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| **Committee:** | Central Health and Disability Ethics Committee |
| **Meeting date:** | 28 January 2020 |
| **Meeting venue:** | Room 1S.1, First Floor, Ministry of Health, 133 Molesworth Street, Wellington |

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| **Time** | **Item of business** |
| 12:00pm | Welcome |
| 12:25-12:30pm | Confirmation of minutes of meeting of 26 November 2019 |
| 12:30pm | New applications (see over for details) |
| 12:30-12:55pm  12:55-1:20pm  1:20-1:45pm  1:45-2:10pm  2:10-2:35pm  2:35-3:00pm  3:00-3:25pm  3:25-3:50pm  3:50-4:15pm  4:15-4:40pm  4:40-5:05pm | 1. 19/CEN/218 2. 20/CEN/2 3. 19/CEN/214 4. 19/CEN/209 5. 19/CEN/210 6. 19/CEN/217 7. 20/CEN/1 8. 19/CEN/219 9. 19/CEN/221 10. 19/CEN/225 11. 19/CEN/224 |
| 5:05pm | General business:  Noting section of agenda |
| 5:15pm | 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 |
| 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 | Apologies |
| Mrs Sandy Gill | Lay (consumer/community perspectives) | 30/07/2015 | 30/07/2018 | Present |

## Welcome

The Chair opened the meeting at 12:00pm and welcomed Committee members, noting that apologies had been received from Ms Helen Davidson.

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 November 2019 were confirmed.

## New applications

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| **1** | **Ethics ref:** | **19/CEN/210** |
|  | Title: | Body composition and propofol infusions in neonates infants and children |
|  | Principal Investigator: | Professor Brian Anderson |
|  | Sponsor: | The University of Auckland |
|  | Clock Start Date: | 09 January 2020 |

Mr James Morse was present 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. There are a lack of dosing guidelines surrounding propofol infusions in neonates and obese children. Current infusion regimens are determined from non-obese children aged 3-11 years, making them unsuitable when applied to neonates or the obese. The correct size metric to guide doses of propofol for these groups that achieves desired anaesthetic targets is unclear. The impact of obesity on propofol pharmacokinetics has not been assessed with a direct measure of body composition, instead it is often estimated from sex weight and height. The pharmacokinetic model developed in this work could inform future dosing of propofol infusions in a broad population from neonates to obese children.

Summary of outstanding ethical issues

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

1. The Committee queried how participants would be recruited. The Researcher stated they would be approached during the pre-operative process. The Committee queried whether parents would be in the right frame of mind to be reading about a study for the first time while waiting for their child to have an operation. The Researcher stated this was a valid concern but was not sure how else they could approach participants. The Committee suggested a pre-operative appointment before the day of surgery would be more appropriate. The Committee recommended the Researcher reconsider the approach and involve potential participants clinician teams. The Committee suggested the clinician could hand out or mail information about the study before the day of surgery. The Committee advised that as surgery can be a high stressful situation it is preferable to have potential participants aware of the study before they arrive on the day.

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

1. The Committee complimented the Researcher on the illustrations in the information sheets and for splitting them into age appropriate ranges of 7-10 and 11-15. The Committee requested the addition of a header to each PIS stating the age range.
2. The Committee requested the inclusion of a cultural tissue statement in all information sheets. The Committee recommended the following statement:

“You may hold beliefs about a sacred and shared value of all or any tissue samples removed. The cultural issues associated with sending your samples overseas and/or storing your tissue should be discussed with your family/ whānau as appropriate.

There are a range of views held by Māori around these issues; some iwi disagree with storage of samples citing whakapapa and advise their people to consult before participating in research where this occurs. However, it is acknowledged that individuals have the right to choose.”

1. The Committee requested a section for the contact numbers at the end of the PIS. The Committee recommended the Researcher consult the [HDEC template](https://ethics.health.govt.nz/system/files/documents/pages/piscf-template-oct-2019-031019b.doc) for an example of this.
2. The Committee requested the insertion of the latest ACC statement. This can be found on the HDEC template.
3. The Committee requested additional information on data storage e.g. how participants’ data will be stored and for how long, who will have access to it etc. The Committee recommended the Researcher consult the HDEC template.
4. The Committee requested the inclusion of a statement advising that the research was being undertaken as part of the fulfilment of a PhD by Mr James Morse.
5. The Committee noted the consent form states ‘I agree to take part in research’ when it should read ‘I agree for my child to take part’. The Committee requested this be revised to reflect that the parent is providing consent on behalf of the child participant.
6. The Committee noted that in New Zealand family / whānau cannot provide proxy consent and this can only come from a parent or legal guardian. The Committee requested references to this be revised.
7. The Committee expressed concern at the emotive nature of the cartoon dog’s speech bubble and requested it be revised to a simple greeting to avoid any potential coercion or pressure on children to agree.
8. The Committee requested the phrase ‘if you are happy to help us’ be revised to state ‘if you agree to be involved’.
9. The Committee requested a statement on the consent form advising that samples will be sent overseas.

Decision

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

* Please reconsider the initial approach to participants and submit an amended protocol. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 11.7c).*
* Please update the participant information sheet and consent form, taking into account feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17).*

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

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| **2** | **Ethics ref:** | **19/CEN/225 (CLOSED)** |
|  | **Title:** | **Immediate v delayed switch study to Doravirine/Islatravir** |
|  | **Principal Investigator:** | **Dr Alan Pithie** |
|  | **Sponsor:** | **Merck Sharpe & Dohme (Australia) Pty Ltd** |
|  | **Clock Start Date:** | **05 December 2019** |

Mr Kieran McAuley, Dr Alan Pithie and Miss Victoria Hoban were present 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.

