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| **Committee:** | Southern Health and Disability Ethics Committee |
| **Meeting date:** | 11 May 2021 |
| **Meeting venue:** | [**https://mohnz.zoom.us/j/9738756003**](https://mohnz.zoom.us/j/9738756003)  Meeting ID: 973 875 6003 |

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| **Time** | **Item of business** |
| 10:00am | Welcome |
| 10:25am | Confirmation of minutes of meeting of 13 April 2021. |
| 10:30am | New applications |
| 10:30 – 10:55am  10:55 – 11:20am  11:20 – 11:45am  11:45 – 12:10pm  12:10 – 12:30pm  12:30 – 12:55pm  12:55 – 1:20pm  1:20 – 1:45pm  1:45 – 2:10pm  2:10 – 2:30pm  2:30 – 2:55pm  2:55pm  2:55 – 3:20pm | 21/STH/92 Helen / Devonie  21/STH/97 Sarah / Mira  21/STH/101 Dominic / Paul  21/STH/102 Helen / Devonie  [break]  21/STH/105 Sarah / Mira  21/STH/111 Dominic / Paul  21/STH/112 Helen / Devonie  21/STH/113 Sarah / Mira  [break]  21/STH/114 Dominic / Paul  New substantial amendments  20/STH/87/AM03 Helen / Devonie |
| 3:20 – 3:30pm | General business:   * Noting section |
| 3:30pm | Meeting ends |

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| **Member Name** | **Member Category** | **Appointed** | **Term Expires** | **Apologies?** |
| Dr Sarah Gunningham | Lay (other) | 05/07/2016 | 05/07/2019 | Present |
| Dr Devonie Waaka | Non-lay (intervention studies) | 18/07/2016 | 18/07/2019 | Present |
| Assc Prof Mira Harrison-Woolrych | Non-lay (intervention studies) | 28/06/2019 | 28/06/2020 | Present |
| Dr Paul Chin | Non-lay (intervention studies) | 27/10/2018 | 27/10/2021 | Present |
| Professor Jean Hay-Smith | Non-lay (health/disability service provision) | 31/10/2018 | 31/10/2021 | Apologies |
| Mrs Helen Walker | Lay (consumer/community perspectives) | 19/08/2020 | 19/08/2021 | Present |
| Mr Dominic Fitchett | Lay (the law) | 05/07/2019 | 05/07/2022 | Present |

## Welcome

The Chair opened the meeting at 10am and welcomed Committee members, noting that apologies had been received from Professor Jean Hay-Smith.

The Chair noted that the meeting was quorate.

The Committee noted and agreed the agenda for the meeting.

## Confirmation of previous minutes

The minutes of the meeting of 13 April 2021 were confirmed.

## New applications

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| **1** | **Ethics ref:** | **21/STH/92** |
|  | Title: | (duplicate) (duplicate) Dignified Dying, Reality of Human Mortality- the New Zealand context |
|  | Principal Investigator: | Mrs Inderpreet Kaur |
|  | Sponsor: | Massey University |
|  | Clock Start Date: | 08 April 2021 |

Inderpreet Kaur, Ian Laird, and Simon Allan were present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. The project aims to gain a comprehensive insight into the factors that influence palliative care choices of terminally ill patients and their wider whanau against a New Zealand context. The study follows 50 patients from the time of expected prognosis of 6 months or less to death of the patient and beyond for family. Study population: patients, whanau, physician.

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 that this application is a resubmission of a previously declined application and acknowledged the good work the Researcher has done to address many of the issues previously raised by the Committee.
2. The Committee queried how the Researcher will address loss of competence during the trial. The Researcher advised that the study requires the participants to be competent to participate in the interviews and should there be loss of competence during the trial, the participant would be withdrawn. She added that the data collected on the participant up to the point of withdrawal would be retained.
3. The Committee stated that the data management plan, while good, was hard to follow as it appeared to be cut and pasted from the template and not fully tailored to the study (i.e. irrelevant information was not removed). Please bear this in mind for future applications.
4. The Committee noted that this submission has made what is expected of the participant's doctor much clearer; that they are to complete a medical screening questionnaire about their patients which in itself does not make them a participant. The Committee stated that only those doctors taking part in the interviews are active participants in the study and will need to consent.
5. The Committee queried that the PISCF implies that the study is an arm of a larger international study but the application form states it is New Zealand only. The Researcher advised that this study will be comparing the NZ population only but that the data collected will go towards a wider international 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 noted that ethnicity does not appear to be used for analysis (in either PhD proposal or iLIVE protocol). This contrasts with the answer to application question p.4.1 “the results will provide valuable insight into the under-explored area of end-of-life experiences of Māori participants. It will provide clear comparison of this experience between Māori and non- Māori New Zealanders, as well as Māori and international counterparts”. Please reconcile this in the next submission by adding it to PhD proposal for example.
2. The Committee requested that the Researchers address loss of competence in the Protocol, including how competence will be assessed.
3. The Committee requested that details of the principal investigator and co-investigators are added to the front page of the protocol.
4. The Committee requested that the protocol includes a footer with title, version number, date last altered, and page number. This is to make it easier to pinpoint the latest version after making amendments.

