the the SpaceOAR hydrogel is part of standard of care. The Researchers explained that it is in addition to standard of care, however is not experimental.

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 asked how the roles of researcher and clinician will be separated in the recruitment of participants. The Researchers stated that eligible patients will be identified at urology staff meetings. The clinician will introduce the study to those patients, and they will take the information home with them to consider it. The voluntariness of the study and that it will not impact on their treatment will be emphasized.

Action requested: the Committee asked for a research nurse to discuss the study with participants, rather than their treating clinician, so as to avoid any undue influence.

1. The Committee noted the that in response to question R.1.4 (withholding standard treatment) the Researchers had answered ‘no’; however, the standard of care is a much longer treatment of radiotherapy than will be given in the study. The Researchers confirmed that neither arms of the study do include a treatment length equal to standard of care at their centre. However, the treatment periods vary throughout New Zealand and the world such that there is not a well-defined standard of care, and a shorter period of treatment is expected to become the standard of care in the future. Furthermore, treatment arm A does include care equivalent to that used at some other centres.

Action requested: please explain in the PIS how both arms differ from standard of care treatment at Waikato Hospital.

1. Further information requested: The Committee asked for the issues raised in the scientific peer review concerning the study design to be addressed.
2. Further information requested: The Committee asked for greater detail around the management of data in the New Zealand part of the study to be added either to the study protocol or to a separate data management plan. This should meet those requirements set out in para 12.15 of the National Ethical Standards. For guidance, please refer to the HDEC data management template (<https://ethics.health.govt.nz/system/files/documents/pages/data-only-management-template-oct2020.docx>).

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

1. Please explain how the risks differ between the treatment arms and with standard of care.
2. Please explain that no tissue samples will be used or analysed in addition to standard of care, but that the data from standard of care samples will be used in this study.
3. Please remove part A of the PIS on clinical trials. This could be given to participants in a separate document.
4. Please amend the study title, removing ‘ninja’ so as to concisely state what the study is about.
5. The Committee asked for future submissions that a clean copy of the PIS is submitted in additional to a tracked-changes version (a tracked changes version is not necessary for the first submission).
6. Please add greater information about how participants’ data will be managed and used, distinguishing between identified, de-identified and anonymous data. See the HDEC PIS template for guidance (https://ethics.health.govt.nz/guides-templates-forms-0)
7. Please explain the “PSMA-PET scan” on pages 11 and 13.
8. Page 19: please correct the HDEC name to “Southern”.
9. Please make clear that the withdrawal form does not need to be signed – any request from the participants to be withdrawn must be respected.

Decision

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

* Please address all outstanding ethical issues, providing the information requested by the Committee.
* Please update the Participant Information Sheet and Consent Form, taking into account the suggestions made by the Committee.

After receipt of the information requested by the Committee, a final decision on the application will be made by Assc Prof Mira Harrison-Woolrych and Dr Pauline Boyles.

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| **3** | **Ethics ref:** | **20/STH/209** |
|  | Title: | A Phase 3 Study of darolutamide in addition to ADT versus placebo plus ADT in men with mHSPC |
|  | Principal Investigator: | Mr Kevin Bax |
|  | Sponsor: | Bayer New Zealand |
|  | Clock Start Date: | 26 November 2020 |

Ms Barbara Joppa 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. This is a phase 3 study to determine the safety and efficacy for darolutamide when added to ADT in men with metastatic hormone-sensitive prostate cancer.
2. Participants will take the study drug (tablets) by mouth twice per day in addition to their recommended ADT. They will have clinic visits every 12 weeks to test for efficacy and safety. Participants will have scans as clinically indicated. Treatment will continue until disease progression, withdrawal, or unacceptable toxicity. Once treatment has ended, participants will be followed up for safety and survival.

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 for confirmation that the Sponsor will provide continued access to the study drug to participants who benefit from it after the end of the trial, which the Researchers confirmed.
2. The Committee asked if there was the possibility of identifying incidental clinical findings during the study. The Researcher stated that the results of blood tests will be available at the site level and discussed with the participant by the local PI. Whole genome sequencing is anonymous so may not be actioned.
3. The Committee asked how the roles of Researcher and Clinician will be separated during the process of seeking consent. The Researcher stated that the original contact would be from either the person’s oncologist or neurologist, however following that they would discuss the study with a research nurse.
4. It was confirmed that any substantial new safety information relating to the study would in be communicated to participants in the first instance.