**CLOSED SESSION**

Decision

This application was *provisionally approved* by consensus.

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

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| **3** | **Ethics ref:** | **19/CEN/224** |
|  | Title: | Study to Assess the Efficacy and Safety of Nemolizumab (CD14152)in Subjects with Moderate-to-Severe Atopic Dermatitis |
|  | Principal Investigator: | Assoc Prof Marius Rademaker |
|  | Sponsor: | Syneos Health New Zealand Ltd |
|  | Clock Start Date: | 05 December 2019 |

Ms Reenu Arora was present 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. Nemolizumab (CD14152) is a humanised monoclonal modified antibody for the treatment of moderate to severe Atopic dermatitis in adult and adolescents who have an inadequate response to topical AD medications. The proposed double blind, placebo controlled, multi centre, parallel group study will consist of 4 periods over approximately 60 weeks: screening (including run in) initial treatment, maintenance and follow up (unless the participant is a non-responder at Week 16, at which their participation could last up to 28 weeks). The screening period of approximately 2-4 weeks will evaluate eligibility and introduce standardized background topical therapy over a run-in period of at least 14 days before Day 1/baseline.
2. 750 participants will be randomised to receive either subcutaneous (SC) injections of nemolizumab 30mg with a loading dose of 60mg at baseline (group 1)or placebo (group 2) on a 2:1 ratio stratified by baseline disease severity and peak pruritic numeric rating scale (PP NRS).
3. Clinical responders at week 16 will be re-randomized (1:1:1) to study medication, as follows: group 1A, nemolizumab 30 mg every 4 weeks; group 1B, nemolizumab 30 mg every 8 weeks; or group 1C, placebo every 4 weeks for 32 weeks. Non-responders may be eligible for a long-term extension study. Clinical responders receiving placebo in first 16 weeks will continue on placebo for the 32-week period.
4. Participants will receive background topical therapy throughout the study and may be prescribed rescue therapies after baseline if deemed medically necessary.
5. An independent data monitoring committee will monitor safety, evaluated by adverse events (AEs) physical examination, vital signs, clinical laboratory tests, electrocardiogram, peak expiratory flow, Asthma Control Test (ACT).

Summary of resolved ethical issues

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

1. The Committee noted the study intended to use mental health questionnaires and requested how this would occur. The Researcher stated they would be completed on-site during an appointment with the research team. The Committee expressed concern at the prospect of a participant indicating suicidality and queried how soon the researchers would know and what they would do. The Researcher stated Dr Rademaker would review each questionnaire shortly after they were filled in and if he believed there was a risk he would make the appropriate referral to the participant’s GP or a specialist if necessary.
2. The Committee queried whether participants on placebo would have all other treatment withheld. The Researcher stated treatment would not be withheld but only used if needed and confirmed rescue treatment would be available. The Researcher clarified the only exception was participants would need to go through the washout period of two weeks where the use of rescue treatment would exclude them from further participation in 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 queried how recruitment would occur. The Researcher stated they were not certain but Dr Rademaker has a database of potential participants and they have used advertisements in the past. The Committee advised that any advertisements would need to be submitted for approval before use. The Researcher agreed to supply these.
2. The Committee queried why participants aged 16 and over had their own PIS instead of the standard adult sheet. The Researcher stated it was the Sponsor’s decision to use it. The Committee stated it was not necessary in New Zealand as once an individual reaches 16 years of age they can legally consent for themselves on the main PIS. The Committee requested the main PIS be used for all participants aged 16 and over.
3. The Committee noted references to participants ‘under 18’ needing a parent / guardian and requested this be amended to state ‘under 16’. The Researcher stated as this was a global study 18 was the default age. The Committee stated that in New Zealand the age of consent was 16 and to comply with New Zealand law the amendment would need to be made as an adult cannot consent on behalf of another adult in New Zealand.

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

1. The Committee requested a general revision to localise the PIS for a New Zealand context (e.g. referring to injections as ‘shots’ is not common in New Zealand for injections and has the potential to cause confusion).
2. The Committee requested the inclusion of a cultural tissue statement in all information sheets. The Committee recommended the following statement:

“You may hold beliefs about a sacred and shared value of all or any tissue samples removed. The cultural issues associated with sending your samples overseas and/or storing your tissue should be discussed with your family/ whānau as appropriate.

There are a range of views held by Māori around these issues; some iwi disagree with storage of samples citing whakapapa and advise their people to consult before participating in research where this occurs. However, it is acknowledged that individuals have the right to choose.”

1. The Committee noted PIS for 12 – 15 year olds was titled ‘consent’ when it should more accurately state ‘assent’. The Committee requested the Researcher amend this along with the signature box at the bottom which should state ‘person obtaining assent’.
2. The Committee requested the inclusion of contact numbers for the HDC and an appropriate local Māori health service contact at the end of the PIS.
3. The Committee advised that it is not acceptable in New Zealand to terminate a study for the commercial interest of the sponsor and requested the reference to this be removed.

