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| **Committee:** | Central Health and Disability Ethics Committee |
| **Meeting date:** | 23 June 2020 |
| **Meeting venue:** | GC.3, Ground Floor, Ministry of Health, 133 Molesworth Street, Wellington |

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| **Time** | **Item of business** |
| 12:00pm | Welcome |
| 12:15pm | Confirmation of minutes of meeting of 26 May 2020 |
| 12:30pm | New applications (see over for details) |
|  | i 20/CEN/125  ii 20/CEN/128  iii 20/CEN/131  iv 20/CEN/132  v 20/CEN/133  vi 20/CEN/134  vii 20/CEN/135  viii 20/CEN/136  ix 20/CEN/138  x 20/CEN/139 |
| 5:00pm | Meeting ends |

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| **Member Name** | **Member Category** | **Appointed** | **Term Expires** | **Apologies?** |  |
| Mrs Helen Walker | Lay (consumer/community perspectives) | 01/07/2018 | 01/07/2021 | Present |  |
| Mrs Sandy Gill | Lay (consumer/community perspectives) | 30/07/2015 | 30/07/2018 | Present |  |
| Dr Patries Herst | Non-lay (intervention studies) | 27/10/2015 | 27/10/2018 | Present |  |
| Dr Cordelia Thomas | Lay (the law) | 20/05/2017 | 20/05/2020 | Present |  |
| Dr Peter Gallagher | Non-lay (health/disability service provision) | 30/07/2015 | 30/07/2018 | Present |  |
| Ms Helen Davidson | Lay (ethical/moral reasoning) | 06/12/2018 | 06/12/2021 | Present |  |
| Ms Julie Jones | Non-lay (intervention studies) | 22/05/2020 | 22/05/2022 | Present |  |
| Dr Jillian Wilkinson | Non-lay (observational studies) | 22/05/2020 | 22/05/2023 | Present |  |

## Welcome

The Chair opened the meeting at 12:00pm and welcomed Committee members.

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 26 May 2020 were confirmed.

## New applications

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| **1** | **Ethics ref:** | **20/CEN/125** |  |
|  | Title: | (duplicate) (duplicate) Klippel-Trenaunay Syndrome (KTS) Study |  |
|  | Principal Investigator: | Dr Swee Tan |  |
|  | Sponsor: |  |  |
|  | Clock Start Date: | 11 June 2020 |  |

Dr Swee Tan & Dr Kimberley Sent-Doux were present by video conference 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. To study the demographics, possible causation and anatomical distribution of the disease and associated anomalies in patients with Klippel-Trenaunay Syndrome (KTS) referred to the Centre for the Study & Treatment of Vascular Birthmarks, based at the Plastic, Maxillofacial & Burns Unit at the Hutt Hospital, Wellington, New Zealand.
2. The study will also focus on identifying potential complications of KTS including venous thromboembolism and its possible association with persistent embryonal vein.

Summary of resolved ethical issues

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

1. The Committee queried why the application form did not appear to reflect feedback given at the time of the previous submission of this application. Subsequent discussion determined that the application form for the previous submission was erroneously uploaded without editing.

Summary of outstanding ethical issues

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

1. Please provide formal, independent scientific peer review, utilising the peer review template found on the HDEC website.

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

1. Please amend all Participant Information Sheets to include footers with PIS versions and dates and include the correct application number on all documentation
2. Please remove the section on reconsent from the main parent PIS, as parents are only consenting on behalf of the participant and only the participants need to be reconsented when they turn 16 years old.
3. Please upload the most recent version of the main PIS for parents of potential participants under 16 years old.
4. Please either clarify the distinction between, or reconcile, the consent for use of excess blood samples for future research, with the consent to obtain a 10ml donation of blood for the tissue bank, found on pages 2 and 6 of the reconsent form.
5. Please ensure that the reconsent form encapsulates reconsent for everything (e.g., tissue, blood, data) that the research team wish to continue to have access to after the participant has turned 16 years old.
6. Please amend the PIS for 6-11-year-olds to include more information about what participation looks like for them; a picture demonstrating study procedures may be helpful.
7. Please simplify the PIS for 12-15-year-olds and compare to the adult PIS and the amended PIS for 6-11-year-olds for reference.
8. Please amend all study PISs to clarify whether an MRI scan is part of, or in addition to, standard of care. If part of standard of care, please ensure that all PISs clearly communicate that the results of this MRI will be accessed for the purposed of the study.
9. Please amend the PIS to include a section on the participant’s right to access and correct information about themselves.
10. Please amend the PIS to include information on management and governance of tissue storage.
11. Please amend all PISs to include the appropriate cultural statements, as per the HDEC PIS template.
12. Please review all study PISs and compare with the PIS template found on the HDEC website for reference.