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 asked for greater detail around the management of tissue and data in the New Zealand part of the study to be added either to the study protocol or to a separate tissue and data management plan. This should meet those requirements set out in para 12.15 of the National Ethical Standards. For guidance, please refer to the HDEC tissue and data management template (<https://ethics.health.govt.nz/system/files/documents/pages/hdec-data-tissue-management-template-oct2020.docx>)

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

1. Please add a lay title to all PIS versions.
2. Please proof-read the main PIS for typos, technical language and ease of reading.
3. Please put the information about study visits into a table so that they may be easily viewed.
4. Please amend “pain and extremity” so that it is less alarming.
5. Under “what happens in the study” please remove “the sponsor of the study is Bayer Consumer AG”
6. Page 2: Therefore, it is expected that darolutamide in addition to ADT will enhance disease control…” as it is overly promising.
7. Page 2: please check the number of participants expected to be involved for this specific study.
8. Page 3: please re-word the description of the study periods.
9. Page 5: please amend so as to make the relevance of the definition of ‘double blind’ clear.
10. Pages 6 and 7 side-effects section: please amend for readability, and remove the replication of side-effects of ADT in the darolutamide section.
11. Page 7: “how the body processes fats and sugars”, please explain the implications of this in lay language.
12. Page 8 drug-drug interaction): please move some of this information up front to “who can be in the study”, or otherwise bold the important information.
13. Page 9 reproductive risks: please remove the requirement for participants to be sexually abstinent. Refer to the HDEC reproductive risks template for guidance.
14. Pages 10 and 11 screening period: suggest combining the two points regarding scans.
15. Page 14: please clarify the sentence “check and record any bone-related event such as radiation therapy…”
16. Pages 11-15: the definitions of testosterone and PSA only need to be given once.
17. Page 15 What biological samples will I be asked to give?: please distinguish clearly between those samples taken as part of standard of care, and those taken/used specifically for research.
18. Pages 16 & 17: please clarify whether this information is referring to the main or optional sub-study.
19. Page 19: please check the period for which information will be stored.
20. Page 20 reimbursement section regarding ADT: please clarify this section.
21. Pregnant partner PIS:
    1. Page 2: information after the baby is born will need to be consented to in a separate PIS.
    2. Page 2: information about the baby collected after birth must be consented to in a separate consent form. Please amend accordingly.
    3. Page 4: check the storage of data.
    4. Page 4: please remove the reference to the European data regulatory authority.
22. Whole genome sequencing PIS: please check the data storage timeframe.
23. Patient alert card: as this is a blinded trial, the ‘I am receiving \_\_’ is not helpful.

Decision

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

* Please address all outstanding ethical issues, providing the information requested by the Committee.
* Please update the Participant Information Sheet and Consent Form, taking into account the suggestions made by the Committee.

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

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| **4** | **Ethics ref:** | **20/STH/210** |
|  | Title: | V201\_01 |
|  | Principal Investigator: | Michael Williams |
|  | Sponsor: | IQVIA RDS Pty. Limited |
|  | Clock Start Date: | 26 November 2020 |

Michael Williams 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. Influenza, commonly called flu, is a major health concern and is one of the leading causes of death in the world. It has been recognized that older adults are at greater risk of serious complications from the flu, such as lung and heart diseases, compared with young, healthy adults. The investigational vaccine, MF59C.1 (MF59)-adjuvanted Quadrivalent Subunit Inactivated Cellderived Influenza Vaccine (aQIVc) may offer important advantages over conventional influenza vaccines for these age groups.

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 if there are any conditions which may cause the sponsor to terminate the study as a whole. The Researcher stated that it is not expected that the study might be terminated, but that it is possible if there were ongoing safety risks identified.
2. The Committee asked how the roles of clinician and researcher will be separated during recruitment. The Researcher stated that both of the study sites are private clinics and potential participants could be patients of the investigators, however other research staff are different. Consequently, the difference between the study and standard of care will be highlighted to participants.
3. The Committee asked if any advertisements will be used in the study. The Researcher stated that advertising is not planned, and if it is needed this would be submitted in an amendment.
4. The Committee asked if Māori are more likely to get influenza or to receive influenza vaccinations. The Researcher stated that influenza vaccine funding is provided on the basis of (co-)morbidity. As Māori have a higher incidence of comorbidities, and are more likely to receive complications from influenza, they are more likely to be eligible for the free or funded vaccine.
5. The Committee asked if, by having the standard flu vaccine as an exclusion criterion, standard of care is being withheld in this study. The Researcher explained that the study is providing a vaccine of a higher standard than the local standard of care, and one which is the standard of care in other countries.
6. The Committee stated that the E-Consent form was acceptable.

Summary of outstanding ethical issues

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

1. Please amend the study title, expanding the abbreviations, and put the lay title before the full title.
2. Please state clearly at the start of the PIS that this is the first time that this particular combination of medicines has been trialled in humans.
3. Page 2: Please amend the paragraph beginning “*aQIVc* is currently being tested in approximately 120 participants aged 50 years and older in the United States” for clarity. The second sentence should either be bolded or moved to the first page of the PIS.
4. Page 12 “what will happen to my information”: please clearly distinguish between identified and de-identified information, and the risks involved with the use of that information. Please refer to the HDEC template for guidance https://ethics.health.govt.nz/system/files/documents/pages/participant-information-sheet-consent-form-template-sep20.doc.