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

Participant PISCF

1. Please review and delete duplicated information.
2. Please provide information about the interviews and whether this is optional or mandatory (i.e. how long they will take, whether they will be recorded, what happens to the recordings, and if recordings are optional).
3. Please include information on what will happen to the participant’s data if they withdraw.
4. Please add a couple of sentences to make it clear that relatives will be asked to complete questionnaires and the relative and doctors may be asked to take part in interviews.
5. Please re-write the 'who can take part' section in plain English as it is currently too technical and includes information from the protocol that the participant does not need to know. A few sentences will suffice.
6. Please remove the final paragraphs from the 'risks' section and add them to the study protocol.
7. Please provide more information than ‘not applicable’ for reimbursement of costs on page 4, (e.g. “There will be no cost for you to participate in this study”).
8. Under ‘Future research using your information’ of the ‘What will happen to my information’ section, please replace the term “your information” with “your coded information”.
9. Please remove the yes/no tick boxes on the consent form for items that are not truly optional.
10. Please include a footer with title, version number, date last altered, and page number.

Relative PISCF

1. Please include information about interviews, as noted above for the Participant PISCF.
2. Please add that there will be questions in the questionnaire about the relative’s own physical and mental health (not just the participant’s) on page 2.
3. Under ‘Future research using your information’ of the ‘What will happen to my information’ section, please replace the term “your information” with “your coded information”.
4. Please remove the yes/no tick boxes on the consent form for items that are not truly optional.
5. Please include the option to receive a lay summary of results for the New Zealand study and also the wider international study when it’s available.
6. Please include a footer with title, version number, date last altered, and page number.

Physician PISCF

1. Please refocus to include information about the interviews as taking part in the interviews makes the doctor a participant in the study.
2. Under ‘Future research using your information’ of the ‘What will happen to my information’ section, please replace the term “your information” with “your coded information”.
3. Please include a footer with title, version number, date last altered, and page number.

Decision

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

* Please address all outstanding ethical issues, providing the information requested by the Committee.
* Please update the participant information sheet and consent form, taking into account feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17).*
* Please update the study protocol, taking into account the feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.7).*

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

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| **2** | **Ethics ref:** | **21/STH/97** |
|  | Title: | NOMAD Study |
|  | Principal Investigator: | Dr Eric Lim |
|  | Sponsor: |  |
|  | Clock Start Date: | 29 April 2021 |

Eric Lim and Adib Khanafer were present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. The observational study aim is to recruit 50 patients presenting acutely with Type B aortic dissection (plus control group of 50 with negative diagnosis) to analyse their blood to determine if specific hormone/s are being released into the blood stream which could be driving the uncontrolled blood pressure during this acute period.
2. The study will also test if the sympathetic nervous system is also involved in driving hypertension by performing peripheral nerve testing as a surrogate marker of muscle sympathetic nerve activity (MSNA).

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 when and how the study will be introduced to participants (including the control group) who have been admitted to the emergency department (ED) and how much time they will be given before being asked to consent.
2. The Researcher advised that patients who present with classic Type B aortic dissection symptoms (e.g. chest pain), will be approached to be part of the study after the CTA scan confirming a positive or negative diagnosis. He added that the ED clinician dealing with the patient will mention the study to the patient, alert the research team who will approach and discuss the study with the patient and consent them from there. The patients with a positive diagnosis will be approached and consented at the same time as the patients with a negative diagnosis (the control group).
3. The Committee asked how long the potential participant will have to digest the study information and to decide to be involved or not. The Researcher advised that, ideally, consent would need to happen within 12 hours (and no more than 24 hours) after admission to ensure they can pick up the indicators in the blood samples. The Committee were comfortable with this as the participant would have time to reconsider and withdraw before the nerve testing if they choose to.
4. The Committee queried how the control group will have blood samples collected once they are sent home. The Researcher confirmed the participants who return home (the control group) will need to come back to the hospital and have samples collected on an outpatient basis.
5. The Committee advised that the description of the risks of nerve testing is a little alarming, that there is a 2-5% chance of residual nerve injury lasting up to 3 months, and asked for more clarity on the nerve testing. The Researcher advised that Professor David Jardine will be performing the testing and his experience over the last 15-20 years of performing similar tests has shown this percentage of temporary numbness (e.g. pins and needles). However, there have been just 3 cases where the patient has developed a severe form of numbness in the peroneal nerve area as a result of this particular testing.
6. The Committee advised that data should be de-identified as early as possible and prior to data analysis, and asked when the blood samples will be de-identified as the study documentation provides different responses. The Researcher advised that the samples will be de-identified (given a participant ID number) before they are sent to the Christchurch Heart Institute or the Canterbury Health Laboratories for analysis. He added that data will be collected and stored on the Starline database used at Christchurch Heart Institute for the statistical analysis.

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 advised that the data & tissue management plan (DTMP) appears to be a generic document for the Christchurch Heart Institute and that some elements are at odds with the information in the application and PISCF. The Committee requested that the DTMP is tailored to the study to include more detail about the samples (e.g. when they will be de-identified, where they will be sent for analysis, and who will have access to the identifiable data), and irrelevant information removed.
2. The Committee noted that the research team’s statistician has recommended that, as this is a pilot study, an approximate sample size of 50 is sufficient and that there will therefore be no power calculations. The Committed suggested an explanation in the protocol similar to the following is usually sufficient to address this matter; “As this is a pilot study, sample size has been selected on a practical basis and no power calculations have been performed. It is expected that this will be sufficient to answer the objectives of this study.”
3. The Committee requested that the protocol includes a footer with title, version number, date last altered, and page number. This is to make it easier to pinpoint the latest version after making amendments.