Decision

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

* Please provide formal, independent scientific peer review, utilising the peer review template found on the HDEC website.
* Please amend Participant Information Sheets and Consent Forms, taking into account feedback provided by the Committee (above).

After receipt of the information requested by the Committee, a final decision on the application will be made by Dr Cordelia Thomas and Dr Patries Herst.

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| **2** | **Ethics ref:** | **20/CEN/128** |  |
|  | Title: | 233AS102: Long-Term Evaluation of BIIB067. |  |
|  | Principal Investigator: | Dr Deborah Mason |  |
|  | Sponsor: | Biogen Idec Research Limited |  |
|  | Clock Start Date: | 11 June 2020 |  |

Dr Deborah Mason was present via video conference 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. Amyotrophic lateral sclerosis (ALS), a rare neuro-degenerative disease resulting in loss of motor neurons within the cortex, brainstem, and spinal cord. Participants suffer gradual loss of muscle mass, strength, and function in bulbar, respiratory, and voluntary muscle.
2. BIIB067 is being developed for the treatment of ALS in participants who have a confirmed mutation of superoxide dismutase 1 (SOD1).
3. Participants who provide informed consent are enrolled in this open-label extension study after completion of the parent study (233AS101). The study will assess the safety, tolerability, effectiveness and pharmacokinetics (study drug levels) of BIIB067, in participants with SOD1-ALS.
4. This application has been submitted specifically for two New Zealanders who were enrolled in the extension study in Canada. Unfortunately, they have been forced to return to New Zealand as a result of the COVID-19 pandemic, with their study participation interrupted as a result. As both individuals are keen to continue in the study, this application will enable them to resume participation at a New Zealand site.

Summary of resolved ethical issues

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

1. The Committee queried whether the participant had the opportunity to consent for a caregiver to give information about them. The Researcher stated that there is a clause in the participant consent to allow for this.
2. The Committee queried whether the section in the PIS pertaining to the travel agency used by the study is relevant to the New Zealand-based participants. The Researcher confirmed that this was not Canada-specific and is relevant.

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

1. Please amend page four of the PIS to account for HIV being a notifiable disease in New Zealand
2. Please amend study documentation to reflect that race/ethnicity is not considered personal (i.e., identifiable) information in New Zealand.
3. Please amend the section of the PIS that states that all research with human participants is reviewed by an HDEC, as the HDEC only reviews some health and disability research.
4. Please remove references to sub-studies in the PIS that the two New Zealand participants will not be involved with.

Decision

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

* Please amend the Participant Information Sheets and Consent Forms, taking into account feedback provided by the Committee (above)

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| **3** | **Ethics ref:** | **20/CEN/131** |  |
|  | Title: | Laissez-faire vs direct closure in eyelid repair |  |
|  | Principal Investigator: | Dr Stephen Ng |  |
|  | Sponsor: |  |  |
|  | Clock Start Date: | 11 June 2020 |  |

Dr Stephen Ng was present by video conference 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. Secondary intention healing, also known as laissez-faire, was first described in eyelid surgery in 1957. However, it is more common for surgical reconstruction to occur after skin lesion excision from the eyelids.
2. There have been a few case series, advocating laissez-faire as a viable alternative treatment option with promising results, that is not inferior to surgical reconstruction.
3. The objective of this randomised control trial is to randomly assign cases that have had lower lid lesions removed to either Laissez-faire or surgical wound closure, and analyse the outcomes.
4. The Researchers predict that there is no difference in outcome or at least no inferiority between Laissez-faire compared to primary direct closure.

Summary of resolved ethical issues

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

1. The Committee queried whether Māori are to be excluded from participating in this study. The Researcher stated that data suggests that Māori are unlikely to present in the study population, however Māori consultation will be taking place nonetheless.