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 feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17).*

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

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| **4** | **Ethics ref:** | **19/CEN/209** |
|  | Title: | The effect of bile acid malabsorption on function and quality of life in patients with major Low Anterior Resection Syndrome (LARS) |
|  | Principal Investigator: | Dr John Woodfield |
|  | Sponsor: |  |
|  | Clock Start Date: | 09 January 2020 |

Dr John Woodfield was present 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. Treatment of rectal cancer, with surgery and often radiotherapy and/or chemotherapy can result in a cure from cancer. However, in many cases also results in poor function, with symptoms of urgency, frequency, leakage and fragmentation. These symptoms, referred to as the Low Anterior Resection Syndrome (LARS), have a severe negative impact on measures of bowel function and quality of life (QoL).
2. Although the causes of LARS are multifactorial, there is an increasing body of evidence that these symptoms can be contributed to by bile acid malabsorption (BAM), which may develop after radiotherapy, but may also be contributed to by chemotherapy and/or surgery. It is unclear what the contribution of BAM will be to symptoms of low anterior resection syndrome in a cohort of New Zealand patients with severe LARS.
3. In this study, the primary objective is to determine the response to therapy for BAM in patients with severe LARS. Researchers will perform a double-blinded cross-over study of treatment for BAM with colesevelam while measuring changes to the LARS score and to QoL. The secondary objective is to assess if testing for BAM in patients with severe LARS after rectal cancer surgery is helpful, both in terms of reliably measuring the prevalence of BAM and predicting response to treatment. To do this the study will test for BAM with the SeHCAT test in a subset of at least ten patients, with more tests dependent on funding. At the completion of the study, researchers will assess if the test results predicted the actual responses to treatment with colesevelam as measured by changes in the LARS score.

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 design of the study and if participants would receive both placebo and the active tablet. The Researcher explained the initial design was a crossover where participants were their own control and then at the end everyone would take the active medicine for an additional four weeks to gather quality of life data. The Researcher stated they have since refined the design to be a single crossover with either the medicine or the placebo for five weeks. The Researcher clarified the timeline would now be a five-week treatment period followed by a five-week washout period and then the crossover period followed by the quality of life period and would adjust the PIS to reflect this.
2. The Committee complimented the Researcher on incorporating the feedback of the peer review to improve the project.

Summary of outstanding ethical issues

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

1. The Committee noted the answer to question P.4.2 in the application and noted a cultural issue the research would certainly encounter will be whakamā, as well as information about participants being a taonga. The Committee requested the Researcher bear this in mind for this research and for future applications.
2. The Researcher stated since the application’s submission the team have decided to establish a formal DMSC and this would involve a statistician. The Committee requested information on the DMSC be supplied.

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

1. The Committee noted there was important privacy information lacking from the PIS e.g. the process of assigning participants a number, data storage, how and where it will be kept and for how long, linking information kept separately etc. The Committee recommended the researcher consult the [HDEC template](https://ethics.health.govt.nz/system/files/documents/pages/piscf-template-oct-2019-031019b.doc) and adapt as necessary.
2. The Committee requested the removal of the ‘yes / no’ boxes on the consent form unless it is for something that is truly optional (i.e. the participant can answer ‘NO’ and still participate in the study e.g. receiving a summary of results).
3. The Committee noted the clause on the consent form agreeing to an appointed auditor accessing records. The Committee stated that information should not appear for the first time in the consent form and should be adequately explained in the information sheet. The Committee requested the PIS be updated with information on who the audit process.

Decision

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

* Please supply details of the DMSC. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 11.25).*

* Please update the participant information sheet and consent form, taking into account feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17).*

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

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| **5** | **Ethics ref:** | **19/CEN/214** |
|  | Title: | GO41767 |
|  | Principal Investigator: | Dr Laird Cameron |
|  | Sponsor: |  |
|  | Clock Start Date: | 09 January 2020 |

Dr Laird Cameron and Ms Pallavi Wyawahare were present 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. This is a phase III, randomised, double- blind placebo controlled study of designed to evaluate the safety and efficacy of Tiragolumab in combination with Atezolizumab plus carboplatin and etoposide (CE) in patients with untreated extensive stage small cell lung cancer. Patients will be randomised 1:1 to either receive:

* Arm A: Tiragolumab +Atezolizumab+ CE
* Arm B: Palcebo +Atezolizumab+CE

1. The first four cycles will be called an induction phase . After the completion of the induction phase, the maintenance phase will start where patients will receive below drugs in each arm:

* Arm A: Tiragolumab +Atezolizumab
* Arm B: Placebo +Atezolizumab

1. Patients will be treated until disease progression per RECIST V1.1 or loss of clinical benefit.
2. The primary objective of the study is to evaluate the efficacy of Tiragolumab plus atezolizumab and CE comapared with placebo plus atezolizumab and CE in patients with untreated ES-SCLC . The hypothesis, objectives and endpoints are detailed in section 2 of the protocol (pg 37- 39).

Summary of resolved ethical issues

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

1. The Committee commended the Researcher on the valuable statistics included in the answer to question P.4.1. in the application form.

Summary of outstanding ethical issues

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

1. The Committee noted that if participants withdraw from the study, they should not have to specifically request their samples be destroyed. If it is intended that participants can withdraw from the main study and allow their optional samples to be kept for future research the Committee requested this be revised to be clearer.
2. The Committee noted a discrepancy between the FUR information sheet and consent form. The optional FUR sheet states samples taken will be used to analyse biomarkers and how variations in biomarkers affect the response to the study disease or drug, whereas the consent form states they may be used in research of any type. The Committee requested this be revised to be consistent.
3. The Committee requested the pregnant participant / partner form be expanded to include more information about sending the tissue overseas.
4. The Committee noted a parent cannot consent for an unborn child and this needs to occur after the birth. The Committee recommended an additional consent box on the pregnant participant / partner form for this purpose.
5. The Committee requested the inclusion of information on post-trial access and whether participants would be able to receive the drug after the study if it benefited them.