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

1. Please amend the ‘What happens to my information section’ (based on the DTMP) that provides relevant, study specific information on how their data and privacy will be protected. Please include the different forms of data, who has access to it, the risks of confidentiality breach, ownership rights, rights of access. For guidance, please see the [HDEC PISCF Template](https://ethics.health.govt.nz/system/files/documents/pages/participant-information-sheet-consent-form-template-sep20.doc).
2. Please revise the technical and medical language used and describe it in a way that a lay person would understand (e.g. define biomarkers, neuroendocrine hormones, and the sympathetic nervous system, etc.). The Committee suggest testing it on family or friends who do not have a scientific or medical background.
3. Please change the study title to a lay title that is easy for participants to understand as per the previous point.
4. Please reduce the irrelevant information to include only what the participant needs to know about their involvement in the study and explain the most important aspects first (e.g. you do not need co-investigators listed first – move this further down the form).
5. Please detail the blood sampling procedure and any other procedures under the ‘What will my participation in the study involve?’ and remove mention of it in the ‘What will happen to my blood samples’ section for both groups.
6. Please clarify that blood samples will only be sent overseas for future unspecified research (FUR) and not for mandatory study analysis.
7. Please clarify that where consent has not been given for FUR blood samples will be destroyed when the study ends.
8. Please provide information about (and consent for) optional FUR in a separate PISCF. For guidance, please see the [HDEC Future Unspecified Use of Tissue PISCF template](https://ethics.health.govt.nz/system/files/documents/pages/fur_piscf_template_april_2021_2.doc). Please remove detail about, and consent for, the optional FUR from the main PISCF.
9. Please explain that the nerve testing is only available to participants in Christchurch and that it is optional.
10. Please ensure the form is also suitable for the control group; including more information on what their participation involves as explained in the application form. For example, adding an explanation in the ‘purpose of the study’ section that participants may be part of control group or the group with Type B aortic dissection.
11. Please remove the yes/no tick boxes on the consent form for items that are not truly optional.
12. Please include a footer with title, version number, date last altered, and page number

Decision

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

* Please address all outstanding ethical issues, providing the information requested by the Committee.
* Please update the participant information sheet and consent form, taking into account feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17).*
* Please update the study protocol, taking into account the feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.7).*

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

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| **3** | **Ethics ref:** | **21/STH/101** |
|  | Title: | Respiration data obtained from pacemakers |
|  | Principal Investigator: | Dr Martin Stiles |
|  | Sponsor: |  |
|  | Clock Start Date: | 29 April 2021 |

Martin Stiles and Khashayar were present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. This is an observational study of breath-by-breath respiration from pacemaker impedance data in participants with Boston Scientific pacemakers and implantable defibrillators. The aim of the study is to see whether exercise / movement affects data. A low risk study with 50 New Zealand participants.

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 that the application was submitted as an intervention study, generating additional questions that are not relevant for an observational study. The Researcher responded that this was because of advice from the DHB that it was an intervention study because they were asking participants to do something different to standard of care/norm.
2. The Committee noted that the application form (question R.2.5) incorrectly states 6 years for retention of health data and the participant information sheet and consent form (PISCF) correctly states 10 years.
3. The Committee queried if the respiratory data collected from the device could reveal an unidentified respiratory problem for the participant. The Researcher responded that he does not believe that the data they are collecting for this study would be enough to diagnose other respiratory disorders.
4. The Committee requested that researchers ensure that a member of the patient's clinical care team obtains verbal permission for a researcher to approach the patient regarding study participation. The Committee recommend this as it softens the approach by giving the patient a heads up and breaks the ice.
5. The Committee suggested the researchers consider how they can make it easier for a participant to be involved in the study, for example notifying them in the appointment letter that they may be asked if they’d like to be involved in a research study involving an extra 15 minutes after their appointment so they can manage their time and parking needs.
6. The Committee noted that the PISCF was well presented with relevant and easy to understand information.

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 advised that as Māori may be enrolled into the study, formal consultation is required. Please ensure formal Māori consultation is undertaken to ensure the study is appropriate for a New Zealand context *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 3.7).*
2. The Committee noted the inclusion criterion for a participant to complete a 6-minute walk and queried if participants who are unable to complete the full 6 minutes will be excluded from the study. The Researcher advised that these participants are not likely to be excluded as there will still be enough useful data collected from a shorter walk. The Committee requested that the wording in the inclusion criteria is amended to make it clearer that participants will not be excluded if they fail the 6-minute walking test.
3. The Committee recommend a study-specific Data Management Plan is provided to ensure the safety and integrity of participant data (*National Ethical Standards for Health and Disability Research and Quality Improvement, chapter 12.15).* This may be incorporated into the protocol or as a standalone document. For guidance, please see the [HDEC Data Management Plan template](https://ethics.health.govt.nz/system/files/documents/pages/data-only-management-template-oct2020.docx).

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

1. Please ensure everything that is mentioned in the consent form is covered in the main body of the information sheet, e.g. the optional notification of GP.
2. Please specify that the treadmill speed will be gentle to reassure participants.
3. Please change the body text in several sections from italics to regular as this appears to be a mistake.
4. Please clarify the inclusion criteria, as noted above.

Decision

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

* Please address all outstanding ethical issues, providing the information requested by the Committee.
* Please update the participant information sheet and consent form, taking into account feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17).*
* Please update the study protocol, taking into account the feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.7).*

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| **4** | **Ethics ref:** | **21/STH/102** |
|  | Title: | Game for Health Level 3 |
|  | Principal Investigator: | Dr Hiran Thabrew |
|  | Sponsor: | Starship Foundation |
|  | Clock Start Date: | 29 April 2021 |

Hiran Thabrew was present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. Starship Rescue is a NZ-designed computer game for treating anxiety in 60 New Zealand 8-18-year-olds using a combination of cognitive behaviour therapy and biofeedback to aid relaxation. In this randomised controlled trial, the study aims to compare the effectiveness of the anxiety game with a “dummy game” that is focused on improving nutrition and physical activity over anxiety.