Correct “pseudonymised” to “de-identified”.

1. Please make the option for the GP to be informed mandatory.
2. Please reduce the contraceptive risks information in the PIS.

Decision

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

* Please address all outstanding ethical issues raised by the Committee.
* Please update the Participant Information Sheet and Consent Form, taking into account the suggestions made by the Committee.

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| **5** | **Ethics ref:** | **20/STH/211** |
|  | Title: | 0171 - Phase 3 Extension Study of TD-9855 for Treating snOH in Subjects with Primary Autonomic Failure |
|  | Principal Investigator: | Prof Timothy Anderson |
|  | Sponsor: | Theravance Biopharma Ireland Ltd |
|  | Clock Start Date: | 26 November 2020 |

No member of the study team was present via videoconference for discussion of this application.

Potential conflicts of interest

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

Paul Chin declared a potential conflict of interest and the Committee decided that it was not substantial

Summary of Study

1. The purpose of this study is to look at how safe and tolerable TD 9855 is when taken over a longer period of time (three and a half years) to treat symptomatic neurogenic orthostatic hypotension (snOH) in people with Parkinson’s disease (PD), multiple system atrophy (MSA), or pure autonomic failure (PAF). The study takes the design of a phase 3, multi-center, open-label study where the study drug is administered to those from the previous phase who are likely to benefit from longer term treatment.

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 sated that the study cannot be terminated for commercial reasons (National Ethical Standards para 11.37).

Further information requested:

1. Question R.2.3: please explain why it is necessary to include participants’ initials in addition to their study ID number, and why health information is needed for 25 years.
2. R.2.4: please reconcile the statement “data are de-identified for storage” with “lab results and source documents are identified by name and date of birth.”
3. R.4.1: please discuss the extent to which the roles of clinician and researcher will be separated so as to avoid any undue influence for participants.
4. Please explain the role of the Catalyst materials.
5. Please provide a safety/monitoring plan relating to the questionnaires uploaded; how any concerning findings (depression, suicidality) will be responded to, will participants’ GP’s be informed etc.
6. The Committee asked for greater detail around the management of tissue and data in the New Zealand part of the study to be added either to the study protocol or to a separate tissue and data management plan. This should meet those requirements set out in para 12.15 of the National Ethical Standards. For guidance, please refer to the HDEC tissue and data management template (<https://ethics.health.govt.nz/system/files/documents/pages/hdec-data-tissue-management-template-oct2020.docx>).

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

1. Please simplify the lay title.
2. Please clarify the length of study in addition to the previous study.
3. The answer “no future research” to question B.4.4 conflicts with the statement “the results and data collected from this study, including your personal data, may lead to the development of commercial products for the diagnosis, cure, mitigation, treatment, or prevention of disease” in the PIS. If the intent is simply to convey the notion that participants will not be compensated for any commercial success of ampreloxetine, then say so.
4. Deep vein thrombosis is listed as a “non-serious side effects” – what is the reason for this?
5. “You should be aware that data collected by the Sponsor up to the time you withdraw will form part of the research project results. If you do not want them to do this, you must tell them before you join the research project.” The second sentence should be something like “This is a requirement of participation.”
6. Please state that it is a requirement of participation that data up to the point of withdrawal will be kept.
7. Reproductive risks: please remove the statement that the hormonal contraceptive pill is a reliable form of contraception. Please refer to the HDEC template for guidance <https://ethics.health.govt.nz/system/files/documents/pages/participant-information-sheet-consent-form-template-reproductive-risks-17apr20.docx>.
8. Please make it clear that pregnancy tests will be required *throughout* the study.
9. Page 8: please check the information about the coding of data, as it is inconsistent with the information on the application form.
10. Page 9 side-effects: please try to reduce the length of this section (e.g. ‘more than’ rather than ‘more than or equal to’).

Decision

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

* Please address all outstanding ethical issues, providing the information requested by the Committee.
* Please update the Participant Information Sheet and Consent Form, taking into account the suggestions made by the Committee.