Summary of outstanding ethical issues

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

1. The Committee stated that a welfare guardian cannot consent on behalf of someone to participate in a medical experiment in New Zealand, unless participation involves potentially life-saving treatment. Please amend study documentation to reflect this, noting that those who cannot give informed consent, such as those with advanced cognitive impairment (e.g., dementia), will be excluded.
2. Please provide formal, independent scientific peer review, utilising the peer review template found on the HDEC website.
3. Please replace the Māori contact for Christchurch participants with a Māori contact based locally.

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

1. Please amend the section on page 2 of the PIS on data confidentiality, to provide greater detail about how data will be kept confidential.
2. Please amend the section of the PIS on risks and benefits of participation, to clarify which risks and benefits apply to which treatment option.
3. Please amend the PIS to include an indication of how many people are expected to participate in the study and over what period of time recruitment will occur.
4. Please amend the statement “you will be included in the study” to clarify that consent will be sought if inclusion criteria are met, and that consenting to participate is optional even if inclusion criteria are met.
5. Please amend the PIS to clarify whether clinic visits post-surgery will occur, and when they will be expected to occur.
6. Please amend the PIS to clarify whether clinic visits can take place virtually, or if they must be in person.
7. Please amend the PIS to discuss the auditors that are mentioned in the Consent Form.
8. Please amend the study data collection sheets to only collect ethnicity data once from each participant.
9. The Committee suggested removal of the grading information in the data collection forms and place in an appendix if appropriate.
10. The Committee queried the statement in the PIS referring to digital data archiving, given that paper copies of many study documents will exist. The Researcher stated that all hard copies will be destroyed and all information will be stored digitally.
11. The Committee queried who will be filling out the post-operation questionnaire. The Researcher stated that it is meant to be the participant but interpreters are available for the consent process as well as all other questionnaires and forms, although this is not often necessary.
12. Please amend the PIS to more clearly distinguish the meanings of “treatment” vs “procedure”, and clarify at which times this refers to standard of care and when it refers to the study treatment.
13. Please amend wording at the start of the PIS to ensure that the correct document length is referred to.
14. Please review the study lay-title and reconsider whether “left to heal on its own” is the most appropriate description for one of the study arms.
15. Please amend the section of the PIS on “what is the purpose of this study” to clearly state that participants will be randomly assigned to a study arm.
16. Please review the PIS for typos, in particular page 2.
17. Please amend the PIS to replace “anonymous” with “de-identified”.
18. Please amend the PIS section on data sharing to ensure that it accurately reflects whether data is only used for this study.
19. Please amend the PIS to clarify the identifiability of photographs taken of the participant.
20. Please amend the Consent Form to ensure that Yes/No tick boxes are only present for truly optional aspects of participation.

Decision

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

* Please amend study documentation to reflect that a welfare guardian cannot consent on behalf of someone to participate in a medical experiment in New Zealand, unless participation involves potentially life-saving treatment.
* Please provide formal, independent scientific peer review, utilising the peer review template found on the HDEC website.
* Please replace the Māori contact for Christchurch participants with a Māori contact based locally.
* Please amend the Participant Information Sheets and Consent Forms, taking into account feedback provided by the Committee (above)

After receipt of the information requested by the Committee, a final decision on the application will be made by Ms Helen Davidson and Ms Julie Jones.

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| **4** | **Ethics ref:** | **20/CEN/132** |  |
|  | Title: | A Study of CLS346 in People with Diabetic Kidney Disease |  |
|  | Principal Investigator: | Professor Russell Scott |  |
|  | Sponsor: | Covance New Zealand |  |
|  | Clock Start Date: | 11 June 2020 |  |

Ms Bobby McEwan was present via video conference 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 prospective study to investigate efficacy, safety, tolerability and PI of repeat doses of CSL346 in participants with Diabetic Kidney Disease.
2. Participants will be randomised to receive one of 2 doses of study drug or placebo (1:1:2).
3. The primary objective is to evaluate efficacy of CSL346 administered every 4 weeks for up to 12 weeks.
4. The change in urinary albumin-to creatinine ratio from baseline will be measured.
5. Secondary objectives will measure safety, SCr concentration, eGFR, and blood pressure.

Summary of resolved ethical issues

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

1. The Committee queried whether de-identified data is potentially re-identifiable, so that a positive test result can be communicated to the participant. The Researcher confirmed that this was correct.
2. The Committee queried how first approach to participants would take place. The Researcher stated that potential participants are participants from a previous study who consented to being contacted about other research projects, otherwise potential participants will already be in the clinic and will be approached by the clinician.
3. The Committee queried whether the remuneration could be indicated as a dollar value in the main PIS. The Researcher stated that this was not possible as each site would apply their own amount specific to the site.
4. The Committee queried what data on any offspring of participants; data would be collected once they were born. The Researcher stated that only the mother’s medical history and the outcome of the birth would be recorded. The Committee noted that, if information about the health of the baby is sought then consent will need to be sought from a parent/guardian on behalf of the child after the birth.