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 that parents will be consenting on behalf of under 16-year-old participants and these participants will be provided with an information sheet.
2. The Committee queried if all participants will be lent a tablet to play the game on or if they can use their own device. The Researcher confirmed that with this study, all participants will need to collect, and use, a tablet from the research team. This is to minimise any connection issues that might arise due to different types of hardware.
3. The Committee queried why the online consenting is necessary when consent could be obtained in person when the participant collects the tablet. The Researcher advised that they provide parents and participants with information material ahead of time and will use the device collection point to gain consent electronically in person. He added that the reason for the e-consent is for the purposes of data collection and analysis to improve the recruitment process.
4. The Committee advised that it is important that the child has their own say and even if the parent consents, the child can still decline to participate. The Researcher responded that they are aware of this potential issue and what they have seen as a theme in previous studies is that children are keen to participate initially and then withdraw later.
5. The Committee asked, if a clinically significant finding arose for a participant during the study, how will the researcher ensure their GP is made aware and can follow up appropriately. The Researcher advised that they have three referral pathways to access assistance for mental health issues; Starship Hospital, Counties Manukau DHB and Waitematā DHB. The Committee were comfortable that the participant’s GP would be informed as a matter of course through these pathways.
6. The Committee noted that the Researcher advised that there is no plan to commercialise the product and the intention is to release it for free.
7. The Committee noted that while the relevant application question stated that it was not required, Māori consultation does apply and has been done for this study.
8. The Committee noted that the Researcher is purposefully withholding details about the games from participants so that they do not have any preconceptions before starting the study and playing the game.

Summary of outstanding ethical issues

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

1. The Committee requested the supply of a data management plan appropriate to the study to ensure the safety and integrity of participant data. (*National Ethical Standards for Health and Disability Research and Quality Improvement, chapter 12.15).* This may be incorporated into the protocol or a separate document. For guidance, please see the [HDEC Data Management Plan template](https://ethics.health.govt.nz/system/files/documents/pages/data-only-management-template-oct2020.docx).
2. The Committee noted that the PISCF states that participants are free to withdraw any information that they have already provided. The Committee, however, advised that they do not consider there to be any ethical issues in an intervention study with data being retained up until the point of a participant’s withdrawal. The Committee added that it would make sense in an intervention study to retain the data so that any adverse events can be reported on, for example. If the researcher sees value in retaining this data, the PISCF will need to be amended accordingly.
3. The Committee advised that as ACC does not cover mental injury it is unlikely it applies to this study. The Committee requested that the Researcher confirm this and remove the ACC statement from the PISCFs if it does not apply.
4. The Committee requested that the protocol includes a footer with title, version number, date last altered, and page number. This is to make it easier to pinpoint the latest version after making amendments.
5. The Committee advised that age/comprehension appropriate assent forms are required for younger participants or those with more limited reading ability (*National Ethical Standards for Health and Disability Research and Quality Improvement,* para 6.27). Please develop an additional assent form that is much simpler and shorter that a child with limited comprehension could understand (i.e. two pages long with bullet points and/or diagrams). For guidance, please see the [HDEC assent form instructions and checklist](https://ethics.health.govt.nz/system/files/documents/pages/hdec-assent-form-instructions-and-checklist-may18.doc).

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

1. Pease make it clear in every form that the child can decline to take part, even if the parent provides consent for them to do so.
2. Please include a lay title that is easy to understand, e.g. “Testing a computer game to help anxiety in young people”.
3. Please proofread all the forms and correct the typos.
4. Please include a footer with title, version number, date last altered, and page number.

Parent/Young People PISCF

1. Please delete the statement on page 1, “'hopefully this will include your child!”
2. Please include guidance on how often and for how long participants are expected to play the game (e.g. 30 mins each night).
3. Please make it clear that the questionnaires will not be reviewed in real time and that, if any mental health issues arise during the study, their health provider should be contacted.
4. Please include the ‘What will happen to my information’ section that aligns to the data management plan and should include what identifiable information will be collected and who will have access to it, the risk of confidentiality / privacy breach. For guidance please see the [HDEC PISCF template](https://ethics.health.govt.nz/system/files/documents/pages/participant-information-sheet-consent-form-template-sep20.doc).
5. Please make it clear that coded data will be used for other research in the future.
6. Please amend the statement on withdrawn data to state that “You’re free to withdraw at any time and we will stop collecting any more information about you, but data that has already been collected will continue to be used and will contribute towards the results of the study.” (if applicable, refer paragraph 11 above)
7. Please remove the ACC compensation statement if it does not apply for this study.
8. Please include a statement that there may be no benefit received from participating in this study.
9. Please amend statement on page 2, paragraph 4 to make it clearer that the participant will know the name of the game they have been allocated but not whether or not it is the anxiety game.
10. Please amend the statement on data retention to say that data will be stored for 10 years after the youngest recruited child turns 16.

