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| **Committee:** | Southern Health and Disability Ethics Committee |
| **Meeting date:** | 09 June 2020 |
| **Meeting venue:** | Zoom Meeting ID: 367 426 700 |

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| **Time** | **Item of business** |
| 11:15am | Welcome |
| 11:30am | Confirmation of minutes of meeting of 12 May 2020 |
| 11:45am | New applications (see over for details) |
| 11:45 – 12:10pm  12:10 – 12:35pm  12:35 – 1:00pm  1:00 – 1:25pm  1:25 – 1:50pm  1:50 – 2:15pm  2:15 – 2:40pm  2:40 – 3:05pm  3:05 – 3:30pm  3:30 - 3:55pm | i 20/STH/79 [ Sarah / Paul]  ii 20/STH/84 [ Dominic / Jean]  iii 20/STH/85 [Pauline / Paul]  iv 20/STH/86 [Sarah / Mira]  v 20/STH/87 [Dominic / Devonie]  [BREAK]  vi 20/STH/88 [Pauline / Jean] [COI: Devonie]  vii 20/STH/92 [Dominic / Mira]  viii 20/STH/93 [Sarah / Devonie] [COI: Jean]  ix 20/STH/94 [Dominic / Paul] |
|  | Substantial amendments (see over for details) |
| 3:55-4:10pm | i 19/STH/7/AM03 [Full committee] |
| 4:10pm | General business:  Noting section |
| 4:15pm | Meeting ends |

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| **Member Name** | **Member Category** | **Appointed** | **Term Expires** | **Apologies?** |  |
| Dr Sarah Gunningham | Lay (other) | 05/07/2019 | 05/07/2022 | 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 | Present |  |
| Mr Dominic Fitchett | Lay (the law) | 05/07/2019 | 05/07/2022 | Present |  |
| Dr Pauline Boyles | Lay (consumer/community perspectives) | 05/07/2019 | 05/07/2022 | Present |  |

## Welcome

The Chair opened the meeting at 11:15am and welcomed Committee members.

The Chair noted that the meeting was quorate.

The Committee noted and agreed the agenda for the meeting.

## Confirmation of previous minutes

The minutes of the meeting of 12 May were confirmed.

## New applications

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| **1** | **Ethics ref:** | **20/STH/79** |  |
|  | Title: | Ketamine and spider phobia replication study |  |
|  | Principal Investigator: | Prof Paul Glue |  |
|  | Sponsor: |  |  |
|  | Clock Start Date: | 28 May 2020 |  |

Professor Paul Glue was present 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 ethical issues

The main ethical issues considered by the Committee were as follows.

1. The Committee requested the Researcher give a brief overview of the study. The Researcher stated it was replication a previous study of ketamine vs midazolam to treat spider phobia which indicated ketamine was more effective. The Researcher stated this study would collect EEG data and attempt to identify a biomarker of ketamine response. The Researcher clarified the EEG is to explain the difference between ketamine and midazolam rather than their efficacy.
2. The Committee noted the supplied peer reviews appeared to be mostly applicable to the previous study (e.g. they did not discuss the EEG in detail) and did not disclose the conflict of interest (i.e. being co-authors on previous papers with the CI). The Committee requested the Researcher supply an independent peer review of the protocol that addresses the current proposed study in more detail, including safety concerns.
3. The Committee expressed concern at a potential conflict of interest as the study would contribute toward building a case for the use of ketamine to treat anxiety disorders. The Committee noted any information on potential uses for a drug product is valuable and even if it does not support a patent it can support the sale of the product after approval. The Researcher stated data generated from the study would be going into the public domain and would not have intellectual property aspects to it. The Researcher stated the justification for the study was not to support a patent or sale of a drug but whether ketamine can be used clinically to treat phobias.
4. The Committee queried how ketamine could be used to clinically treat phobias. The Researcher stated pre-dosing with ketamine could be used to alleviate symptoms for specific phobias e.g. a fear of needles when an injection is necessary or an acute fear of flying when travel is necessary. The Committee queried whether a slow-release tablet of ketamine could be used for this purpose. The Researcher stated this was not yet known but would not likely be effective as a stronger concentration of ketamine in the blood would be required to treat acute phobias.
5. The Committee queried whether the study required SCOTT approval. The Researcher stated it did not as it would be using approved formulations only.
6. The Committee requested the Researcher supply a data management plan that complies with [Chapter 12 of the National Ethical Standards for Health and Disability Research and Quality Improvement](https://neac.health.govt.nz/national-ethical-standards-health-and-disability-research-and-quality-improvement/part-two/12-health)
7. The Committee requested the Researcher revise the protocol exclusion criteria be revised to include the following:
   1. Individuals who had participated in the previous ketamine spider phobia study
   2. Individuals where exposure to ketamine or midazolam may place the participant at increased risk (refer to contraindications and precautions sections of the datasheets). The current exclusion criteria do not adequately protect against this,
   3. Individuals with a history of intolerance, allergic reaction or hypersensitivity to benzodiazepines or ketamine
   4. Concomitant medication restrictions (along with restriction windows
8. The Committee questioned whether alcohol consumption should be restricted, given its potential interactions with the study drugs.
9. The Committee requested that a screen for alcohol, DOA and urine pregnancy test should be added to the protocol pre-dose on each planned dosing day.
10. The Committee requested the insertion in the PIS of a statement advising that neither ketamine nor midazolam are approved for phobia treatment in New Zealand.
11. The Committee requested the insertion in the PIS of a statement advising whether the site will provide transport to and from the unit, as participants will be unable to drive on the day of dosing.
12. The Committee requested adverse events (AEs) with frequency and severity from the previous spider study be added to the PIS. Please also state whether there were any severe or serious AEs. Please state that, should an AE persist at two hours post dose, the participant will remain at the clinic under medical observation until the AE has resolved.
13. The Committee requested a lay title be used as the main heading for the PIS.
14. The Committee requested that an explanation of who Medsafe are be added to the PIS.
15. The Committee requested a definition of hair products on page 4 be added to the PIS (i.e. whether restricted hair products include shampoo, conditioner).
16. The Committee requested more information on data storage and management (at which point is data de-identified, who has access to identifiable or de-identified data, how and where is it stored, what it will be used for etc).