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

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| **6** | **Ethics ref:** | **20/STH/212** |
|  | Title: | ALXN1830-HV-108: A study assessing single and multiple doses of ALXN1830 in healthy adults. |
|  | Principal Investigator: | Dr Mark Marshall |
|  | Sponsor: | Syneos Health New Zealand Limited |
|  | Clock Start Date: | 26 November 2020 |

Dr Mark Marshall and Shuruthi 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. ALXN1830 is being developed as a potential treatment for auto-immune disorders, and has been trialled in 100 participants so far. This is the sixth study of ALXN1830 in humans, and will assess single and multiple doses of the study drug when administered as an injection under the skin (subcutaneous or SC).
2. Approval is being sought for Part A only. Part A of the study aims to see:
   * How safe and well-tolerated single SC doses of ALXN1830 are.
   * How single SC doses of ALXN1830 are absorbed, processed, and cleared by the body.
   * How single doses of ALXN1830 affect immune system markers in the blood.
   * If the body produces antibodies against ALXN1830 16 healthy men and women will take part

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 a separate study which has previously been conducted in Japan, and its relation to the present study. The Researcher explained that the Japanese population has distinct genetic characteristics, which was why that previous study specifically targeted that population.
2. The Committee asked how many individuals have previously been exposed to the dose of medication to be used in this study. The Reseachers explained that previous studies have involved up to 30mg per kg doses administered via IV infusion. IV is expected to lead to greater exposure than the subcut-administered doses used in this study. The Committee was satisfied that the doses used in this study are not properly considered first in human.

Summary of outstanding ethical issues

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

1. Action requested: The Committee requested that the insurance certificate be updated with the policy territory specified as New Zealand.

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

1. Please remove “multiple dose” from the lay study title.
2. The Committee asked why oestrogen pills cannot be taken during the study. The Researchers explained that prescribed medications should be held constant over the study, so as to reduce the risk of drug-drug interaction or drug metabolism. Please amend the PIS to make it clear that participants can continue their medication, but should not start any new medication while on the study. Please refer to the combined oral contraception pill, rather than only the oestrogen pill.
3. Please correct the clinicaltrials.govt URL.

Decision

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

* Please update the Participant Information Sheet and Consent Form, taking into account the suggestions made by the Committee.
* Please update the sponsor insurance certificate, specifying New Zealand as the policy territory.

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| **7** | **Ethics ref:** | **20/STH/213** |
|  | Title: | The New Zealand Indigo naturalis dose-escalation study (NZ-INDES) |
|  | Principal Investigator: | Dr. Olivier Gasser |
|  | Sponsor: |  |
|  | Clock Start Date: | 26 November 2020 |

Dr. Olivier Gasser 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.

It was noted that one of the attending researchers, Dr Patries Herst, was a member of the Central HDEC committee. As Dr Herst was a supporting investigator rather than the CI for this study, this was not thought to be substantial.

Summary of Study

1. This is a phase 1b open label dose escalation study of a Chinese medicine, indigo naturalis, to study its effect on the activity of an inflammatory marker (aryl hydrocarbon receptors on blood cells) and its effect on liver function in healthy participants.
2. The study will involve 25 participants (in NZ only): the first 5 will receive an inactive placebo tablet; the next 5 will be given the lowest dose of indigo naturalis; the next 5 will receive 0.5g indigo, etc. until the last 5 participants receive 2g of the active medicine. 5 different individuals will receive each dose, rather than escalating the dose in the same person. As such this is a single dose escalation study, rather than increasing the dose in the same person.
3. Participation will involve 3 visits to the clinical trials unit in Wellington, one for screening, two subsequent visits for dosing (after fasting) and blood measurements over a 24 hour period.

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 how many participants were involved in a study involving the active ingredient in osteoarthritis patients, and the Researchers stated that around 100 participants were involved. The Committee was satisfied that this is not a first in human study.
2. The potential for adverse events, particularly liver failure, for herbal medicines was noted and the Committee was satisfied that this risk is well communicated to participants in the Participant Information Sheet (PIS).
3. The Committee asked if 5 participants in each treatment group would be sufficient to be able to reach confident conclusions about liver function. The Researchers explained that the primary purpose of the study is to assess safety before proceeding to the next highest dose where efficacy will be evaluated. They further stated that the only adverse events documented in the literature are from individuals who have taken indigo naturalis without QC and in unsupervised doses. Consequently, the expected risk of adverse events in this study is low.
4. The Committee asked about advertising for the study. The Researchers stated that they are intending to post advertisements for the study in public venues, in order to obtain a relatively representative sample of the different ethnicities in the region.
5. The Committee noted the modest compensation offered for participation, which the Researchers explained was intended to not provide any undue influence for participation, given the relatively short duration of the study.

Summary of outstanding ethical issues

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

1. The Committee stated that the treatment should be considered as a new medicine, and the related ethical and regulatory requirements apply. The Committee asked if there are any previous studies that have been done with the active ingredient (indigo naturalis). The Researchers were not aware of any such studies.   
   Action requested: the Committee stated that scientific review from SCOTT will be required.