Decision

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

* Please address all outstanding ethical issues, providing the information requested by the Committee.
* Please update the participant information sheet and consent form, taking into account feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17).*
* Please update the study protocol, taking into account the feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.7).*

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

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| **5** | **Ethics ref:** | **21/STH/105** |
|  | Title: | Impairment-based rehabilitation for dysphagia post-stroke |
|  | Principal Investigator: | Mrs Marion VALLET |
|  | Sponsor: | University of Canterbury - Rose Centre for Stroke |
|  | Clock Start Date: | 29 April 2021 |

Marion Vallet and Maggie-Lee Huckabee were present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. Dysphagia (difficulty swallowing) is common following stroke. Post-stroke dysphagia (PSD) is a serious condition reported to compromise nutritional, hydration and respiratory status, and to be associated with increased mortality, poor functional outcomes, decreased quality of life and increased burden on patients and caregivers.
2. A previous study was aimed at documenting the 6-month evolution of PSD and characterising it based on its underlying deficits (strength or skill-impairments). The purpose of this second prospective, exploratory study is to investigate the effectiveness of swallowing rehabilitation targeting the reported underlying deficit (strength or skill). This will provide an opportunity to probe the clinical outcomes of this distinction and further, to better tailor rehabilitation protocols that may enable a faster resolution of dysphagic symptoms and improve patients’ quality of life.

Summary of resolved ethical issues

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

1. The researcher clarified that the software used in this study is being removed from the market, as the medical device certification is about to expire and they will not renew it.

Summary of outstanding ethical issues

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

1. The Committee requested that the researchers clarify in their documentation that the device being used was developed by their research team and marketed by the University of Canterbury.
2. The Committee requested that the researchers clarify the following in their documentation: that the intervention that is being tested is the combination of the software and patch with exercises, rather than the software or the patch themselves. The research hopes to show that biofeedback leads to useful rehabilitation of swallowing. If it cannot do this, it will inform interested parties not to pursue developing devices for this commercial purpose. If the hypothesis is proven, a different patch and software will be developed and marketed by the University.
3. The Committee requested that as per the *National Ethical Standards for Health and Disability Research and Quality Improvement* para 11.20.a, the researchers should reimburse participants for travel expenses and parking. The Committee noted that the $30 Countdown voucher is not reasonable, nor is the offer of the researcher coming to the participant’s home instead. The Committee noted that there is a difference between paying people for their time and for reimbursing them for their expenses. Participants must not be financially disadvantaged for participating.
4. The Committee requested that the researchers do not collect date of birth in the questionnaire, as this is identifiable information. Rather, the researchers can collect year of birth and age.

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

Main PIS

1. Please clarify the roles of the intervention, patch and BiSSkiT™ software. Please consider including a link to the explanatory video.
2. Please clarify that this software has already been approved for use.
3. Please use the simple lay title used in the pictorial PISCF.
4. Please begin with the most important information on the first page, rather than the names of the researchers.
5. Please remove technical language, such as “intervention”. E.g. say “we want to test” rather than “we want to evaluate”.
6. Please remove contact details from page 1, as they are included on the last page.
7. Please clarify that this is a research study and the intervention is unproven – that is why you are doing the study. Clarify what exactly it is you are testing.
8. Please clarify in the risk section that there may be no benefits to being in this research study. The current statement implies a therapeutic benefit, but this is currently unproven.
9. Clarify the relationship with the software package, the study team and the sponsor.
10. Please remove the optional tick box about notifying the GP about clinically significant abnormal results, as you have a duty to inform the GP in this event.
11. On page 5, please remove the phrase “under instrumentation”.

Pictorial PIS

1. Please do not say that there are no risks involved in this study. Rather, explain that there are minimal risks involved which will be monitored by the research team.
2. Please ensure that the pictorial PIS includes basically the same information as the main PIS, albeit in a simplified version.
3. Please remove the photos of the researchers from the front page. Begin with the most important information.
4. On page 3, please remove the sentence about patients coughing when eating and drinking and the sentence about patients having a chest infection.
5. On page 7, please clarify that this is a research study rather than a therapy study.

Decision

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

* Please address all outstanding ethical issues, providing the information requested by the Committee.
* Please update the participant information sheet and consent form, taking into account feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17).*
* Please update the study protocol, taking into account the feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.7).*

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

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| **6** | **Ethics ref:** | **21/STH/111** |
|  | Title: | Long COVID Study |
|  | Principal Investigator: | Dr Nethmi Kearns |
|  | Sponsor: |  |
|  | Clock Start Date: | 29 April 2021 |

Nethmi Kearns and Richard Beasley were present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. Long-term sequelae of COVID-19 are unknown but there is increasing evidence that some people who have recovered from COVID-19 report lasting effects of the infection or have had the usual symptoms for far longer than would be expected, namely ‘Long COVID’. This study aims to get a better understanding of how COVID-19 impacts both physical and mental health in the long run. This will be done via blood tests and questionnaires to identify any abnormalities.

Summary of resolved ethical issues

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

1. The researcher clarified the recruitment and consenting procedures.
2. The researcher agree that date of birth will not be stored with samples sent to the MRINZ tissue bank for storage. Rather, they will just have study ID.
3. The researcher clarified that there is a follow up plan in place for clinically actionable results.

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 ensure the data management plan is consistent with what has been discussed in point 2 above regarding tissue samples.

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

Main PIS

1. Please clarify that no genetic testing will be undertaken in the main study.
2. Please proofread for typos.
3. Please remove the long title.
4. In the consent form, please include information about the blood samples being stored and analysed up until the point of withdrawal.
5. Please clarify the process for de-identifying the tissue samples (regarding date of birth).

Future PIS

1. Please clarify that you will not be doing any genomic analysis.
2. Please provide information about return of results.
3. Please include a statement about the potential risk of confidentiality or privacy breach.