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 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 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).*
* Please provide a Data Management Plan *(National Ethical Standards for Health and Disability Research and Quality Improvement, 12.15a).*
* Please supply ketamine and midazolam data sheets. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 8.1).*

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

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| **2** | **Ethics ref:** | **20/STH/84** |  |
|  | Title: | Galderma LTE study - 118163 |  |
|  | Principal Investigator: | Prof Marius Rademaker |  |
|  | Sponsor: | Syneos Health New Zealand Limited |  |
|  | Clock Start Date: | 28 May 2020 |  |

Professor Marius Rademaker was present 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 ethical issues

The main ethical issues considered by the Committee were as follows.

1. The Committee noted the application form had been answered incorrectly and so questions concerning vulnerable participants had not been populated. The Committee requested the Researcher supply answers to the following questions:

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|  | Potentially vulnerable people |
| p.3.2 | Will your study involve potentially vulnerable people – that is, people who may have a restricted ability to make independent decisions about their participation?  yes  no |
| p.3.2.1 | Please explain how your study’s informed consent process takes the needs of these potentially vulnerable people into account.  [<100 words] |
| p.3.2.2 | Will informed assent also be sought from people responsible for the welfare of potentially vulnerable people involved in your study?  yes  no |
| p.3.2.2.1 | Please explain why you will not obtain such assent.  [<100 words] |
| p.3.2.2.2 | *A* ***generic*** *version of the information sheet that will be provided to people interested in or responsible for the welfare of potentially vulnerable people involved in your study must be uploaded in the “Documents” tab before submission to an HDEC. You don’t need to submit information sheets specific to each study locality.*  Please explain how informed assent will be obtained.  [<100 words] |

1. The Committee queried how likely it was that the study would recruit participants under 16. The Researcher stated they believe it is very unlikely but it is still part of the protocol. The Committee advised that if the study does recruit any children then their health information must be retained for 10 years after they turn 16.
2. The Committee advised that site-facing documents are out of scope and do not require and cannot receive HDEC approval. The Committee requested this be relayed back to the Sponsor. The out of scope documents are:
   * 37: eCRF (site-facing)
   * 05 EASI (site-facing)
   * 06 IGA (site-facing)
   * 07 BSA (site-facing)
3. The Committee requested that, for future HDEC application forms, the first use of any acronyms should include the term in full.
4. The Committee noted the answer to B.4.5. in the application form stated tissue will not be made available for future research and other parts of the application stated tissue would be destroyed, but elsewhere it was stated that tissue will be used for optional DNA research. The Researcher stated all main samples would be destroyed and only optional DNA for Future Unspecified Research would be stored. The Researcher confirmed this was optional and a separate consent would be obtained for this. The Committee requested the Researcher supply answers to the following questions that were not answered in the application form:

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|  | Future use of human tissue |
| b.4.5 | Will any human tissue collected or otherwise obtained from participants in this study but not used in it be made available for use in future research, for instance by being stored in a tissue bank?  yes  no  not applicable |
| b.4.5.1 | *You should explain this clearly to potential participants.*  Will consent for future unspecified use of human tissue be obtained separately from consent to participate in your study?  yes  no |
|  | *You must obtain consent for future unspecified use of human tissue separately from consent to participate in the study.* |
| b.4.5.2 | Please briefly describe the possible future uses for human tissue collected in your study.  [<200 words] |
| b.4.5.3 | Will any human tissue collected or otherwise obtained from participants in this study but not used in it be stored or sent overseas?  yes  no |
|  | *You should explain this clearly to potential participants.* |

1. The Committee noted a placebo justification letter had been supplied even though the application stated there was no placebo for the open-label extension. The Researcher clarified participants that had been on placebo required a loading dose before switching to the open label extension. The Researcher explained participants already receiving the active ingredient did not require a loading dose and would receive placebo in its place.
2. The Committee advised it would not be necessary to have a separate PIS for this and instead the Researcher could amend the consent form to include an option
3. The Committee noted the insurance policy referred to the ‘policy territory’ but this was not defined or specified anywhere. Please provide an updated insurance certificate that specifies New Zealand as the policy territory.
4. The Committee noted it is possible for children under the age of 16 to possess the competence to consent for themselves and it is up to the Researcher to make this assessment. If the child is competent then parental consent is not required. The Committee noted that children under 16 that comprehend the assent form would likely be capable of giving consent.
5. The Committee noted the statement in the Costs and Reimbursement section of the PIS that states the Sponsor “denies any and all liability related to any health issues related to your asthma and/or difficulty breathing”. The Committee requested this statement be removed, as if a participant’s breathing or asthma is made worse by the study drug then the Sponsor may be liable and the Sponsor’s insurance policy would then apply.
6. The Committee requested the Researcher supply a data management plan that complies with [Chapter 12 of the National Ethical Standards for Health and Disability Research and Quality Improvement](https://neac.health.govt.nz/national-ethical-standards-health-and-disability-research-and-quality-improvement/part-two/12-health).
7. The Committee requested the inclusion of relevant information from the [HDEC reproductive risks template](https://ethics.health.govt.nz/system/files/documents/pages/participant-information-sheet-consent-form-template-reproductive-risks-17apr20.docx). Alternatively, if there is suitable justification on why males do not need contraception (e.g. there is evidence the drug is not present in semen), please provide this.
8. The Committee queried what safety monitoring was in place for the questionnaires containing questions about mood and anxiety. The Researcher stated there is not a formal mechanism for it as they are intended to show whether there is a benefit from improvement of eczema, so is a patient-led outcome for trying to assess the value of getting rid of the itch / eczema. The Researcher stated there they do not have an assumption that it would cause a mood change. The Committee queried what action the Researcher would take if a participant scored very highly on a depression/anxiety score. The Researcher stated that the participant would be assessed clinically and appropriate follow-up arranged if indicated.