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

1. Please amend the sentence in the PIS that states that the study can be stopped for any reason, as studies cannot be stopped for commercial reasons in New Zealand.
2. Please amend the sentence on page 16 of the PIS that states that information gathering from public sources may occur, to clarify under what circumstances that would take place.
3. Please amend the PIS to clarify that future research is not future unspecified research, as it has been specified in the PIS.
4. Please reconcile duration of sample storage as described in different sections of the PIS.
5. Please review the duration which participants are required to fast for, as the times in the application form and PIS differ.
6. Please amend the PIS for pregnancy to clarify what specific types of birth control are considered “reliable” for the purposes of this study.

Decision

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

* Please amend Participant Information Sheets and Consent Forms, taking into account feedback provided by the Committee (above)

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| **5** | **Ethics ref:** | **20/CEN/136** |  |
|  | Title: | CT-P43 1.1: A study comparing the trial drug CT-P43 and Stelara®, in healthy male participants. |  |
|  | Principal Investigator: | Dr Chris Wynne |  |
|  | Sponsor: | CELLTRION |  |
|  | Clock Start Date: | 11 June 2020 |  |

Dr Chris Wynne was present via video conference 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. Stelara (ustekinumab) is currently approved for the treatment of psoriasis and the inflammatory bowel disorders Crohn’s disease and ulcerative colitis.
2. Celltrion has developed their own preparation of ustekinumab, called CT-P43. This study aims to show that CT-P43 has a high degree of similarity to Stelara, in terms of:
   * Levels of drug in the blood over time after single injection
   * Safety and side effects
   * Whether the body produces antibodies against the drug.
3. Approximately 270 healthy males will be enrolled in the study. Participants will receive a single 45 mg dose of either CT-P43, US-licensed Stelara, or EU-approved Stelara. The dose will be administered as an injection under the skin in the abdomen.
4. Blood samples to measure study drug levels and immune response will be collected at specific time points; safety will be monitored; and any changes in health will be recorded.
5. The results will be used to inform further development of CT-P43.

Summary of resolved ethical issues

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

1. The Committee queried why page 12 of the PIS states that participants accessing study specific information could result in their removal from the study. The researcher responded that this was because of the risk of them becoming unblinded to the study arm they are enrolled in.

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

1. Please amend the front page of the PIS to include a highlighted lay-title.

Decision

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

* Please amend the front page of the PIS to include a highlighted lay-title.

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| **6** | **Ethics ref:** | **20/CEN/134** |  |
|  | Title: | A serological survey of SARS-CoV-2 in the Auckland population |  |
|  | Principal Investigator: | Professor Chris Bullen |  |
|  | Sponsor: | The University of Auckland |  |
|  | Clock Start Date: | 11 June 2020 |  |

Professor Chris Bullen was present by video conference 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 current lack of accurate, empirical data on the prevalence of COVID-19 infection is the most urgent data needed in New Zealand’s response to the epidemic. Initial surveillance focussed primarily on travellers with significant symptoms of disease, and, as such the full spectrum of the disease, including the extent and fraction of mild or asymptomatic infections that do not require medical attention and those infections from community spread are not clear.
2. The proposed study is a cross-sectional survey of residents of Auckland. The sample will be a stratified random sample of an individual from each of up to 7,500 households. In the first instance 2,500 individuals will be selected with numbers increased according to the number positive. Each selected individual will complete a questionnaire and have blood taken for antibody testing.
3. The Researchers hypothesise that the prevalence of antibodies to the COVID-19 virus in the Auckland population is less than 1%. Findings will be made available to the Ministry of Health to support their COVID-19 elimination strategy.