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 feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17).*

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| **6** | **Ethics ref:** | **19/CEN/217** |
|  | Title: | PENGUIN 1 |
|  | Principal Investigator: | Dr Ketna Parekh |
|  | Sponsor: | Gilead Sciences Inc |
|  | Clock Start Date: | 09 January 2020 |

Dr Ketna Parekh and Ms Marina Dzhelali were present 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. This is a randomised, double-blind, placebo-and active-controlled, Phase3 study in adult subjects with active PsA who have had an inadequate response or intolerance to 1 or more therapies for PsA, such as conventional synthetic disease-modifying anti-rheumatic drugs (csDMARDs), apremilast and/or non-steroidal anti-inflammatory drugs (NSAIDs), but have never received a biologic DMARD (bioDMARD) for PsAor psoriasis.
2. This study evaluates the effect of filgotinib compared to placebo and adalimumab on the signs and symptoms, physical function, quality of life, and preservation of joint structure in PsA.
3. Safety and tolerability of filgotinib will also be assessed.

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 what information would be collected in the event of a pregnancy. The Researcher stated they understand the sponsor will want information about the pregnancy and outcome of delivery and that is it. The Researcher stated they usually request information on the baby but in this study they will not.
2. The Committee noted the response to B.4.2. stated the Sponsor would not be restricting publication. The Committee queried whether this was accurate. The Researcher stated that was what was initially said, however, they have since received the contract which contains the usual clause that they cannot publish without the Sponsor’s approval.
3. The Committee queried why the optional genomic sub-studies had been split in two with the HLA-B27 study as a separate option. The Researcher stated the Sponsor had made this decision and believed the reasoning was so the participant could have either both or just one. The Researcher stated they believed the samples would go to different labs depending on the testing chosen.

Summary of outstanding ethical issues

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

1. The Committee noted it was inappropriate to cite the Treaty of Waitangi when discussing cultural issues. The Researcher stated the Sponsor had insisted on its inclusion as a previously approved application included it. The Committee requested the Researcher relay to the Sponsor that citing the treaty in this way is patronising. In addition the wrong article has been invoked as [Article 1](https://nzhistory.govt.nz/politics/treaty/read-the-treaty/english-text) relates to the Government and Crown. The Committee advised the salient cultural issues with this application include information as a taonga and the use of human tissue samples from participants. The Committee requested the Researcher keep this in mind for future applications.
2. The Committee queried whether an independent person (e.g. a research nurse) would be more appropriate to introduce the study to potential participants.
3. The Committee queried whether the optional PK study would make use of a catheter or cannula. The Researcher stated they usually inserted a 20 gauge needle and samples would be drawn from it, if participants consented. The Committee requested information about this be added to the PIS.

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

1. The Committee requested the inclusion of a logo and lay-friendly title to the PIS header.
2. The Committee requested the cultural statement included in the main PIS be copied into the others.
3. The Committee noted much of the information was repetitive e.g. in the HLA-B27 sheet under ‘What is the purpose of the test’ the first paragraph describes it very well and the second paragraph repeats the same information. The Researcher agreed to revise and simplify the information sheets.
4. The Committee noted when the PIS discusses privacy it states participants’ names will not be attached to samples. The Committee requested this be revised to clarify that no identifiable information (e.g. name, date of birth, NHI, address etc) would be included with the sample.
5. The Committee requested the removal of information about using coded study data for future unspecified research from the main PIS as it had the potential to be confusing and this information can be explained in the optional FUR sheets.
6. The Committee noted on page 5 the sheet instructed participants to withdraw in writing if they wished to leave the study. The Committee advised that in New Zealand participants can withdraw verbally and requested the removal of the words ‘in writing’.
7. The Committee requested the inclusion of information on where the samples will be sent overseas to the information sheet and consent form.

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 feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17).*

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

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| **7** | **Ethics ref:** | **19/CEN/218** |
|  | Title: | WV41073 Phase II Combination Therapies for CHB |
|  | Principal Investigator: | Professor Edward Gane |
|  | Sponsor: | Covance New Zealand Limited |
|  | Clock Start Date: | 09 January 2020 |

Professor Edward Gane was present 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. This platform study will investigate how safe and effective different combination therapies are at achieving a sustained functional cure within a finite duration.
2. This will include study medications that have not yet been approved for the treatment of chronic hepatitis B virus but were shown to be safe and well tolerated in earlier studies with healthy volunteers and patients with chronic hepatitis B virus.
3. Initially, patients will be randomised into a combination arm or a control arm. The combination arm includes two investigational drugs developed by Roche called RO7020531 and RO7049389 with NUC. The control arm will be NUC alone. RO7020531 is an oral drug that is expected to enhance the response of the body’s natural defense mechanisms (immune system) via TLR7 agonist pathway to help fight the hepatitis B virus and keep the virus from harming the liver. RO7049389 is an oral drug and is expected to inhibit the formation of the protein shell of the hepatitis B virus (capsid inhibitor) with the aim to reduce the virus multiplication in your body.
4. This study consists of several treatment groups. Each treatment group will enroll approximately 30 chronic hepatitis B patients who will enroll into one of the combination treatment or control arm and receive treatment for up to 48 weeks. There will be a 48 week follow up period after treatment.
5. The aim is to result in therapeutic benefit for participants, represented by higher functional cure rates than observed with current standard-of-care therapies.