**Main adult PISCF**

1. Please remove the italics and quotation marks from the Cultural Tissue statement.
2. On page 16 please state that data may be used for future research; who the data may be shared with; whether the data may be combined with other data to form larger data sets; whether data may be anonymised in the future; and the potential risks associated with data collection and use.
3. Please include the following statement: 'Rarely, it may be necessary for [Study Doctor] to share your information with other people – for example, if there is a serious threat to public health or safety, or to the life or health of you or another person OR if the information is required in certain legal situations. The Sponsor may also access or share your identifiable information in the event you make a claim for compensation for study-related injury'.
4. Please replace the statement on page 17 regarding the National Statement on Ethical Conduct in Human Research with a statement referencing the [NEAC Guidelines.](https://neac.health.govt.nz/national-ethical-standards-health-and-disability-research-and-quality-improvement)

**ASSENT FORM:**

1. A simplified asset form is required for adolescents with a younger reading age. The current assent form is far too complicated for most 12-year olds.

**PREGNANCY PISCF**

1. Please confirm whether information will be sought about previous pregnancies (including abortions or miscarriages); whether any information will be sought regarding the participant's sexual history (including sexually transmitted diseases); and whether information will be sought regarding the circumstances of the pregnancy (e.g. contraceptive failure / failure to use contraception). Please also state whether this will involve accessing records from GP / midwife / hospital etc.
2. Please state how long information about the baby will be collected for after birth. Will longer follow-up be undertaken in the event of a congenital anomaly or other significant medical disorder?
3. Potential risks include distress or anxiety as a result of the follow-up. How will this be managed? Will counselling or other appropriate support be arranged by the study team?
4. How will the baby be identified? Who will have access to the coded information? Will it be used for future research? Could it be used in the event the participant made a compensation claim due to an adverse pregnancy outcome? Please also state specifically that some countries have mandatory safety reporting requirements and that the information may be included in health or regulatory agency safety databases overseas.
5. Please delete clauses in the consent form that are not applicable.
6. A separate consent is required after the birth of the baby. An additional signature can be added to the consent form for this purpose.

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 a data governance plan to ensure the safety and integrity of participant data

*National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15).*

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

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| **3** | **Ethics ref:** | **20/STH/85** |  |
|  | Title: | The MoPED Study |  |
|  | Principal Investigator: | Dr Eleanor Kennedy |  |
|  | Sponsor: | University of Auckland |  |
|  | Clock Start Date: | 28 May 2020 |  |

Dr Eleanor Kennedy was present 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 ethical issues

The main ethical issues considered by the Committee were as follows.

1. The Committee queried if the benefits of the research could justify the risk of an MRI to a new-born baby. The Researcher stated in other clinical settings babies born at earlier gestations undergo MRI as part of their standard care, and it is a safe procedure that has been used in neonatal care for many years. The Researcher stated they are aware of the need for sensitivity when explaining things to the parents and their experience has shown parents can be reassured when the MRI does not show concerning findings. The Researcher stated the study is important because we do not properly understand what the white matter changes in these babies mean, and stated they will be honest with parents about this.
2. The Committee queried how the Researcher would perform an MRI on a toddler for the two-year follow-up. The Researcher stated they would do cognitive motor development assessments and not another MRI. The Researcher stated the MRI would be done very close to birth (once the baby is stable) and on the expected due date only.
3. The Committee noted the application did not contain details of the two year follow-up. The Researcher stated this would be submitted as a separate application.
4. The Committee raised the possibility of false positives and false negatives on the MRI. The Researcher stated there is still a lot unknown about early white matter changes and for false negatives the evidence on MRI scans and later developmental outcomes is still evolving. The Researcher stated it is known that pre-term babies still have a higher risk of adverse outcomes even without abnormalities on the MRI. The Researcher stated they explain to parents that even if an MRI shows no abnormalities this is not a confirmation that there will be no adverse developments.

The Committee requested the line in the PIS advising that ‘most scans are normal and this is reassuring’ be revised to clearly state that this is not a guarantee of normal development.

1. The Committee queried why the study would not have a control group and if the study would get its answers without a control group of infants to compare to. The Researcher stated the primary focus of the study is on early white matter changes rather than a comparison.
2. The Committee noted parents in this context would be vulnerable as it is a time of significant anxiety and uncertainty and the PIS would benefit from being written with this in mind.
3. The Committee requested the Researcher supply a data management plan that complies with [Chapter 12 of the National Ethical Standards for Health and Disability Research and Quality Improvement](https://neac.health.govt.nz/national-ethical-standards-health-and-disability-research-and-quality-improvement/part-two/12-health).
4. The Committee requested an independent peer review and recommended the Researcher use the [scientific peer review template available on the HDEC website.](https://ethics.health.govt.nz/system/files/documents/pages/HDEC-Peer-Review-Template.docx)
5. The Committee queried if the initial approach to participants would be done by their treating clinician. The Researcher stated the clinician would ask the parents if they would be interested in participating and if they express interest a member of the study team would approach them to discuss.
6. The Committee noted page 2 of the PIS mentioned questionnaires on stress. The Researcher stated this was from an earlier version of the study but was now removed. The Researcher agreed to amend the form.
7. The Committee queried whether the study would request information on any of a participant’s previous pregnancies or only the current one. The Researcher stated only the current pregnancy. The Committee requested the form be revised to specify this.
8. The Committee requested the Researcher include the new ACC statement available from the [PIS template available on the HDEC website.:](https://ethics.health.govt.nz/system/files/documents/pages/piscf-template-feb-2020-270220.doc)

“If you were injured in this study, you would be eligible **to apply** for compensation from ACC just as you would be if you were injured in an accident at work or at home. This does not mean that your claim will automatically be accepted. You will have to lodge a claim with ACC, which may take some time to assess. If your claim is accepted, you will receive funding to assist in your recovery.  
  
If you have private health or life insurance, you may wish to check with your insurer that taking part in this study won’t affect your cover.”

1. The Committee noted the protocol detailed a consent to be contacted for a two-year follow-up but could not find this information in the PIS/CF. The Researcher stated it should be included in the PIS/CF and agreed to check.
2. The Committee queried whether the one consent form is intended to consent to both the mother’s pregnancy information and the child to an MRI. The Researcher confirmed it was. The Committee stated normally this would be discouraged but, in this study, it is pragmatic to keep it combined.
3. The Committee queried whether the MRI images would be included with the baby’s clinical records or only the research database. The Researcher stated it would be uploaded to both. The Committee queried whether this information was in the PIS. The Researcher stated they believe so and agreed to check.