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 process of visiting houses of participants. The Researcher responded that this process was being adopted to try and get the best representation of Māori participants.
2. The Committee queried whether tests would be analysed in laboratories. The researcher stated that initially these were to be done at point of care, but now laboratories are deemed more accurate.
3. The Committee queried whether it is plausible to get potential participants from the street into the hospital. The Researcher agreed that while it may pose a challenge, retention is unlikely to be worse than testing as a follow-up to a GP appointment. The Researcher also stated that if going to a laboratory is not possible then home visits for blood collection can be arranged (with appropriate PPE and in a way that will avoid stigmatisation of participants).
4. The Committee queried whether younger children would be likely to agree to a blood test. The Researcher responded that they are unlikely to be keen on the test, however there is no suitable alternative available. Further, discomfort can be minimised by performing this test during a home visit.
5. The Committee queried whether participants will be notified of negative test results. The Researcher stated that they will be able to do so if the participant indicates that they would like a negative result communicated to them.

Summary of outstanding ethical issues

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

1. Please demonstrate that those in the study team undertaking home visits involving children of diverse cultural backgrounds are appropriately trained and prepared.
2. Please provide HDEC with the safety protocol for field workers on research teams, including any protocols already established at an institutional level and how it differs from public health protocols.

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

1. Please separate the child assent forms to create separate and age appropriate forms for 7-11-year-olds and 12-15-year-olds.
2. Please amend the PIS to contain more information as per the HDEC template, including (but not limited to): data management and governance, ACC statement, cultural statement, and Māori contact details
3. Please amend the phrase “mid-epidemic” in the PIS to more accurately describe the current pandemic status of New Zealand.
4. Please ensure that all participants under 16 years old provide assent and their parents provide written consent.
5. Please amend the PIS to clearly state that researchers will be wearing PPE during home visits.
6. Please amend the statement in the PIS that reads “your household has been randomly selected to participate in this study” to “your household has been randomly selected to be *invited* to participate in this study” to clarify that participation is optional.

Decision

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

* Protocols must include all information that is relevant for the type of study (Standard 9.8, National Ethical Standards for Health and Disability Research and Quality Improvement, 2019)
* In considering individuals’ capacity to consent, researchers need to take into account the level of complexity of the study. They must provide information in an appropriate format (e.g. they should consider abbreviating or simplifying it, if necessary) (Standard 6.8.a, National Ethical Standards for Health and Disability Research and Quality Improvement, 2019).
* It is the responsibility of health professionals to impart information in a way age appropriate to the child. The time that a child has to digest and understand the information is another relevant factor (and may be a barrier to obtaining meaningful consent in an acute setting). (Standard 6.22.d, National Ethical Standards for Health and Disability Research and Quality Improvement, 2019)

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| **7** | **Ethics ref:** | **20/CEN/139** |
|  | Title: | Efficacy and safety of finerenone in participants with symptomatic heart failure and left ventricular ejection fraction ≥ 40% (LVEF ≥ 40%) |
|  | Principal Investigator: | Professor Richard Troughton |
|  | Sponsor: | Bayer Australia Limited |
|  | Clock Start Date: | 11 June 2020 |

Professor Richard Troughton was present by video conference 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 will investigate the efficacy and safety of Finerenone for symptomatic heart failure and left ventricular ejection fraction > 40% in comparison to placebo and in addition to standard of care therapy for congestion and comorbidities.
2. The main objective is to demonstrate the superiority of finerenone to placebo in reducing the rate of composite cardiovascular (CV) endpoint.
3. Participants will receive one tablet daily treatment with finerenone or placebo for up to 42 months until expected events are reported. Provided patient’s safety not affected, the participant may be up-titrated to next higher dose level after 4 weeks of treatment keeping maximum tolerated dose as long as possible. Additional safety visit will be attended by participant after each up-titration.
4. Post treatment follow-up period for participants still taking the treatment when study end reached, will last 35 days upon completion of phone call.

Summary of resolved ethical issues

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

1. The Committee queried how any potential conflicts of interest or undue influence will be managed, given that some potential participants will be under the care of the CI. The Researcher stated that the lead investigator on site will not make the initial approach, but will be available to answer questions from the participants. Other members of the clinical team, or the research coordinators, will make the initial approach.
2. The Committee queried whether a participant’s GP will be informed of the study. The Researcher confirmed that this would happen; the GP is described as the participant’s “health professional” in the PIS.
3. The Committee queried how data safety would be monitored so that participants can be triaged if necessary. The Researcher stated that local study coordinators will check data as it is entered at their site.