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 if in the event of a participant or their partner becoming pregnant would the study want to collect information on the baby. The Researcher stated they would only want to follow the pregnancy and its outcome and would not require health information about the child.
2. The Committee noted the reimbursement was currently listed as “XX” and queried what the level of reimbursement would be. The Researcher stated it is determined on length and number of study visits but has not been approved yet. The Researcher stated the standard arm would receive $100 per visit over 19 visits for $1,900 in total and the combination arm would receive $100 per visit over 30 visits for $3,000 total. The Researcher stated up to $100 in travel would also be reimbursed. The Committee accepted this amount as reasonable and did not consider it an inducement. The Researcher stated these numbers would need to be approved by the Sponsor but for now this was the intended amount.

Summary of outstanding ethical issues

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

1. The Committee noted a discrepancy where the PIS stated it was up to the participant to inform their GP whereas the consent form requested the participant’s consent to inform the GP. The Researcher stated every participant’s GP would receive a copy of the letter during the screening process and this was standard practice. The Committee requested this be clarified in the PIS.
2. The Committee requested the inclusion of a cultural tissue statement in the pregnant participant / partner information sheet. The Committee advised that information was also a taonga and requested the researcher bear this in mind. The Committee recommended the following statement:

“You may hold beliefs about a sacred and shared value of all or any tissue samples removed. The cultural issues associated with sending your samples overseas and/or storing your tissue should be discussed with your family/ whānau as appropriate.

There are a range of views held by Māori around these issues; some iwi disagree with storage of samples citing whakapapa and advise their people to consult before participating in research where this occurs. However, it is acknowledged that individuals have the right to choose.”

1. The Committee queried whether samples would be sent overseas. The Researcher stated they would be sent to Singapore for analysis and if the participant consented to the RBR they would be stored in Switzerland. The Committee requested information explaining this be added to the FUR and pregnant participant / partner information sheets.
2. The Committee noted Singapore was not mentioned on the main consent form and requested this be added in.
3. The Committee requested the addition of an optional ‘yes / no’ tick box on the main PIS consent form for if a participant wishes to receive a summary of the study results.
4. The Committee queried whether the study would likely be ongoing by the time participants turn 16. The Researcher stated he expected the study do go for about two years and then conclude. The Researcher stated that by the time these participants reached 16 there would hopefully be no need for further research on Hepatitis B.

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 feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17).*

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| **8** | **Ethics ref:** | **19/CEN/219** |
|  | Title: | The SUN Study |
|  | Principal Investigator: | Associate Professor Clare Wall |
|  | Sponsor: |  |
|  | Clock Start Date: | 09 January 2020 |

Associate Professor Clare Wall was present 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. This study is a double-blind, randomised controlled trial that randomises 300 infants, that have not yet started complementary feeding to one of two groups (n=150 per group) receiving a daily prebiotic food intervention (kumara powder) with different levels of resistant starch (RS); intervention (RS2) and comparator control (RS1).
2. Infants eligible for participation in the trial are healthy children less than 4 months of age (and their mothers), with the expectation that they will be introduced to their first complimentary foods at around 6 months of age, and not before 4 months of age, as per the Ministry of Health Food and Nutrition Guidelines for Infants. Infants will not be eligible for participation in the trial if they were born <32 weeks gestation or small for gestational age (as they may have special dietary requirements); have a developmental disability (i.e. autism, intellectual disability); have an illness likely to influence their nutritional status (e.g. a chronic illness known to cause malabsorption, any digestive or metabolic disorders); have health conditions that affect feeding; are undergoing treatment with antibiotics; are receiving a supplement with a pre- and/or probiotic; or whose parents written or spoken English comprehension is likely to make participation difficult for them.
3. The allocated prebiotic intervention is intended to commence as soon as parents/caregivers introduce the first complementary food to their child, according to The New Zealand Ministry of Health and World Health Organisation recommended age for introducing complementary foods, and is to be consumed daily (approx. 5 g kumara powder/day, reconstituted to an age-appropriate consistency) for a period of 6 months, until the child is approximately 12-months-of-age. The prebiotic intervention is provided in a form that is safe for infants to consume ad libitum, where the required daily amount will not displace other foods of important nutrient composition in the infant’s diet.

Summary of outstanding ethical issues

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

1. The Committee noted the response to question P.4.1. in the application and queried whether Māori children had more respiratory problems or reactions to vaccines. The Researcher stated Māori children did have a higher risk for vulnerability to respiratory infections but unfortunately the study was not powered to analyse different ethnicities. The Committee stated any relevant demographical information or statistics on prevalence of the issue being studied would be useful to include when answering this question in future applications.
2. The Committee noted the response to question P.4.2. and stated it was inappropriate to cite the Treaty of Waitangi for it. Specifically, [Article 2](https://nzhistory.govt.nz/politics/treaty/read-the-treaty/english-text) relates to land rights and is not relevant in the context of health research. The Committee advised the salient cultural issues with this application include information as a taonga and the use of human tissue samples from participants. The Committee requested the Researcher keep this in mind for the resubmission
3. The Committee noted that photographs would be taken of food and waste. The Committee queried the photography process and whether the photographs taken would identify participants. The Researcher explained the parents would take the photos of the food and not the research team. The Committee requested the addition of a statement explaining this. The Committee noted the answer to R.1.1 explained much of this clearly and recommended this information be carried over to the PIS.
4. The Committee queried the intervention participants would receive and how it differed. The Researcher explained all participants would receive kumara but starch levels would vary due to the preparation method. The Committee stated this was not clear from the PIS and requested a lay-friendly overview of the study’s design, methods and objectives be included.
5. The Committee queried whether the study would be double-blinded. The Researcher confirmed it would. The Committee requested additional information in the PIS to explain in lay-friendly terms that the study would be blinded and what this meant.
6. The Committee requested the exclusion criteria be updated to include parents who refuse to vaccinate their children.
7. The Committee noted that as the mother would technically be a participant in the study, if she would provide breast milk and stool samples, she would need an information sheet and consent form for herself. The Committee stated the information sheets and consent forms for the mother and child could either be split into two separate documents or remain within one PIS, as long as they were clearly separated into different sections.
8. The Committee noted page 24 of the application discussed media releases and flyers to advertise the study. The Researcher stated these should have been provided with the application. The Committee stated it did not appear to be and requested all material related to potential advertisements / media releases be included with the resubmission.
9. The Committee noted the supplied peer review appeared to relate to the pilot study only and requested a peer review of this protocol be included with the re-submission.