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

1. Please amend the lay title so that it is meaningful for a lay audience.
2. Please proof-read and simplify the language for a lay audience, reducing all technical language where possible.
3. Please state how many people have been exposed to this medicine in previous trials.
4. Please amend the PIS so as to make the aims of the study clear: that the study is measuring the inflammatory markers in the dose escalation and measuring LFTs for the purpose of assessing safety, rather than efficacy/usefulness.
5. The Committee asked about risks relating to pregnancy for this investigational medicine, noting that an intention to become pregnant was an exclusion criterion. The Researchers stated that, as the study duration was only one day, they did not intend to require that participants use contraception.   
   Please add compensation information (and requirements) to the PIS, and refer to the HDEC PIS template for compensation guidance (see: <https://ethics.health.govt.nz/guides-templates-forms-0> )
6. Please remove all statements that indigo naturalis is effective in treating bowel disease. You may instead state that it may be useful in the future.
7. Page 4, exclusion criteria: please correct “normal body weight”.
8. Please make the option for the GP to be informed about the individual’s participation mandatory.

Decision

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

* Please update the Participant Information Sheet and Consent Form, taking into account the suggestions made by the Committee.

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| **8** | **Ethics ref:** | **20/STH/214** |
|  | Title: | Real World Advanced Hybrid Closed loop in children and adults with type 1 diabetes |
|  | Principal Investigator: | A/Prof Benjamin J Wheeler |
|  | Sponsor: | University of Otago |
|  | Clock Start Date: | 26 November 2020 |

A/Prof Benjamin J Wheeler 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.

Paul Chin and Jean Hay-Smith declared a potential conflict of interest. The Committee decided that the conflicts were not significant and that they could stay for the discussion of the application.

Summary of Study

1. The study aims to evaluate the effectiveness of an Advanced Hybrid Closed Loop insulin pump system in both children and adults with type 1 diabetes in a real world setting. The added advantage of this system is that it prevents hyperglycaemia by adjusting the doses frequently, gently bringing glucose levels down. In particular this allows for good glucose control overnight.
2. This longer duration single arm study follows on from a short duration randomised cross over study that was conducted previously in adults and children. Following a 6 week lead-in period of progressive automation, patients will spend 6 months where the AHCL assists in the adjustment of insulin levels. The settings of this system will be optimised with the aim to achieve healthier control than was achieved in the short duration previous trial. The effectiveness of the Advanced Hybrid closed loop will be evaluated in achieving optimal blood glucose control targets and in improving sleep quality.
3. 65 participants will be recruited between 2 and 80 years of age.

Summary of resolved ethical issues

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

1. The Researcher explained that the side-effect profile for the device will be no different from the previous HDEC-approved trial. Previous experience has not shown any serious side-effects. In those studies, hyperglycaemia rates were reduced relative to the SOC technology.
2. The Committee was satisfied that the study is not being conducted primarily for commercial benefit.
3. The Committee stated that children under the age of 16 should still be able to sign the adult PIS if they are deemed to have the capacity to understand and consent to the study. It was further noted that due to their own experience using similar devices, the children may be particularly well able to understand the details of the study. The Researchers expressed concern at having to make the judgement about a child’s ability to provide consent, however the Committee reassured them that participants only need to understand what participation involves rather than the clinical details.
4. The Committee asked for clarity around what data is being stored, in which level of identifiability, where and how it will be shared. The Researcher explained that most data stored locally will be de-identified, and all data that leaves the local site will be de-identified.
5. The Committee asked if pregnancy would result in a participant being excluded from the trial. The Researcher confirmed this, and explained that there is no data on pregnancy with the device.
6. The Committee asked if any of the blood and urine tests conducted are specifically planned for the study. The Researcher stated that these tests are also included in standard of care, and the only collection of tissue is a finger-prick test.
7. The Committee asked if requiring access to a computer and internet connection could provide a barrier to participation. The Researcher stated that as existing pump users they will already have access to a computer and internet connection.

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

1. Please correct the page numbers on each form.
2. **Main PIS**
3. Please make sure that all abbreviations are explained.
4. Please update the contraceptive risks information, and refer to the HDEC PIS template for compensation guidance (<https://ethics.health.govt.nz/system/files/documents/pages/participant-information-sheet-consent-form-template-sep20.doc>. )
5. . It should be clearly stated that pregnancy is an exclusion criterion for the study, and that as there is no experience of this device in pregnancy the associated risks are unknown.
6. Page 2: please explain the difference between the two run-in periods.
7. Page 3, who can take part in this study: please amend remove “you must” so as to strike a softer tone.
8. Risks related to the insulin-pump page 5: please amend the list or add an explanation to make this less alarming, and add frequencies for each risk (e.g. common, 1 in 10).
9. Please explain what ‘Carelink’ is.
10. Main PIS information about me: please separate out identified from de-identified information, and the risks associated with the use and sharing of each type. Refer to the HDEC PIS/CF template for guidance <https://ethics.health.govt.nz/system/files/documents/pages/participant-information-sheet-consent-form-template-sep20.doc>.
11. **Caregiver PIS**
12. Page 1: amend “you”’ to “your child”.
13. **Assent form:** please create two different forms, one for 8-12 years and another for 13-16 years.
14. Please create a separate PIS and consent form for the exploratory, qualitative sub-study involving 16 people, to be given to participants at a later date. This can be submitted later as an amendment.  
    In the main PIS, state that not all participants will be asked to take part in the sub-study.