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

1. Please amend the PIS to include information on what screening tests will be administered and what they will involve for potential participants.
2. Please amend page 5 of the PIS to include all potential side effects, including those that are considered uncommon. It can be stated that the uncommon side effects occur infrequently; ideally all potential side effects will include evidence-based frequencies. Idiosyncratic side effects may be omitted.
3. Please amend the PIS to include information about what happens to samples once the storage period has ended.
4. Please amend the PIS to include a section that informs participants that they can access data about themselves.
5. Please ensure that the Consent Form contains reference to samples being sent overseas.
6. Please ensure that the PIS contains information on the circumstances in which a participant’s dose may be increased over time, including what this means for the participant.
7. The Committee queried the statement on page 9 of the PIS, regarding withdrawal from the study and that samples and images will still be used. The Researcher stated that they will clarify the wording in this section to better reflect participants’ options of withdrawing from the protocol or withdrawing from the study completely, and that a discussion will occur between researchers and participants about what the participant would like to do.
8. Please review the consent form and PIS for pregnant partners to ensure that the correct individual is referred to (e.g., in some places in the pregnant partner form, the pregnant participant is referred to).
9. Please remove the space for the signature of the partner of a pregnant partner (e.g., the participant) in the pregnant partner consent form, as the non-pregnant partner’s consent is not required for data to be collected about the pregnant partner.
10. If a baby is born to a participant or their partner during their participation in the study, please submit an amendment to state whether data will be collected on the baby once they are born, and how consent of the parent/guardian on behalf of the child will take place.
11. Please amend the PIS to include a statement informing participants that they will need to carry a study contact card with them.
12. Please soften the wording on participant’s responsibilities in section 3 of the PIS.
13. Please amend the sentence in the PIS that states a participant’s doctor can “find out in case of an emergency” to “can find out in the event of an emergency”.
14. Recommend that frequencies of side-effects in the PIS are in percentages rather than referring to ‘less than 1 person’.
15. Please ensure all relevant statements at the end of the HDEC template PIS are included in the PIS for this study.
16. Please ensure that all relevant contact numbers are available on the pregnant partner and pregnant participant PIS.
17. Please include information on data safety monitoring in the PIS.
18. Please include information on data governance and confidentiality in the PIS.
19. Please amend the consent form to include an optional tick box for participants who wish to receive a lay-summary of study results.
20. Please ensure the ICF statement contains the following:
    * I have had the opportunity to use a legal representative, whanau/ family support or a friend to help me ask questions and understand the study.
    * I am satisfied with the answers I have been given regarding the study and I have a copy of this consent form and information sheet.
    * If I decide to withdraw from the study, I agree that the information collected about me up to the point when I withdraw may continue to be processed.
    * I understand that there may be risks associated with the treatment in the event of myself or my partner becoming pregnant. I undertake to inform my partner of the risks and to take responsibility for the prevention of pregnancy.
    * I agree to my (type of tissue) samples being sent overseas and I am aware that these samples will be disposed of using established guidelines for discarding biohazard waste.
    * I agree to an approved auditor appointed by the New Zealand Health and Disability Ethic Committees, or any relevant regulatory authority or their approved representative reviewing my relevant medical records for the sole purpose of checking the accuracy of the information recorded for the study.
    * I understand that my participation in this study is confidential and that no material, which could identify me personally, will be used in any reports on this study.
    * I understand the compensation provisions in case of injury during the study.
    * I know who to contact if I have any questions about the study in general.
    * I understand my responsibilities as a study participant.

Decision

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

* Please amend the Participant Information Sheets and Consent Forms, taking into account feedback provided by the Committee (above)

After receipt of the information requested by the Committee, a final decision on the application will be made by Ms Helen Davidson and Ms Julie Jones.

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| **8** | **Ethics ref:** | **20/CEN/138** |  |
|  | Title: | Shape and Growth Modelling in Cerebral Palsy - An MRI Study |  |
|  | Principal Investigator: | Mr Salim Bin Ghouth |  |
|  | Sponsor: | The University of Auckland |  |
|  | Clock Start Date: | 11 June 2020 |  |

Mr Salim Bin Ghouth and Dr Geoffrey Handsfield were present by video conference 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. Muscle size deficiencies are common among children with cerebral palsy (CP) and recent research has shown that muscle size impairments are non-uniform in CP, with the soleus muscle severely affected by this pathology. Impairments of the soleus muscle are important to study because this muscle has a very important role in walking, standing, and maintaining balance.
2. Currently, it is not clear how shape and growth differ in populations with CP when compared with a typically developing population.
3. To answer this question, researchers intend to image the soleus muscles in a cohort of participants with ambulatory CP aged between 6 -14 years old and a typically developing control cohort and compare their shape and growth trajectories.
4. The study aims to acquire T2-weighted MR images of participants during three imaging sessions, each 12 months (±2months) apart, conducted at the Centre for Advanced MRI (CAMRI) in Auckland or the Mātai Medical Imaging Research in Gisborne.