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

1. The Committee queried the statement that participants may learn complementary information on feeding. The Researcher stated they did not wish to interfere with normal feeding behaviour and so this statement may be inaccurate. The Committee requested this be removed from the PIS.
2. The Committee queried whether the study would analyse stool samples from the mother or baby. The Researcher stated the study would test both, although this was on an optional opt-in basis.
3. The Committee requested the inclusion of a cultural tissue statement in the PIS. The Committee recommended the following statement:

“You may hold beliefs about a sacred and shared value of all or any tissue samples removed. The cultural issues associated with sending your samples overseas and/or storing your tissue should be discussed with your family/ whānau as appropriate.

There are a range of views held by Māori around these issues; some iwi disagree with storage of samples citing whakapapa and advise their people to consult before participating in research where this occurs. However, it is acknowledged that individuals have the right to choose.”

1. The Committee advised that if any samples are to be sent overseas for analysis / storage then this must be clearly stated in the PIS and agreed to on the consent form.
2. The Committee queried whether the Researcher intended to recruit the mother of the baby or whether another parent could participate. The Researcher stated as the study involved breastfeeding they intended to recruit the mother only. The Committee noted the PIS referred to a ‘parent / guardian’ in places and recommended the Researcher amend this to state mother.
3. The Committee requested information in the PIS explaining that participants will be required to fill out the complementary food frequency questionnaire.
4. The Committee queried a statement on page 2 of the consent form regarding consenting to specimen storage for other research approved by an ethics committee. The Committee queried whether the Researcher intended to use the samples for additional research. The Researcher stated they were not and that samples and data from this study would only be used within the objectives of this study. The Committee suggested this be amended to state that if new techniques to analyse samples are developed within the storage timeline they may be tested again as part of this study. The Committee noted another mention of future unspecified research in the last paragraph on page 4 and suggested this be edited too.
5. The Committee advised that any statements in the consent form must be sufficiently explained in the information sheet, so participants do not encounter any new information when signing.

Decision

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

* Please update the participant information sheet and consent form, taking into account feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17).*
* Please supply an independent peer review for the current version of the study protocol. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.26).*
* Please supply intended advertisements for review to ensure they comply with ethical requirements (*National Ethical Standards for Health and Disability Research and Quality Improvement, para 11.10 – 11.13).*

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| **9** | **Ethics ref:** | **19/CEN/221** |
|  | Title: | PACE in COPD |
|  | Principal Investigator: | Professor Robert Hancox |
|  | Sponsor: | University of Otago |
|  | Clock Start Date: | 09 January 2020 |

Professor Robert Hancox was present 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. Chronic Obstructive Pulmonary Disease (COPD) is the most important cause of progressive lung disease in older adults and is now the third leading cause of global illness and death. Many patients with COPD have also heart disease and 30-50% of deaths in COPD patients are believed to be caused by heart disease. However, heart disease is often under-treated in COPD patients. One of the reasons for this is because β-blockers, which are used to treat heart disease, are often avoided in COPD for fear of making the lung disease worse. Several retrospective studies suggest that the use of some types of β-blockers are probably safe in COPD and may even reduce worsening of COPD as well as death from heart disease. A recent trial however, suggests that one type of β-blocker (metoprolol) may make COPD exacerbations worse. This leaves uncertainty about how to treat heart disease in patients with COPD.
2. The aim of this research is to test if treatment with the β-blocker, bisoprolol, in COPD patients with known cardiovascular disease will result in overall improvement of both respiratory and cardiac illnesses. Of the β-blockers currently available in New Zealand bisoprolol is the one with the least effect on the lungs. The study will compare randomly assigned treatment with bisoprolol or placebo in 1164 COPD (582 each arm) participants across 20 hospital sites in Australia and New Zealand. Treatment will continue for 2 years and participants will attend clinic visits at baseline, 1, 3, 6, 12 ,18 and 24 months.
3. The main measures to assess treatment success will be death, hospitalisations for COPD or heart disease, or major cardiac events.