Decision

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

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

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| **7** | **Ethics ref:** | **21/STH/112** |
|  | Title: | NKT-203: Study of the efficacy and safety of norketotifen (NKT) in patients with acute uncomplicated influenza-like illness (ILI) |
|  | Principal Investigator: | Dr Claire Thurlow |
|  | Sponsor: | Emergo Therapeutics Inc. |
|  | Clock Start Date: | 29 April 2021 |

Claire Thurlow, Simon Carson, Melinda Ho and Hazar Granko were present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. The purpose of this double-blind, placebo controlled study is to test the safety and efficacy of NKT vs placebo in treating the symptoms of ILI, to confirm the preliminary trends in efficacy observed in a previous phase 2b study, and to explore whether a higher dose could improve the potential efficacy of NKT in ILI.
2. Adults with acute uncomplicated influenza-like illness and symptom onset within ≤48 hours will be randomised to receive either NKT or placebo twice daily for 1 week.
3. Approximately 320 participants are planned to be enrolled in Australia, New Zealand and USA.

Summary of resolved ethical issues

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

1. The researchers assured the Committee that there will be separation between patients’ normal care providers and the researchers during the recruitment process, so that nobody feels pressured by their doctor to participate in the study.
2. The Committee noted that the screenshots of the e-diaries were in American English because the NZ English versions are not ready yet. The Committee approved the American English version, noting that they did not need to see the NZ English version.
3. The researchers clarified that participants requiring antivirals will not have standard treatment withheld. Rather, the daily paracetamol dose permitted is capped at 6 tablets, rather than the usual 8.

Summary of outstanding ethical issues

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

1. The Committee requested that the advertisement is tailored to a NZ setting, in particular regarding insurance and stating that the study drug will be provided at no cost.
2. The Committee noted that the Data Management Plan states that swabs and blood tests are identifiable. However, PIS and application form state that samples are de-identified. The Committee requested that the researchers decide which is correct and ensure consistency across documentation.
3. Please clarify how much the reimbursement for time and travel will be. If this varies across localities, provide the details for each study site.

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

1. Please provide a short, plain English lay title.
2. On page 2, please provide important eligibility criteria so potential participants can self-screen.
3. On page 3, please clarify that participants testing positive for notifiable diseases will not be withdrawn from the study. Rather, they will be taken off medication and will stop completing the e-diaries, but they will still have two visits to complete.
4. Please state approximately how long it will take to complete the diaries each day.
5. Please state that each participant’s GP will be notified of his / her participation in the study.
6. Please provide the frequencies of the severe side effects of norketotifen.
7. In the side effects section, please clarify some of the terminology and remove double-ups. Clarify what is meant by severe as opposed to serious side effects.
8. On page 8, please review the risks of having blood samples taken, as this appears to be overstated compared to the risks section for the investigational product.
9. Please remove discussion of genetic material in the Māori tissue statement, as no genetic material is being collected for this study.
10. In the statement about notifiable diseases, please include COVID-19. Delete “also known as the AIDs virus” after HIV.
11. Please remove the inclusion of diaphragm cap for contraception as this is not used in New Zealand.
12. Please make the titles easier to read in the consent form.
13. Please clarify how much the reimbursement for time and travel will be.
14. Please remove repeated information and descriptions.
15. On page 2, please explain what is meant by NKT being a breakdown product of KT.

Decision

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

* Please address all outstanding ethical issues, providing the information requested by the Committee.
* Please update the participant information sheet and consent form, taking into account 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 Devonie Waaka.

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| **8** | **Ethics ref:** | **21/STH/113** |
|  | Title: | Pharmacokinetics of Dexmedetomidine administered by Jet Injection- The DexJet Trial |
|  | Principal Investigator: | Dr Nicola Whittle |
|  | Sponsor: |  |
|  | Clock Start Date: | 29 April 2021 |

Dr Nicole Whittle, Jonothan Termaat and James McKeage were present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. This study aims to look at the blood levels of a sedative pain relief medication dexmedetomidine achieved by jet injection.

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 researchers are using EEG monitoring in their study. The researchers responded that this is to monitor for changes in sedation. This will not require a full EEG monitoring device, rather it will just entail three sticky patches on the forehead.
2. The researchers clarified that a crash team will be available during use of the PACU for 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 whether this device has been tested and approved in humans. The researchers responded that this is the first time this device is being used to deliver medicine intramuscularly. The novel aspect of the jet injection device is the electric motor rather than spring.
2. The Committee noted that this study should be submitted to SCOTT for approval, as it involves an approved medicine being delivered through a new route of administration. The medicine is approved in New Zealand for intravenous administration.
3. The Committee requested that the researchers clarify in their application that this is the first time this device has been used this way in humans.
4. The Committee noted that the protocol was insufficient. According to the *National Ethics Standards for Health and Disability Research and Quality Improvement* paras 9.7 and 9.7a, researchers must conduct their research according to a suitably detailed protocol. Please review Standards 9.7 and 9.7a, and amend the protocol accordingly.
5. Please review the safety aspects of the protocol, and include adverse events of special interest, such as sedation, hypotension and bradycardia.
6. Please include pregnancy and contraindications to dexmedetomidine use as exclusion criteria in the protocol. Ensure that the eligibility criteria first and foremost prioritise participant safety.
7. The Committee commented that recruiting participants from the hospital community was ethically concerning, as it raised potential conflicts of interest and might not be representative of patients. The Committee requested that the researchers consider how they might recruit participants outside of the medical community and reimburse them for their time. *(National Ethical Standards for Health and Disability Research and Quality Improvement,* para 7.14, para 11.20, 11.20.a, 11.21*).*
8. Please include in your application that participants will be eligible for ACC cover.
9. Please supply a data management plan to ensure the safety and integrity of participant data *(National Ethical Standards for Health and Disability Research and Quality Improvement,* para 12.15*).*
10. The Committee requested that the researchers 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*).* For guidance, please refer to the [HDEC peer review template](https://ethics.health.govt.nz/system/files/documents/pages/hdec-peer-review-template-june-2020.docx).
11. The Committee noted that the participant information sheet lacked sufficient information for participants to be able to provide informed consent (*National Ethical Standards for Health and Disability Research and Quality Improvement*, para 7.15).