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

1. Please amend the PIS to clarify that the koha offered at every visit is for the children and not the parents.
2. Please provide evidence of Māori consultation.
3. Please amend the section of the PIS on what happens after the study, or if the participant changes their mind, to remove repetitive language.
4. Please simplify the PIS for 7-11-year-olds; the use if graphics and images, such as an image of a child with their leg in a scanner, is advised.
5. Please amend age ranges for child PISs to comply with HDEC templates; i.e., 7-11 years old, 12-15 years old, and 16+ years.
6. Please separate PISs for control group and study group participants.
7. Please amend the section in the PIS on what does participation involve, to describe whether participants will have to visit a clinic, what will happen in those visits, and how often those visits will occur.
8. Please increase the line spacing in the PIS to improve readability.
9. Please amend the PIS to include that the participant has the right to access and correct data about themselves.
10. Please ensure that the clause in the Consent Form regarding the participant’s GP being contacted, is already included in the PIS.
11. Please amend the section of the PIS that states that younger participants need to contact the researchers for reconsenting when they turn 16, as the responsibility for seeking consent lies with the Researchers.
12. Please provide the HDEC with a copy of the reconsent form for participants once they turn 16 years old.
13. Please review the PIS for typos.
14. Please amend the sentence on page 8 of the consent form so that it reads as “consent for my child taking part”, not for “me taking part”.

Decision

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

* Please amend the Participant Information Sheets and Consent Forms, taking into account feedback provided by the Committee (above).

After receipt of the information requested by the Committee, a final decision on the application will be made by Mrs Sandy Gill and Dr Jillian Wilkinson.

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| **9** | **Ethics ref:** | **20/CEN/135** |  |
|  | Title: | STEP II |  |
|  | Principal Investigator: | Dr Matthew Daly |  |
|  | Sponsor: | AtaCor medical, Inc |  |
|  | Clock Start Date: | 11 June 2020 |  |

Dr Matthew Daly was present [in person/by teleconference] 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. Pacing is an effective treatment for a slow heartbeat. Typical pacing wires attach to the inside or outside of the heart.
2. This research wire is inserted between the ribs near the heart.
3. Participants will be having another cardiac procedure done. There will be no direct benefit to having the Study Wire in place.
4. The wire will be connected to a pacemaker and heart will be paced. Recordings of the heart will be taken. The heart may be briefly paced at a high rate using the study wire. X-rays and ultrasound images will be taken before and after the new wire is placed.
5. The purpose is to collect information about the electrical measurement performance of the Study Wire and 3 strategies for stabilising the performance of the Study Wire over a two to seven day period.
6. The 3 strategies being tested are:
   * A special bandage-like dressing over the incision that connects to a small vacuum pump. This treatment is intended to pull excess fluid away from the incision site.
   * An anti-inflammatory drug intended to reduce inflammation, swelling and fluid collecting near the device. Initially given intravenously, but changed to oral for use at home.
   * A second Study Wire, which will allow testing of different Study Wire configurations.
7. These treatments will be assigned randomly, or the doctor may decide on additional treatment in particular.
8. There is a requirement to stay in hospital for a minimum of two days following the procedure. These two days may not be necessary for the procedure but are necessary for the study so that other tests can be performed on the study wire. Measurements will be taken while in various positions; questions will be asked about sensations experienced while testing the Study Wire.
9. An ECG monitor will be used record the heart’s electrical activity at rest and while active. Participants may be discharged with the study wire still in place.
10. 48 hourly visits to check wound or device after discharge.
11. The study wire will not be in for more than seven days. Participants must return to the hospital to have the study wire removed. One follow-up visit at 30 days is planned.