Decision

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

* Please update the Participant Information Sheet and Consent Form, taking into account the suggestions made by the Committee.

After receipt of the information requested by the Committee, a final decision on the application will be made by Professor Jean Hay-Smith and Mr Dominic Fitchett.

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| **9** | **Ethics ref:** | **20/STH/216** |
|  | Title: | Effect of carbonic anhydrase inhibitor eye drops on visual outcomes after macular hole surgery |
|  | Principal Investigator: | Dr Thiyagaraj Krishnan |
|  | Sponsor: |  |
|  | Clock Start Date: | 26 November 2020 |

Dr Stephen Guest 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 objective of this study is to determine if faster resolution of fluid beneath the macula, with the use of topical brinzolamide, post macular-hole-surgery, improves final best corrected visual acuity at 1 year.
2. This is a randomized controlled study. Patients in the control group will receive the standard postoperative topical regime of prednisolone acetate 1% and chloramphenicol 0.5%; both of which are administered four times daily. Patients in the treatment group will receive Brinzolamide 1% (carbonic anhydrase inhibitor) twice daily in addition to the standard regime given in the control arm. This design will allow the Researchers to determine if the intervention is superior to the control.

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 cultural issues for Māori in this study. It was clarified that Māori consultation would be undertaken following ethical review. The Committee noted that touching the head (which is tapu) may be an issue for some Māori.
2. The Committee asked about the prevalence of macular hole in Māori. The Researcher stated that they believe it to be less prevalent for Māori.
3. It was clarified that participants in this study are not expected to be of reproductive age.

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 asked for clarification about how the roles of researcher and clinician will be separated in the recruitment process, and whether patients be spoken to about the study before or after their surgery. The Researcher clarified that participants would not be recruited until the 2 week point if they still have fluid remaining. It was planned for the treating clinician to introduce the study to patients.   
   Action requested: the Committee asked for treating clinicians to refer interested patients to a research nurse who will explain the study in full to them.

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

1. Please reduce the size of the front-page header.
2. Please add page numbers.
3. Please improve the formatting where possible, making the lay title more prominent, making spacing consistent, and removing the “*please explain in plain English”* text.
4. Please detail all the possible adverse reactions for the drops, with approximate frequencies.
5. Please explain whether there is any possibility of reaction between the medications.
6. Please state that participants will not be able to drive after the study visit.
7. Please explain more clearly the benefit which the drops may provide, as well as that they may provide no benefit.
8. Please remove the option for the GP to be informed about the participants’ involvement in the study, and make this mandatory.
9. Page 2: remove the statement “if it does, we can treat everyone with this drop”, as it is promotional.
10. The investigational product is not named until quite late in the form, please state this earlier.
11. Please explain “sulphur drugs”.
12. Please state whether participants will be compensated for travel costs.
13. Consider qualifying the statement “it is also possible that research findings could be used inappropriately to support negative stereotypes, stigmatize, or discriminate against members of the same groups as you", as it is alarming. Reinforce what you will do to minimise risk.

Decision

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

* Please address all outstanding ethical issues, providing the information requested by the Committee.
* Please update the Participant Information Sheet and Consent Form, taking into account the suggestions made by the Committee.

After receipt of the information requested by the Committee, a final decision on the application will be made by Assc Prof Mira Harrison-Woolrych and Dr Pauline Boyles.

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| **10** | **Ethics ref:** | **20/STH/218** |
|  | Title: | Comparison of two lidocaine patches. |
|  | Principal Investigator: | Dr Noelyn Hung |
|  | Sponsor: | Aspen Australia |
|  | Clock Start Date: | 26 November 2020 |