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 a data governance plan to ensure the safety and integrity of participant data

*National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15).*

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

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| **4** | **Ethics ref:** | **20/STH/86** |  |
|  | Title: | Study of Cemiplimab (REGN2810 (Anti-PD-1)) in Patients With Advanced Malignancies |  |
|  | Principal Investigator: | Associate Professor Michael Jameson |  |
|  | Sponsor: | Regeneron |  |
|  | Clock Start Date: | 28 May 2020 |  |

Associate Professor Michael Jameson was present 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 ethical issues

The main ethical issues considered by the Committee were as follows.

1. The Committee noted the application form was incomplete. Question D had been completed incorrectly, and as a result the risk and consent sections had not been populated. The Committee requested the Researcher supply answers to the following questions:

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| **r.1** | **Risk of physical harm to participants** |
| r.1.1 | Briefly and in plain English, please describe:   * the procedures to be undertaken by participants in your study, and * any risks associated with these procedures that potential participants may reasonably wish to be informed of.   ***Do not*** *describe procedures that will be undertaken as part of normal clinical care regardless of participation in your study, or the risks of such procedures.*  [<400 words] |
| r.1.2 | Will you seek consent from participants to inform health practitioners with responsibility for their health care that they are taking part in your study?  yes  no |
| r.1.2.1 | Please briefly explain why you will not do so.  [<100 words] |
| r.1.3 | Will your study involve withholding standard treatment from participants?  yes  no |
| r.1.3.1 | Please briefly explain why it is appropriate to withhold standard treatment from participants.  [<200 words] |
|  | Arrangements for monitoring serious adverse events |
| r.1.4 | How will serious adverse events occurring in your study be monitored?  independent data safety monitoring committee  internal data safety monitoring committee  other data safety monitoring arrangements  no formal data safety monitoring arrangements |
| r.1.5 | Please briefly explain *either:*   * the monitoring arrangements in place for your study, and explain why they are appropriate (including reference to your study’s protocol where appropriate), *or* * why you do not consider formal monitoring arrangements to be necessary for your study.   [<200 words] |
| r.1.6 | Please briefly outline the criteria (if any) for terminating your intervention study, including reference to your study’s protocol where appropriate.  [<100 words] |
|  | Compensation for injury to participants |
| r.1.7 | Will any participants seek or be given treatment by or at the direction of a registered health professional (as defined in the [Accident Compensation Act 2001](http://www.legislation.govt.nz/act/public/2001/0049/latest/DLM99494.html)) as part of your intervention study?  yes  no |
| r.1.7.1 | Will any of these participants have given written consent to participate?  yes  no |
| r.1.7.1.1 | Does your intervention study involve trialling a medicine or item?  yes  no |
| r.1.7.1.2 | Having regard to the following questions, will your study be carried out principally for the benefit of the manufacturer or distributor of the medicine or item being trialled?   * + *Who is initiating the study?*   + *Who is designing and planning the research questions that the study will ask?*   + *Will the PI or other investigators receive remuneration from the manufacturer or distributor?*   + *Is the manufacturer or distributor putting any unreasonable restrictions or delays on the timely publication of the results of the study?*   + *Is the manufacturer or distributor providing any funding and/or materials for the study?*   **yes**, my study will be carried out principally for the benefit of the manufacturer or distributor of the medicine or item in question  **no**, my study will **not** be carried out principally for the benefit of the manufacturer or distributor of the medicine or item in question |
| r.1.8 | Please briefly explain your answer(s) to questions r.1.7- above.  [<200 words] |
|  | *Subject to an HDEC being satisfied with your answer(s) above, participants injured as a result of treatment given as part of your intervention study will be eligible for publicly funded no-fault compensation through ACC.* |
| r.1.9 | *Participants injured as a result of treatment given as part of your intervention study may not be eligible for publicly funded no-fault compensation from the Accident Compensation Corporation. Researchers and sponsors must ensure that they have arrangements in place to ensure that at least ACC-equivalent compensation would be available in case of such injury.*  In the event of injury to a participant in your intervention study, will compensation potentially be available for all of the following entitlements, which would be available through ACC?   * rehabilitation (comprising treatment, social rehabilitation, and vocational rehabilitation) * first week compensation * weekly compensation * lump sum compensation for permanent impairment * funeral grants, survivors' grants, weekly compensation for the spouse or partner, children and other dependants of a deceased claimant, and child care payments   yes  no |
|  | *The arrangements in place for your intervention study must ensure that compensation would be available for all of these entitlements, which would be available through ACC, in the event of injury to participants as a result of treatment given as part of the study.* |
| r.1.10 | Please confirm that:   * the study’s sponsor agrees to abide by Medicines NZ’s [Guidelines on Clinical Trials Compensation for Injury Resulting from Participation in an Industry-Sponsored Clinical Trial](http://www.medicinesnz.co.nz/clinical-trials/?flush=1), *and* * insurance cover will be in place for the duration of the study in New Zealand, *and* * participation in the trial does not affect the right of participants to pursue legal remedies in respect of any injury alleged to have been suffered as a result of participation.   yes  no |
| r.1.11 | *Evidence that the study sponsor holds insurance in respect of this intervention study must be uploaded in the “Documents” tab before submission to an HDEC.* |
| r.1.12 | *Evidence that the Principal Investigator is professional indemnified, for example through membership of the Medical Protection Society (MPS), must be uploaded in the “Documents” tab before submission to an HDEC.* |
|  | Ionising radiation not needed for normal clinical management |
| r.1.13 | Will your study involve the administration of ionising radiation that is not needed for participants’ normal clinical management?  yes  no |
| r.1.13.1 | Please briefly describe the form(s) in which ionising radiation not needed for normal clinical management will be administered.  [<100 words] |
| r.1.13.2 | Please provide the name(s) of the person(s) licenced under the [Radiation Protection Act 1965](http://legislation.govt.nz/act/public/1965/0023/latest/DLM372539.html) under whose supervision ionising radiation will be administered to participants in your study. |