Summary of resolved ethical issues

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

1. The Committee noted the quality of life data would include a questionnaire on mental health. The Committee queried how this data would be analysed and how the researchers would know if a participant indicating severe depression or suicidality in their answers. The Researcher stated they did not believe the questionnaires would be analysed at clinic and would be used for statistical analysis later. The Researcher stated if a participant was experiencing distress a doctor or nurse would manage this.
2. The Committee queried whether patients with COPD are closely monitored by clinicians anyway. The Researcher stated not necessarily, and their primary relationship is to the GP with hospital visits from time to time. The Researcher stated participants would likely be a lot more closely monitored within the study than during regular clinical practice.
3. The Committee stated its ethical concern was if someone indicates on the questionnaire that they are severely depressed that data may be used statistically but not to help the person giving it who is indicating distress. The Committee stated if a participant indicated suicidal ideation and the research team did nothing this would be an unsafe situation. The Researcher stated as the questionnaire is only five questions, they could monitor it in real time and check participants’ answers and act if warranted e.g. make an appropriate referral. The Committee stated it was satisfied with this arrangement.
4. The Committee queried where the testing would be performed, and if it would be in New Zealand or internationally. The Researcher stated it would most likely be performed at the Christchurch Heart Institute.

Summary of outstanding ethical issues

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

1. The Committee noted the response to P.4.2. in the application stated the study had no specific cultural issues. The Committee advised that obtaining health information from participants is an issue as information is a taonga. The Committee requested the Researcher be aware of this during the study and to keep it in mind for future applications.
2. The Committee queried whether samples from this study could be used in any future unspecified research. The Researcher stated no, the idea was to know where there are ways of predicting who will do well or badly in terms of heart function while on beta blockers. The Researcher stated because cardio biomarkers are in evolution the samples would only be used in this study and not in other research. The Committee requested this explanation be added to the PIS.
3. The Committee queried if any of the data would be sent overseas. The Researcher stated yes, as a trans-Tasman study data analysis would occur in Australia as well. The Committee requested this information be added to the PIS and preferably with the specific location in Australia the data will be stored (e.g. which city / university).

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

1. The Committee noted the incorrect phrase that ‘all research involving humans comes before a HDEC’. The Committee clarified that only health and disability research above minimal risk requires HDEC approval.

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 feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17).*

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| **10** | **Ethics ref:** | **20/CEN/1** |
|  | Title: | The EDGI study |
|  | Principal Investigator: | Prof Martin Kennedy |
|  | Sponsor: |  |
|  | Clock Start Date: | 09 January 2020 |

Prof Martin Kennedy and Dr Jennifer Jordan were present 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. Eating disorders are serious psychiatric disorders with significant psychosocial impacts and physical morbidity. Anorexia nervosa (AN) has the highest mortality rate of any mental health disorder. Bulimia nervosa (BN) also has elevated mortality rates, while binge eating disorder has longer-term physical risk factors related to its association with obesity. There is increasing evidence of strong genetic influences, however sample sizes to date for EDs have been relatively small and there is still much to learn about the underlying biology of these conditions, how they relate to each other and how long-observed physical and psychiatric comorbid conditions are related.
2. The EDGI project is an international research collaboration aiming to undertake genetic analyses of samples from adults with a lifetime history of AN, BN or BED. We aim to recruit 3500 New Zealand (NZ) participants as part of the international EDGI project (international target n=20,000).
3. Participants will complete an in-depth online survey, providing information about their eating disorder symptoms and treatment history, about other mental health and physical health problems, and the impacts on their quality of life. They will also provide a saliva sample for DNA extraction for the genotyping analyses.
4. De-identified data and samples will be sent overseas for DNA extraction (Queensland Institute for Medical Research, QIMR, Australia) and genotyping analyses (Erasmus, Netherlands) before being sent to be stored in National Institute of Health (NIH) approved repositories in the USA. Phenotypic and genotypic data will be stored indefinitely but saliva samples will be disposed of 10 years after the end of the study. The intention is to provide an ongoing resource for ethically-approved health-related research. This research will identify genes that contribute to ED risk, clarifying pathophysiological pathways and informing development of novel treatments.

Summary of resolved ethical issues

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

1. The Committee noted the study was to be conducted entirely online with no on-site visits by participants. The Researchers stated the only way to get the participant numbers necessary for the study is through the online consent interface. The Researchers explained the patient information and consenting process would be done online as well as the surveys. The Researchers stated once these were completed the study team would send the participants a saliva kit for them to provide a sample for genetic testing.
2. The Committee queried how the Researchers would know participants are at least 16 years old. The Researcher stated it could not be guaranteed and they would have to operate on a model of trust. The Researchers stated since the study would run for four years if they had younger people interested who were honest about their age they could tell them to return once they’ve reached 16 years.
3. The Committee queried whether participants would require a formal diagnosis only or if people who self-identify with eating problems could participate. The Researchers stated as the study requires detailed information about treatment history this would limit the inclusion to those with a formal diagnosis.
4. The Committee queried how the Researchers planned to recruit. The Researchers stated they intend to have media stories about the launch of the study and have previously engaged with the Eating Disorder Support Group as well as Voices of Hope. The Researchers stated they have close networks of clinicians and people with eating disorders. The Researchers stated advertisements would primarily be transmitted via the media campaign and Facebook. The Researchers stated they have consulted with an Australian PR company to manage the media campaign (TV, print, social media) and this would be their approach, subject to approval by the Committee.
5. The Committee queried what the media release would involve. The Researchers stated they would plan one about anorexia nervosa in general and one about the EDGI study specifically. The Researchers stated it was important to give the media correct facts, so they do not spread misinformation. The Researcher agreed to supply all media material to the Committee before use.
6. The Committee noted study intended to keep tissue from Māori participants in New Zealand and everyone else would be sent overseas. The Committee queried why all samples would not go to the same lab, as separate labs could have the potential to harm the scientific validity of the testing. The Researchers stated this approach was to manage sensitivities around the disposal of samples. The Committee suggested a karakia could be performed when the sample was taken and then they could be sent overseas with the rest. The Researchers agreed this was a good idea and would consider it.
7. The Committee stated it was acceptable for samples to be sent overseas if there was no option of a karakia as long as the Researchers were upfront about it and stated so on the PIS. That way participants would have a choice on whether they wished to participate or not.
8. The Committee queried whether the proposed recruitment numbers were feasible. The Researchers stated the control numbers can mostly be provided by the team in Australia and they would only seek about 150 controls here. The Researchers stated recruiting the full number of participants would be challenging but believed it achievable. The Researchers stated anorexia nervosa is relatively rare but they recruited 550 participants for the ANGI study and as the EDGI study involves a wider range of eating disorders they were confident it was a realistic target.
9. The Committee requested the removal of the statements about the direct benefits the research may have on Māori as this could be perceived to be coercive. The Researchers stated Ngai Tahu had requested these statements during the consultation process. The Committee stated if they had been specifically requested then they could remain.