Dr Noelyn Hung 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. This study is designed to evaluate the bioequivalence of lidocaine 5% w/w transdermal patches (Aspen, Australia) compared to that of the branded formulation Nervoderm patches (Seqirus, Australia) following a single application in healthy subjects under fasting conditions. This study will also assess the safety and tolerability of the formulations (i.e.. local irritation, adhesiveness and sensitivity).
2. The duration of the study is approximately 5 weeks, including up to 3 weeks for screening and a minimum of 10 days on study (Two periods of 2-day dosing and a 1-week washout period). Subjects will stay at the Zenith Clinical Site from 12 hours before dosing until the PK blood sample of each period taken at 28 hours after dosing.
3. During each treatment period, the enrolled and randomised healthy subjects will receive 2 patches of either formulation applied to the lower mid back area and kept in place for 12 hours. Subjects will receive the Test patches on one occasion and the Reference patches on one occasion.
4. There will be at least 1 week washout (7 days) between each application period.
5. Blood samples will be collected at baseline (0 hours before dosing) and at specified times up to 36 hours after dosing. The plasma will be assayed for lidocaine using a fully validated LC MS/MS method.
6. To assure the good health of subjects, pre-study physical examinations, ECG and clinical laboratory tests will be performed. Post-study laboratory tests, vital signs and safety assessments will also be carried out and subjects will be monitored for AE’s throughout the study.

Summary of outstanding ethical issues

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

1. Please update the contraception wording, and refer to the HDEC contraceptive risks template for guidance <https://ethics.health.govt.nz/system/files/documents/pages/participant-information-sheet-consent-form-template-reproductive-risks-17apr20.docx>.
2. Please proof-read and simplify technical language where possible. For example, “compare how the lidocaine patches are absorbed, distributed and eliminated in your body” could be changed to “compare how the lidocaine patches are handled by your body”.
3. Page 5: please correct the sentence “You must not tale from taking…”
4. At the ‘other additional side effects’ section: please include the incidence and likelihoods as they would be of concern to the participant.

Decision

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

* Please update the Participant Information Sheet and Consent Form, taking into account the suggestions made by the Committee.

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| **11** | **Ethics ref:** | **20/STH/219** |
|  | Title: | BRII-179-835-001: Safety and efficacy of BRII-835 (VIR-2218) and BRII-179 (VBI-2601) in CHB |
|  | Principal Investigator: | Dr Tien Huey Lim |
|  | Sponsor: | Clinical trial Sponsor |
|  | Clock Start Date: | 26 November 2020 |

Dr Tien Huey Lim, Lisa Chang, and Dong Li 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 is an international multicentre randomized controlled trial of two new drugs for chronic Hepatitis B infection, added to the best proven intervention for this condition. 75 participants will be recruited in 8 countries, with 15 in NZ.
2. The study will test the 2 new sub-cutaneous drugs in patients who have been on reverse-transcriptor inhibitor therapy for at least 12 months. There will be 3 cohorts:

A) BRII-835 sub-cutaneously (6 doses over several weeks)

B) BRII-835 as above + 9 doses of BRII-179 + IFNalpha (interferon) low dose IM week 8 to 40

C) As for B, but only 7 doses of BRII-179 and interferon only to week 32.

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 number of participants who have previously been exposed to each of the investigational products in this study. The Researcher stated that the BRII-835 has been trialled in more than 100 people
2. The Committee asked if an external data safety monitoring committee will be set up for this study. The Researchers confirmed this, and explained that the sponsor would analyse the data from all the centres internationally.
3. The Committee stated that in New Zealand the sponsor cannot stop the study for commercial reasons.
4. With regards to the Researchers’ answer to question r.3.8, the Committee asked whether Māori and Pacifica participants will be specifically targeted in this study. The Researchers clarified that no particular effort will be made to recruit a greater number of Māori/Pacifica participants.
5. The Committee asked how participants would be recruited onto the study. The Researcher explained that recruitment information would be given to treating clinicians who would pass it on to interested patients to take home and read before providing consent. As the patients are already on Hepatitis B therapy, and the study treatment does not involve withholding any standard of care treatment, the difference to standard of care will be made clear to interested patients. The Committee was satisfied, due to the small patient group and their familiarity with the standard of care therapy, that there is not likely to be any undue influence by having their treating clinicians invite them onto the study.
6. The Committee asked, for clarification, whether the Researchers would inform their participants first in the event that any significant safety information became available, which the Researchers confirmed.
7. The Committee asked if there is any risk of drug interaction between the investigational medications in this study and other medication which participants would be taking. The Researcher confirmed that no interaction is anticipated.
8. The Committee asked if the lower dose of interferon posed any risk regarding its efficacy, which the Researcher confirmed, however it was explained that this is to reduce the chance of any side-effects.
9. It was clarified that there are no plans to collect information on the baby after it is born, and consequently no re-consent form is needed.

Summary of outstanding ethical issues

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

1. **Main PIS**:

a) Please add a lay title to both the information sheet and consent form.

1. Please add greater information in the PIS about the extent of testing of these medicines in humans so far, and the safety information available as a result of that, making clear that it is an (unapproved) investigational medicine. It would also be useful to outline the relationship of BRII-179 to the approved vaccine.
2. Please state where tissue sent overseas will go to.
3. Please remove the statement on page 13 that withdrawal from the study must be communicated in writing.
4. **Pregnancy PIS:** p
5. Please add greater information (to the level of the main PIS) about data management.
6. Please check that the PIS does not cover any information on the baby after it is born.