| r.1.13.3 | Has a medical physics expert verified that accurate effective doses have been calculated for this ionising radiation?  yes  no |
|  | *A medical physics expert must verify this aspect of your study before you apply to an HDEC. Localities at which ionising radiation is to be administered should be able to provide the contact details of a medical physics expert. You can also contact the* [*National Radiation Laboratory*](http://www.nrl.moh.govt.nz/) *for assistance in locating a medical physics expert.* |
| **p.1** | **Participants should consent to their participation in research.** |
| p.1.1 | Briefly and in plain English, please describe what taking part in your study will involve for participants.  [<200 words] |
| p.1.2 | Will **all** participants in your study give their informed consent to participate?  yes, all participants will give informed consent  no, one or more participants will not give informed consent |
|  | Studies involving non-consenting participants |
| p.1.3 | *New Zealand law – particularly the* [*Protection of Personal and Property Rights Act 1988*](http://legislation.govt.nz/act/public/1988/0004/latest/DLM126528.html)*, the* [*Code of Patients’ Rights*](http://www.hdc.org.nz/the-act--code/the-code-of-rights)*, and the* [*Care of Children Act 2004*](http://legislation.govt.nz/act/public/2004/0090/latest/DLM317233.html) *– substantially limits the powers of health practitioners to offer treatment without consent in the context of research. It is the Principal Investigator’s responsibility to ensure that all applicable legal standards are met in non-consensual studies.*  Please indicate the groups to which non-consenting participants in your study belong, and provide brief details.  children and young people (under the age of 16) who are not competent to give informed consent  unconscious adults  adults with serious mental illness  adults with serious intellectual disability  other  Details: |
| p.1.4 | Please briefly explain why it is appropriate that your study involve non-consenting participants.  [<100 words] |
| p.1.5 | Will you seek the informed consentof parents, guardians, relatives or other persons who are able to advise on the presumed wishes of non-consenting participants?  yes  no |
| p.1.5.1 | Please briefly explain why you will not obtain such consent.  [<100 words] |
| p.1.5.2 | *A* ***generic*** *version of the information sheet that will be provided to parent, guardians, relatives or other persons must be uploaded in the “Documents” tab before submission to an HDEC. You don’t need to submit information sheets specific to each study locality.*  Please briefly explain how informed consent will be obtained from such persons.  [<100 words] |
| p.1.6 | What steps will you take to provide non-consenting participants with information about the study, and to consider their wishes and feelings about participating?  [<100words] |
| p.1.7 | Is it possible that non-consenting participants’ ability to give informed consent could change during your study?  yes  no |
| p.1.7.1 | How would such changes be managed?  [<100 words] |
| p.1.8 | Will **any** participants in your study have given their prior informed consent to participate?  yes, one or more participants will give informed consent  no, no participants will give informed consent |
| p.1.9 | Will informed consent be recorded in writing?  yes  no |
| p.1.9.1 | Please describe how participants’ informed consent will be recorded.  [<100 words] |
| **p.2** | **Consent should be informed by adequate understanding of relevant information.** |
| p.2.1 | Briefly explain the process by which potential participants in your study will be provided with information on the study, have the opportunity to ask questions, and asked to give their informed consent.  [<200 words] |
| p.2.2 | *A* ***generic*** *version of the participant information sheet and consent form (PIS/CF) that you will provide to potential participants must be uploaded in the “Documents” tab before submission to an HDEC. You don’t need to submit information sheets specific to each study locality.*  *A suggested pro forma for your PIS/CF can be found here.* |
| p.2.3 | How have you checked that the participant information sheet is appropriate for your study population?  [<100 words] |
| p.2.4 | How many words does your participant information sheet contain? |
| p.2.5 | What is the Flesch Reading Ease Score for your participant infornation sheet?  *You can use* [*Microsoft Word*](http://office.microsoft.com/en-us/word-help/test-your-document-s-readability-HP010148506.aspx#BM2) *to calculate this score.*  *While there are no hard and fast rules for the readability of information sheets, a score of 65 or above usually indicates that a document is written in plain English.* |
|  | Withholding or concealing information from participants |
| p.2.6 | Does your study involve deliberately withholding or concealing information from participants?  *Blinding procedures in randomised controlled trials are not normally considered to involve withholding or concealing information from participants.*  yes  no |
| p.2.6.1 | Please explain why it is appropriate to withhold or conceal information from participants in your study.  [<100 words] |
|  | Information that becomes available during the study and that may be relevant to continued participation |
| p.2.7 | How will you ensure that participants receive information that becomes available during the study and that may be relevant to their continued participation?  [<200 words] |
|  | Information about the results of the study |
| p.2.8 | Will you inform participants of the results of your study?  yes  no |
| p.2.9 | Please *either* explain how you will inform participants *or* explain why you do not intend to do so.  [<100 words] |
| **p.3** | **Consent should be voluntary.** |
| p.3.1 | *Generic copies of any advertising that you intend to use to encourage potential participants to take part in your study must be uploaded in the “Documents” tab before submission to an HDEC.*  Please explain how potential participants will be identified and approached in a way that ensures they can give informed consent free from undue influence.  [<200 words] |
|  | Potentially vulnerable people |
| p.3.2 | Will your study involve potentially vulnerable people – that is, people who may have a restricted ability to make independent decisions about their participation?  yes  no |
| p.3.2.1 | Please explain how your study’s informed consent process takes the needs of these potentially vulnerable people into account.  [<100 words] |
| p.3.2.2 | Will informed assent also be sought from people responsible for the welfare of potentially vulnerable people involved in your study?  yes  no |
| p.3.2.2.1 | Please explain why you will not obtain such assent.  [<100 words] |
| p.3.2.2.2 | *A* ***generic*** *version of the information sheet that will be provided to people interested in or responsible for the welfare of potentially vulnerable people involved in your study must be uploaded in the “Documents” tab before submission to an HDEC. You don’t need to submit information sheets specific to each study locality.*  Please explain how informed assent will be obtained.  [<100 words] |
|  | Inducements |
| p.3.3 | Will participants receive any payments, reimbursement of expenses or any other benefits or incentives for taking part in your study?  yes  no |
| p.3.3.1 | Please describe these, and explain why they are appropriate.  [<100 words] |