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

1. Please refer to the [HDEC PISCF template](https://ethics.health.govt.nz/system/files/documents/pages/participant-information-sheet-consent-form-template-sep20.doc).
2. Please state that this is the first time this device has been used this way in humans.
3. Please clarify what Dexjet is in lay terms. Explain what the device is, where it will be administered, whether it will hurt, and what it means for the participant to have the device placed on them.
4. Explain the study in easy to understand terms, considering the information the participant needs to know, such as the primary study outcomes and how the dosing compares with doses used clinically.
5. Please include in the PIS that participants will be eligible for ACC cover. Please remove this from the CF.
6. Please include that the risk of sedation means that participants will not be allowed to drive home.
7. Please include information about protecting participants’ data, taking care to separate into identifiable and de-identified data.
8. In section 2, the implied potential benefit of this study to children is not relevant to the adult population under study. Rather, state that you are trying to find a better way to deliver this sedative by trying out a new method.
9. Put the most important information first, e.g. what participants will be requested to do. Next, state the possible risks.
10. Do not say “there may be no direct benefit”. Make it clear there is no benefit to the participant, as this is a proof of concept research study rather than a therapeutic study.
11. Please include the frequencies or likelihoods of the possible risks.
12. Please include the reproductive risks of involvement in this study. Please use the [HDEC reproductive risks template](https://ethics.health.govt.nz/system/files/documents/pages/participant-information-sheet-consent-form-template-reproductive-risks-17apr20.docx).
13. Please include pregnancy as an exclusion criterion.
14. Please provide more information about the EEG procedure, especially for Māori participants, for whom the head may be tapu.
15. The protocol states “we will monitor for signs of tissue damage at the site of injection on… the following day.” Please detail this in the PIS, which currently only mentions the day of the injection.
16. Withdrawal from the study could occur some time after the injection day, including after data analyses have commenced. Please modify the statement about withdrawing/destroying data.
17. Please include in the CF a statement about informing the GP.
18. Please indicate which laboratory will analyse the dexmedetomidine concentrations.

Decision

This application was *declined* by consensus, as the Committee did not consider that the study would meet the ethical standards referenced above. The Committee encouraged the researchers to resubmit their application to the Southern HDEC for the sake of continuity once the changes to their application have been made.

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| **9** | **Ethics ref:** | **21/STH/114** |
|  | Title: | AROANG3-2001: A Study to Investigate the Clinical Effectiveness and Safety of ARO-ANG3 in Adults with Mixed Dyslipidemia |
|  | Principal Investigator: | Dr Michael Williams |
|  | Sponsor: | IQVIA RDS Pty. Limited |
|  | Clock Start Date: | 29 April 2021 |

Dr Michael Williams was present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. The study involves the use of an active drug, ARO-ANG3 and a placebo. Both will be given as SC injection. The study is conducted to determine if the drug is effective and safe in adults with Mixed Dyslipidemia. The study also aims at selecting a suitable dosage regimen for later stages in study.
2. Three dose levels of ARO-ANG3 will be compared against placebo.
3. A total of approximately 180 participants will be recruited into the study. 60 participants per cohort will be randomly assigned in a 3:1 ratio to receive ARO-ANG3 or placebo. Each participant will receive SC injection on Day 1 and Week 12 for a total of 2 injections.

Summary of resolved ethical issues

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

1. The Committee was satisfied that there is adequate separation between the clinical and research roles in the recruitment and consenting process.

Summary of outstanding ethical issues

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

1. The Committee requested that the researcher provide a different response to question A1.6, which currently states that there are no ethical issues involved in their study.
2. The Committee requested that the research team ensures that each site has a home visit SOP in place which covers researcher safety, participant safety and tikanga (*National Ethical Standards for Health and Disability Research and Quality Improvement* para 11.62).
3. The Committee requested reassurance from the researcher that publication of the research will not be withheld by the manufacturer for a significant time period.
4. The Committee requested that the sponsor insurance is study specific (*National Ethical Standards for Health and Disability Research and Quality Improvement* para 17.1 – 17.6).
5. The Committee requested that the researcher ensures that if someone withdraws from the main study, they are asked if they would like to revoke their consent for the other substudies as well.