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

1. Please review the PIS and replace technical language with clear and concise lay-friendly language where applicable. Please consider using images to help explain the difference between standard of care and the study treatment.
2. Please amend the PIS to reflect the fact that a study nurse, and not the treating doctor, will be approaching potential participants. Please include a reiteration in this section that there is no detriment to the individual’s care if they do not wish to participate.
3. Please amend the risks and benefits section of the PIS to clearly state that there are no benefits as a result of the study treatment to participants.
4. Please amend the PIS to clarify that the right to withdraw from the study includes that the wire will be removed in that case.
5. Please amend the PIS to include a statement that participants have the right to access and correct information about themselves.
6. Please amend the PIS to include information on the photographs of the wound where the wire is inserted, namely what body parts will be included in the photograph and how identifiable those photographs will be (i.e., will include breasts/chest, will not include the face).
7. Please amend the PIS to clarify that studies cannot be stopped for commercial reasons in New Zealand.
8. Please add a statement to the PIS, in bold, that a patient’s stay in hospital will be longer if they choose to participate.
9. Please amend the PIS to include information on whether any study data will be sent overseas, including clarifying that New Zealand data protection laws do not apply in other jurisdictions.

Decision

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

* Please amend the Participant Information Sheets and Consent Forms, taking into account feedback provided by the Committee (above).

After receipt of the information requested by the Committee, a final decision on the application will be made by Dr Cordelia Thomas and Dr Peter Gallagher.

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| **10** | **Ethics ref:** | **20/CEN/133** |  |
|  | Title: | Lenvatinib for Pediatric Patients with Relapsed/Refractory Solid Tumors |  |
|  | Principal Investigator: | Dr Karen Tsui |  |
|  | Sponsor: | Merck Sharp & Dohme (New Zealand) Ltd. |  |
|  | Clock Start Date: | 11 June 2020 |  |

Dr Karen Tsui and Mrs Jane Wylie were present by video conference for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. The proposed study is a multicentre, open-label Phase 2 study to evaluate whether the study medication lenvatinib can improve outcomes in young people with relapsed or refractory solid tumours, including brain tumours. Approximately 150 subjects internationally aged 2-21 will be enrolled in cohorts according to four tumour groups. Starship hospital expects to enrol 3-5 patients.
2. All will receive lenvatinib orally once daily until their tumour no longer responds (they have progressive disease), they are intolerant or other reason for stopping treatment. Outcomes will be evaluated by tumour response as measured by sequential CT scan or MRI at 8 weekly, then 12 weekly intervals during the study.
3. Participants are estimated to average 12 months on treatment from starting therapy. Participants discontinuing treatment will be followed up by 8 or 12 weekly visits and imaging depending on time enrolled. Participants whose disease progresses will be followed by 3-monthly phone call (or other means) for survival.
4. During the study, safety and toxicity evaluations include monthly physical exams (more frequent in the first 2 months on study), laboratory analyses and cardiac monitoring by echocardiogram (ECHO).
5. Other procedures include a palatability questionnaire, Pharmacokinetic (PK), pharmacogenetic and biomarker research.

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

1. Please amend page 3 of the PIS to clarify that continuation of the study treatment depends on whether the participant’s doctor agrees.
2. Please amend the PIS to clarify that follow up visits will be to Starship Hospital.
3. Please amend page 5 of the PIS to clarify that only positive blood tests will be reported.
4. Please amend page 10 of the PIS to clarify what is considered to be acceptable birth control, including that the participant can discuss this with their doctor (i.e. their parent/guardian does not have to be present).
5. Please amend the section of the PIS on participants withdrawing from the study to clarify that withdrawal does not have to be conditional.
6. Please reconcile pages 3 and 24 of the PIS to clarify under what circumstances participants can continue to receive the study drug post-study.
7. Please amend page 15 of the PIS t clarify whether the participant will be notified if the Sponsor transfers the licence or sells the trial.
8. Please amend the second-to-last clause of the Consent Form regarding informing the participant’s GP, to clarify that this is also to access their health information from their GP.
9. Please include a separate point in the Consent Form regarding consent for participants’ samples to be sent overseas.
10. Please amend the PIS for 11-15-year-olds to include a Māori contact number.

Decision

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

* Please amend the Participant Information Sheets and Consent Forms, taking into account feedback provided by the Committee (above).

After receipt of the information requested by the Committee, a final decision on the application will be made by Dr Cordelia Thomas and Dr Peter Gallagher.

## 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:** | 28 July 2020, 12:00 PM |
| **Meeting venue:** | GC.3, Ministry of Health, 133 Molesworth Street, Wellington, 6011 |

1. **Problem with Last Minutes**

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

The meeting closed at 5.00pm