1. The Committee noted the PIS disclosed that seven clinical studies on 885 participants resulted in 9 deaths associated with the drug. The Committee requested reassurance about the risks of the drug. The Researcher explained the drug is one of a class of immunotherapy treatments for cancer, targeting receptors which carries a small risk from an ‘over-activation’ of the immune system but can also cause damage to other systems. The Committee noted page 11 of the PIS discusses known risks and side effects of the drug.
2. The Committee queried the recruitment process. The Researcher explained patients being referred to medical oncology for this study would not normally be seen by a medical oncologist and would usually be managed by plastics or radiation. The Researcher explained clinicians in those departments would offer eligible patients an opportunity to see a medical oncologist to discuss the trial. The Committee stated this was acceptable.
3. The Committee stated an overseas Sponsor representative filling out the application form is not optimal as they often do not understand New Zealand’s cultural context or site-specific details and it is preferable for a member of the local study team to complete the application. The Committee requested the Researcher provide study-specific answers to the following questions:

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| **p.4** | **Population groups, particularly Māori, should be consulted in the design and conduct of research that is of relevance to them.** |
|  | Consultation with Māori |
| p.4.1 | Please describe whether and how your study may benefit Māori.  [<200 words] |
| p.4.2 | Please identify the main cultural issues that may arise for Māori who may participate in your study, and explain how these issues will be managed.  [<200 words]  *If Māori will be excluded from participating, please state this. You will be asked to explain your inclusion/exclusion criteria in the next section of the Form.* |
| p.4.3 | According to the Health Research Council’s [*Guidelines for Researchers on Health Research Involving Māori*](http://www.hrc.govt.nz/sites/default/files/Guidelines%20for%20HR%20on%20Maori-%20Jul10%20revised%20for%20Te%20Ara%20Tika%20v2%20FINAL%5b1%5d.pdf), is formal consultation with Māori required for your study?  yes  no |
| p.4.3.1 | Please *either* describe your study’s consultation process, *or* explain why you do not consider that formal consultation with Māori is required.  [<200 words] |
| p.4.4 | Does your study involve kaupapa Māori research methodologies?  yes  no |
|  | Consultation with other relevant population groups |
| p.4.5 | Will any other population groups be specifically targeted for recruitment into your study?  yes  no |
| p.4.5.1 | Please indicate which population groups will be specifically targeted for recruitment, and briefly describe:   * how these populations have been or will be consulted, and * how your study may benefit these populations.   [<200 words] |
|  | Collection of ethnicity status |
| p.4.6 | Will participants’ ethnicity status be collected as part of your study?  yes  no |
|  | Community intervention studies |
| p.4.7 | Is your study a community intervention study?  yes  no |
| p.4.7.1 | Please explain how you have engaged with the relevant communities.  [<100 words] |

| **Question number** | **Question** |
| --- | --- |
| **f.1** | **Where possible, research should reduce health inequalities.** |
| f.1.1 | Might your intervention study contribute to reducing inequalities in health outcomes between different populations, and particularly between Maori, Pacific peoples and other New Zealanders?  yes  no |
| f.1.2 | Please explain your answer above.  [<200 words] |
| **f.2** | **Participants and non-participants should be treated fairly compared to each other.** |
|  | Inclusion and exclusion criteria |
| f.2.1 | Please briefly describe the inclusion and exclusion criteria for your study.  *You can refer to page numbers of your study’s protocol where further detail is required.*  [<300 words] |
| f.2.2 | Please explain how these inclusion and exclusion criteria ensure that the risks and benefits of your study are distributed fairly.  [<200 words] |
|  | Placebo-controlled studies |
| f.2.3 | Does your study involve the use of placebo?  yes  no |
| f.2.3.1 | Please explain why the use of placebo is justified in your study.  [<100 words] |
|  | Impact on health and disability support service provision |
| f.2.4 | Might your study adversely impact on the provision of health and disability services?  yes  no |
| f.2.4.1 | How will this possibility be minimised and managed?  [<100 words] |
|  | Best intervention standard |
| f.2.5 | *An intervention study meets the best intervention standard if the intervention(s) in the study are tested against the best proven intervention(s) available outside the study.*  Please explain how your study meets the “best intervention standard”.  [<200 words] |
| **f.3** | **Different groups of participants should be treated fairly compared to each other.** |
|  | Post-study access for participants to best-proven intervention |
| f.3.1 | Will all participants have continued access to the best-proven intervention after the end of your intervention study?  yes  no |
|  | *You need to explain this clearly to participants.* |
|  | Equipoise standard |
| f.3.2 | *An intervention study meets the equipoise standard if the evidence is ‘equally poised’ as to the overall balance of risks and benefits of each of the interventions offered in the study, so that it cannot be determined in advance which of the groups in a proposed study will be better off.*  Please briefly explain how your intervention study meets the equipoise standard.  [<100 words] |

1. The Committee requested the Researcher supply a data management plan that complies with [Chapter 12 of the National Ethical Standards for Health and Disability Research and Quality Improvement](https://neac.health.govt.nz/national-ethical-standards-health-and-disability-research-and-quality-improvement/part-two/12-health).
2. The Committee noted the insurance policy referred to the ‘policy territory’ but this was not defined or specified anywhere. Please provide an updated insurance certificate that specifies New Zealand as the policy territory.