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

Main PISCF

1. Please replace ‘may’ with ‘will’ be reimbursed and state the amount of participant compensation. This amount will need to be approved by the HDEC. HDEC expects reasonable expenses should be reimbursed, plus time and inconvenience. There should not be unreasonable discrepancies between compensation amounts depending on locality. (*National Ethical Standards for Health and Disability Research and Quality Improvement* para 11.20-11.22).
2. Please change small fonts and large footers.
3. Remove repeated information.
4. Please remove the home visit PIS and rather include it as a brief entry in the main form with a tickbox.
5. Please use the [HDEC reproductive risks template](https://ethics.health.govt.nz/system/files/documents/pages/participant-information-sheet-consent-form-template-reproductive-risks-17apr20.docx). Do not include birth control methods that are not available in NZ. Address restrictions for egg donations.
6. Page 15 says participants will be withdrawn from the study if they become pregnant, but page 13 says they will stop taking the study drug but stay in study. Please ensure statements are consistent.
7. Please remove the extra text that has been added to the HDEC compensation template.
8. Please review for lay terms, e.g. “extremities”.
9. Please make the statements about notifiable diseases NZ specific.
10. Please state the city and country in which overseas labs are based.
11. Please edit the samples section for clarity, as it is currently confusing.
12. On page 9, please clarify what sample results participants will have access to. At a minimum, they should have access to screening and safety results during the study.
13. Please edit every section to remove duplication of information.
14. Please remove references to the sub-studies from everywhere besides the text at the end of page 7.
15. The Committee did not approve of participants having to pay for medication to reduce side effects, as stated on page 9 of the main PIS. Please delete this statement.
16. Please state in the PIS that participants can have usual care, but should try not to find out lipid levels from their GP so as to not unblind them from the study.
17. Please edit the sentence on page 3 to read “the day you have your *first* dose of study drug…”.

MRI PISCF

1. Review and delete repeated/duplicate information
2. Include the amount of time participants will be in the scanner.
3. Provide the reimbursement details, as noted above.
4. State whether the first MRI will be included in the participant’s clinical record.
5. Confirm that the researcher will contact the participant’s GP directly in the event of a potentially clinically significant abnormality on the MRI.

PK PISCF

1. Discuss what life-threatening or fatal side effects could occur from blood being taken, or delete if not applicable.
2. Provide the reimbursement details, as noted above.

Future Research PISCF

1. Review and delete repeated/duplicated information.
2. Review for use of different fonts and formatting.
3. Delete information that pertains to the main study rather than the optional sub-study.
4. Describe genes in lay language and clarify what testing ‘all genes in a sample’ means.
5. Include risks of privacy/confidentiality breach and statement that much of a person’s genetic code is shared with blood relatives (e.g. include potential for partial or full matches across genetic data-banks if this is a possibility).
6. Include risk of sending tissue overseas.
7. The consent states ‘I agree for my blood samples to be stored and used in future research of any type’; the body of the PISCF restricts this to research related to dyslipidemia and the study drug. Amend for consistency.
8. State clearly in the consent form that the participant agrees that samples may be used for genetic research.

Genetic PISCF

1. Most of the points listed above for the optional PISCFs apply. Please address as indicated.

Decision

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

* Please address all outstanding ethical issues, providing the information requested by the Committee.
* Please update the participant information sheet and consent form, taking into account 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 Mr Dominic Fitchett and Dr Paul Chin.

## Substantial amendments

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| **1** | **Ethics ref:** | **20/STH/87/AM03** |
|  | Title: | (duplicate) A study of the Efficacy and Safety of Guselkumab in Participants with Moderately to Severely Active Crohn’s Disease Study to evaluate the safety and effectiveness of guselkumab - GALAXI |
|  | Principal Investigator: | Prof Michael Schultz |
|  | Sponsor: | Ms Natasha Steyn |
|  | Clock Start Date: | 29 April 2021 |

Prof Michael Schultz was present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. The study objectives are to evaluate the clinical efficacy of Guselkumab in treating Crohn's Disease and to evaluate the safety of Guselkumab. Other purposes are to compare the effects of guselkumab to those of ustekinumab and placebo.

Summary of resolved ethical issues

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

1. The Committee clarified that this study involves an open-label extension study following on from two previously approved phase 2 and 3 double-blinded studies. The DSURs of these studies have been returning as satisfactory. There are no participants in screening or on study in New Zealand at the moment for these studies.
2. The researcher clarified that enrolment in the first studies will last a year before they roll over into the open-label extension study.
3. The researcher clarified that participants on the placebo drug who stop responding or worsen will be transferred to the active drug in the long-term extension 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 requested that participants on the extension study who are failing to improve or have stopped responding to the highest treatment arm are readvised of the possibility of a sham increase before being given it. Please include this in the study protocol.

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

1. Please state approximately how long inclusion in each part of the study will last.
2. Please clarify whether participants will continue on the same treatment allocation as they had in the first study in the long-term extension, and whether this will remain blinded.
3. Please inform participants that if they have not been responding to or are worsening on the placebo drug, they will be switched to the active drug for the long-term extension study.
4. Please include the following statement: “if you stop responding during the long-term extension period, this will be discussed with you again in clinic”.
5. Please add an optional consent clause regarding collection of long-term follow-up information after completion of the study. Please discuss this in the PIS.
6. Please remove the optional tick box for withdrawal of data, as the PIS says that this is not an option.

Decision

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

* Please address all outstanding ethical issues, providing the information requested by the Committee.
* Please update the participant information sheet and consent form, taking into account feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17).*
* Please update the study protocol, taking into account the feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.7).*

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

## General business

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

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| **Meeting date:** | 08 June 2021, 10:00 AM |
| **Meeting venue:** | ONLINE - Zoom Meeting |

The following members tendered apologies for this meeting.

* Dr Sarah Gunningham

1. **Review of Last Minutes**

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

1. **Matters Arising**

Suggestion to start future meetings at 9am rather than 10am.

Pass on thanks to Moana for receiving agenda on time.

1. **Other business**

The meeting closed at 3.30pm.