Summary of outstanding ethical issues

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

1. The Committee queried how soon data entered by participants would be collated. The Researcher stated from the survey it goes straight into the database and can be accessed at any time, although they intended to let it accumulate. The Committee expressed concern at the scenario of a participant answering ‘nearly every day’ to the question about wanting to die and that information sitting in the database for a long period without the Researchers being aware. The Researcher stated a pop-up would appear instructing the participant to contact their GP. The Committee stated the issue was the Researchers were asking these questions and then potentially doing nothing to manage a participant answering them and indicating severe distress. The Researchers suggested in addition to a pop-up an alert could be sent to the trial coordinator for follow-up. The Committee stated this was a good idea and requested the Researchers incorporate it. The Committee requested information about this alert system be added to the PIS.

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

1. The Committee expressed concern at the emotive tone of some of the language and requested this be revised to mitigate any risk of potential coercion.
2. The Committee noted the main PIS contained information about future unspecified data use and requested this be moved to the future unspecified research PIS.
3. The Committee requested the removal of the ‘yes / no’ boxes on the consent form unless it is for something that is truly optional (i.e. the participant can answer ‘NO’ and still participate in the study e.g. receiving a summary of results).
4. The Committee requested additional information in the PIS about who an approved auditor would be and why they would be able to access study data.
5. The Committee requested the removal of statements about public benefit as this could put undue pressure on people to participate.
6. The Committee requested the addition of a statement to the FUR consent form advising that samples will be sent overseas.

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 feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17).*
* Please supply any advertising materials and information about the study intended for use in the media campaign to ensure they comply with ethical requirements. (*National Ethical Standards for Health and Disability Research and Quality Improvement, para 11.10 – 11.13).*

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

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| **11** | **Ethics ref:** | **20/CEN/2** |
|  | Title: | Study of ARO-HSD in Adult Healthy Volunteers as well as in Patients with NASH or suspected NASH |
|  | Principal Investigator: | Prof Ed Gane |
|  | Sponsor: | Novotech Pty Ltd |
|  | Clock Start Date: | 16 January 2020 |

Professor Ed Gane was present 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. ARO-HSD (or ADS-006) is an RNA interference (RNAi)-based liver targeted therapeutic for the treatment of patients with Nonalcoholic Steatohepatitis (NASH). NASH is a disease which can develop in people with obesity or diabetes. When too much fat builds up in the liver, it can cause inflammation and scarring that can lead to severe liver disease.
2. This is the first study where ARO-HSD will be given to humans. The primary objective of this study is to assess how safe and tolerable ARO-HSD is in normal healthy volunteers and patients with NASH or suspected NASH.

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 this was a first in human study. The Researcher confirmed it was and stated the platform has been used for other diseases, some previously in New Zealand but this RNA has not been used in humans before. The Researcher confirmed the principle has been tested and is approved by the FDA.
2. The Committee queried whether the study would obtain SCOTT approval. The Researcher confirmed it would.
3. The Committee noted the study contained a lot of cohorts and requested a flow diagram in the PIS to illustrate the study design. The Researcher agreed to find a way to simplify the explanations throughout the different information sheets.
4. The Committee noted a discrepancy where the PIS stated it was up to the participant to inform their GP whereas the consent form requested the participant’s consent to inform the GP. The Researcher stated every participant’s GP would receive a copy of the letter during the screening process and this was standard practice. The Committee requested this be clarified in the PIS.
5. The Committee noted the phrase ‘consent when participant is pregnant’ and queried whether this should read participant or participant’s partner. The Researcher confirmed it should and would amend the form.
6. The Committee complimented the Researcher on their answers to the cultural questions in the application. The Committee commended the Researcher on supplying useful statistics when answering question P.4.1.
7. The Committee requested the addition of ‘unless you withdraw from the study’ to the sheet when it discusses participants being unable to leave during the study period.
8. The Committee noted the liability insurance certificate has expired. The Researcher agreed to supply a new one.
9. The Committee requested the inclusion of the cultural tissue statement in all information sheets.
10. The Committee queried whether information on pregnant participants / partners would go overseas. The Researcher stated they believed it would. The Committee requested a clause for this be added to the consent form.

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 feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17).*
* Please ensure a valid insurance certificate is obtained before the trial begins to ensure ACC-equivalent coverage is available to all participants. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 17.1).*

## 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:** | 25 February 2020, 12:00 PM |
| **Meeting venue:** | Room GC.3, Ground Floor, 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 and Co-ordinator as a true record.

The meeting closed at 5:00pm.