**MAIN PISCF**

1. The Committee noted a discrepancy where page 20 states all tissue samples are labelled with a number, where earlier in the sheet it states some samples would be labelled with a name and date of birth. The Committee requested this be reconciled or explained.
2. The Committee noted the statement that the risks of alternative treatment depend on the alternative treatment does not provide useful information and requested this be revised or deleted.
3. The Committee noted a number of tests are included that do not apply to group 6. The Committee requested a revision to only include tests relevant to group 6.
4. The Committee requested the Researcher adapt the [HDEC Reproductive Risks template.](https://ethics.health.govt.nz/system/files/documents/pages/participant-information-sheet-consent-form-template-reproductive-risks-17apr20.docx)
5. The Committee noted repeated references to an optional PET scan and queried whether this was an error, or if a PET scan would be performed.
6. Please standardise the font size and formatting throughout the document.
7. Please delete repeated references to group 6, as this information sheet is clearly stated to be specific to Group 6.
8. Please state the number of NZ participants expected to be enrolled on page 2
9. Please remove the references to optional DNA samples / pharmacogenetics/optional samples for future research on pages 5 and 18.
10. On page 11 when discussing the biopsy it states that 'these samples will be used for research purposes by the Sponsor. For this study? Or for unspecified research? Please clarify.
11. Page 13 includes the statement 'if you have already started study treatment...'. Please delete as does not apply to any New Zealand participants.
12. The information about HIV and hepatitis is repeated (p17 and p19). Please delete one.
13. The cultural tissue statement is repeated (p18 and p19). Please delete one.
14. On pages 23/24 please make it clear in this section which data is identifiable and which is coded.
15. On page 24 remove tests that do not apply to Group 6. There are two blood sample sections, which contain somewhat contradictory information. Retention times differ. Some sections are repeated (for examples lists of what safety test will be performed). It is very unclear whether there is mandatory use of samples for future research.
16. What does 'the Sponsor's Data Retention Schedule' mean on page 25? Please state in years.
17. On page 25, what Future Research Samples are being discussed here - are these optional samples? If yes, delete. Please note a third cultural tissue statement has been inserted in this section, please remove.
18. On page 26 when discussing digital images, some of the information discussed in this section is not mandatory (broader sharing of images, for example). Please delete.

**CONSENT FORM**

1. Withdrawal of data is not an option according to body of PIS. Please delete optional tickbox.
2. Informing GP of study participation is not an option per body of PIS. Please delete optional tickbox.

**PISCF PHARMACOGENOMICS**

1. Please make it clear if this may include research unrelated to the current drug or disorder (unspecified medical or scientific research).
2. A significant amount of information provided in this document is repeated using different wording. The wording in the final pages of the document is much more concise and lay-friendly than some of the earlier wording. Please thoroughly proofread and remove redundancies. Please make it clear who will have access to identifiable data and who will have access to coded (or double-coded) data. It is very unclear whether the sponsor will receive double-coded or single-coded genetic data from the laboratory.

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 a data governance plan to ensure the safety and integrity of participant data

*National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15).*

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

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| **5** | **Ethics ref:** | **20/STH/87** |  |
|  | 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: | Janssen-Cilag (New Zealand) Limited |  |
|  | Clock Start Date: | 28 May 2020 |  |

Professor Michael Schultz 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 ethical issues

The main ethical issues considered by the Committee were as follows.

1. The Committee queried the difference between GALAXI 2 and GALAXI 3. The Researcher stated they are similar studies being done separately but the Sponsor has decided to do both at the same time.
2. The Committee noted the ‘main ethical issues’ section of the application appeared to contain a ‘cut and paste’ response that does not address issues associated with this particular study and queried what they may be. The Researcher stated the main issue is the placebo arm but did not see issues particular to this research which are not present in other studies.
3. The Committee noted R.1.1.3. in the application stated no ionising radiation will be used, however, the study will use X-rays. The Committee stated it was reassured the risk from a single X-ray is low but requested the Researcher be mindful of incorrect responses for future applications.
4. The Committee queried the pre-screening procedure on sharing information with the Sponsor before participant consent is obtained, as this was not allowed. The Researcher clarified personal information would not be shared, only generalised medical information e.g. number of surgeries and whether this would exclude them. The Committee stated if there was no potentially identifiable information included then this was permissible.
5. The Committee noted the study would be conducted in a public hospital and queried how the Researcher would ensure public clinical resources would not be consumed for research. The Researcher stated the locality assessment would be authorised by the clinical director of gastroenterology who would not sign unless this was managed. The Researcher confirmed if there were any constraints on the public service the study would shift to a private setting.
6. The Committee queried the process for unexpected findings as R.4.1. in the application implied this was not a possibility. The Researcher stated this was an error and any unexpected findings would be managed the normal way e.g. if a chest X-ray revealed a lung mass the participant would be removed from the study, referred as appropriate and their GP notified.
7. The Committee noted the study would be introduced by a participant’s usual doctor and queried whether the consent process could be undertaken by someone else to avoid any perceived conflict of interest. The Researcher stated there are two investigators on the trial so this was possible.
8. The Committee queried how adverse findings on depression, anxiety questionnaires would be managed. The Researcher stated there was no particular way to screen for it but if anything was brought to the study team’s attention they would act on it. The Committee queried how long it would take from the participant completing the questionnaire to the study team reviewing it and acting if necessary. The Researcher stated this has not yet happened so was unsure and agreed to provide clarification.
9. The Committee noted if participants on the placebo arm do not show a response in 12 weeks they will be moved to the active control arm. The Committee queried the scenario if a participant on the placebo arm showed a response would they continue on placebo and if so what would happen if their condition later deteriorated. The Researcher stated the safety mechanism would be to either withdraw them and return to standard care or transfer to active treatment. The Researcher stated crossover is only at certain timepoints and they would not know whether a participant is on active or placebo but if anyone worsens they can either crossover or withdraw. The Researcher confirmed rescue medication would be available. The Committee requested information explaining this be added to the PIS.
10. The Committee requested the Researcher supply a data management plan that complies with [Chapter 12 of the National Ethical Standards for Health and Disability Research and Quality Improvement](https://neac.health.govt.nz/national-ethical-standards-health-and-disability-research-and-quality-improvement/part-two/12-health).

**INFORMED CONSENT DOCUMENTS**

1. The Committee requested a lay title be used as the main heading for the PIS.
2. The Committee noted it was ambiguous whether the section about what happens to participant samples applied to mandatory samples for the main study or future unspecified research. Please confirm whether the information provided relates to mandatory analysis only, as some of the statements are very broad. If referring to mandatory analysis, please add the following statement to: 'Your samples may also be shared with research partners, but only for the scientific research purposes stated above'.
3. The Committee requested the statement about relocating samples be revised to simply state that, although unlikely, it is possible samples could be transferred to a Sponsor approved lab anywhere in the world.
4. The Committee requested removal of the section about stopping the study earlier and agreeing not to limit information as this is worded better later on in the sheet.