Decision

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

* Please update the Participant Information Sheet and Consent Form, taking into account the suggestions made by the Committee.

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| **12** | **Ethics ref:** | **20/STH/220** |
|  | Title: | A feasibility study to investigate individualised exercise prescription for cancer patients |
|  | Principal Investigator: | Ms Jessica Allan |
|  | Sponsor: | University of Canterbury |
|  | Clock Start Date: | 26 November 2020 |

Ms Jessica Allan 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 is a longitudinal study involving 90 participants who have recently been diagnosed breast or colon cancer, seeking to determine the feasibility and efficacy of an individualised exercise prescription and 2 - 3 supervised exercise sessions per week (moderate to high intensity). Participants are recruited from those who opt in to the supervised exercise program, as well as a control arm of those who do not participate in the exercise program.
2. Blood samples will be taken to analyse biomarkers.

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 for clarification on the study design, which the Researcher explained as a single-case design. The Committee clarified that the design is of a longitudinal study, whereas a single case design is a retrospective, in-depth study of one person or group.
2. The Committee asked what health information will be collected from participants, who will have access to it and in what form. The Researcher explained that participants will be referred from their oncologists, and health information relating to the inclusion/exclusion criteria (including information about their diagnosis and treatment) will be provided by their oncologist or surgeon to the Researchers.
3. The Committee asked if the questionnaires about mood will be monitored, and what will happen if a participant’s answers show concern for their mental health. The Researcher explained that if a participant’s answers are of concern then they will have a conversation with their oncologist or surgeon. If during the study the questionnaires show a drop in mood, then the Researcher will have a conversation with them directly and if serious also have a conversation with their oncologist/surgeon.

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 asked how participants would be invited onto the study, and noted that this is a very sensitive time for those people. The Researcher stated that interested individuals will be given information early in their treatment, but are given a choice about when they begin the exercise programme, in order to give them the time that they need to decide about their participation. The control group will consist of individuals who choose not to take part in the exercise programme.  
   The Committee stated that a randomised control group, of individuals who are willing to take part in the intervention, would be more effective as a control group. The Committee further expressed concern at the variability that would be introduced by allowing participants to begin the exercise programme at different points in their treatment.  
   Action requested: please add greater information about the control group to the study protocol, explaining in greater detail its role and how that data will be analysed.  
   (*National Ethical Standards* para *9.1; 9.8*)
2. The Committee further noted the complexity of asking people to consent to the intervention arm of the study, and then further, if they do not wish to take part in the exercise program, to consent to take part in the observational ‘control’ arm.
3. The Committee asked about how tissue (blood) samples collected in this study would be stored and managed. The Researcher explained that samples would be stored at the cancer society tissue bank. Samples will be analysed for cell counts, for safety information, and also for the effect of exercise on circulating inflammatory cytokines (amongst other elements).   
   Action requested: the Committee asked for this information on the use and management of tissue to be added to the Participant Information Sheet, along with how long the tissue samples are likely to be stored for.  
   (*National Ethical Standards* para *7.15*)
4. The Committee stated that the qualitative interviews, although mentioned in the protocol and in questionnaires attached to the application, were not described in the application form itself or the PIS.  
   Further information requested: in re-submitting this application, please describe who is asked to take part in the qualitative interviews and on what basis; and what data are collected, how it will be protected/accessed, analysed, or shared afterwards. Please add information about the questionnaires to the PIS.  
   (*National Ethical Standards* para *7.15*)
5. Action requested: please state in the protocol that the control group will need to wear an accelerometer.
6. The Committee asked for the PhD supervisor to attend the next HDEC meeting.

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

1. Please amend the PIS for the control group so as to only include information relevant to them (i.e. most of the information about the exercise programme does not need to be included).
2. Please proof-read for readability, reducing jargon to make the form appropriate for lay readers.
3. Please explain what biomarkers are and what you are planning to do with those blood samples, including where they will be stored and for how long, who will have access to them, and whether they might be shared for future research or sent overseas.
4. Please explain the potential cultural issues relating to the use of blood samples in this study, and refer to the HDEC template for recommended wording.
5. Please refer to those invited onto the study as ‘participants’, rather than ‘cancer patients’.
6. Please explain data-linking for lay participants.
7. Please explain in greater detail what participants should expect from the exercise programme: that blood samples will be taken by finger-prick, how long assessments will take to complete, screening etc.

Decision

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

## 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:** | 09 February 2021 |
| **Meeting venue:** | Via videoconference |

1. **Review of Last Minutes**

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

The meeting closed at 4:00pm.