The Committee requested the Researcher replace the compensation section with the appropriate statement on the [PIS template available on the HDEC website.](https://ethics.health.govt.nz/system/files/documents/pages/piscf-template-feb-2020-270220.doc)

1. Please amend the 'Who pays for treatment' section to apply to the NZ health care system.
2. The Committee requested the recruitment letters come from the participant’s usual specialists rather than from a member of the research team to avoid the feeling of being ‘cold called’.
3. The Committee requested the insertion of a statement into the introduction explaining to participants that after screening they will be randomised into either galaxi 2 or 3 and will be told which study they are part of.
4. The Committee requested a revision to the risks section to use lay-friendly language.
5. The Committee requested a general revision to the PIS to simplify any overly complex information.
6. The Committee requested the removal of the ‘yes / no’ option to notify the participant’s GP on the consent form as it should be mandatory in a study of this nature.
7. The Committee requested the removal of the last paragraph on page 23 when discussing doctor visits.
8. The Committee requested the insertion of a statement advising participants that they would need to sign the standard colonoscopy form too and this would include all necessary information about the procedure.
9. The Committee requested the payment section of the genetic PISCF be simplified; participants will not be paid or reimbursed as the blood draw will be taken during a visit for the main study.
10. The Committee advised that if participants withdraw the onus is on the study team to ask if they also withdraw consent for their samples/data to be used for FUR / Genetic Research.
11. The Committee noted the pregnant partner sheet contains information not relevant to pregnant partners (e.g. about study procedures) as they are not in the main study. The Committee requested removal of information that does not apply to pregnant partners and to clarify what does (e.g. a clause giving permission to give study results to the Sponsor, but it is unclear what ‘study results’ for the pregnant partner are). The Committee requested the sheet explain exactly what information the study will be collecting about pregnant partners.
12. The Committee noted the following documents submitted with the application are out of scope for HDEC review and have not been assessed:
    * Global Chart Flag
    * Global Eligibility Card
    * CAN No Objection letter
    * Physician Referral Letter
13. The Information section needs: - to split identifiable and de-identified information - to make it clearer who may assess identifiable information (and purposes) - to discuss sharing of data for future (un)related research - to acknowledge the potential risks of confidentiality breach
14. The statement that 'If you decide to stop the study early, you agree not to limit our use of your study information' is repeated in better detail below. Please delete.

**PISCF FUR**

1. Return of results section missing, please add whether this will happen.

**PISCF PREGNANCY**

1. Please explain what information will be required. It appears that no data will be collected regarding sexual and contraceptive history; previous pregnancies (including any terminations or miscarriages); or non-obstetric health information.
2. Withdrawal of consent for obtaining health information does not need to be made in writing.
3. Is the privacy section applicable to this information sheet? How can there be study procedures if the partner is not a participant?
4. Please explain the following statement: 'By signing this document, you also give permission to the study doctor to disclose the study results to the Sponsor and representatives of the Sponsor'. What study results does this apply to?
5. Please explain why reviewing data collected for pregnancy surveillance would impact on the scientific integrity of the data ('However, to ensure the reliability of the Study, you agree that you will not be able to see or copy some of your records until the Sponsor has completed all the work related to the study in case such access may impact on the scientific integrity of the study)
6. . Is this data stored in the main study database, or in the Sponsor safety database? Please clarify.
7. The Committee requested the removal of the ‘yes / no’ boxes from the pregnant partner/participant consent form unless it is for an item that is truly optional (i.e. the participant can answer ‘NO’ and still participate in the study).

Decision

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

* Please update the participant information sheet and consent forms, 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 a data governance plan to ensure the safety and integrity of participant data

*National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15).*

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

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| **6** | **Ethics ref:** | **20/STH/88** |  |
|  | Title: | A study comparing the pharmacokinetic similarity of MB02-SP, MB02-DM and US-licensed Avastin®. |  |
|  | Principal Investigator: | Doctor Christian Schwabe |  |
|  | Sponsor: | Syneos Health |  |
|  | Clock Start Date: | 28 May 2020 |  |

Dr Christian Schwabe was present for discussion of this application.

Potential conflicts of interest

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

Devonie Waaka declared a conflict of interest, relinquished voting rights and agreed not to participate in the discussion but would remain in the room as an observer. d

Summary of ethical issues

The main ethical issues considered by the Committee were as follows.

1. The Committee noted this was a phase 1 biosimilar study with multiple formulations and queried if there would be a time delay / sentinel dosing. The Researcher stated the Sponsor had decided this was not required. The Committee expressed concern that if the formulations were different enough they needed to be tested separately there is the potential for different effects. The Committee queried if this was a first in human study. The Researcher stated three formulations will be used and one has not been given to healthy volunteers before. The Committee requested information explaining all this be added to the PIS and the protocol be revised to incorporate a sentinel dosing schedule.
2. The Committee queried how long samples would be stored for as the documentation had differing values (e.g. 15 years versus end of study). The Researcher stated local samples would be destroyed at the end of the study.
3. The Committee noted the baseline levels for neutrophils, haemoglobin, blood pressure etc was lower than the normal healthy range and queried whether this was to widen the potential participant pool. The Researcher stated ‘normal ranges’ are not developed with healthy volunteers in mind and are intended for a hospital population and research will sometimes use different cut-off values.
4. The Committee noted women would be excluded from the study and the justification is sex differences and different clearance rates of the drug. The Committee queried whether further studies would include women and expressed concern that these medicines would be used by women and noted the long history of women being excluded from research. The Researcher stated other studies in later phases would include both sexes but phase 1 studies for pharmacokinetics are usually just for males to minimise variables. The Committee accepted this and stated it was reassured future studies would include women.
5. The Committee requested a general revision of the PIS to simplify for lay-friendly reading and to explain technical terms when their use is necessary (e.g. ‘biosimilar’).
6. The Committee requested the Researcher adapt the information for males from the [new HDEC reproductive risks template.](https://ethics.health.govt.nz/system/files/documents/pages/participant-information-sheet-consent-form-template-reproductive-risks-17apr20.docx)
7. The Committee requested the Researcher supply a data management plan that complies with [Chapter 12 of the National Ethical Standards for Health and Disability Research and Quality Improvement](https://neac.health.govt.nz/national-ethical-standards-health-and-disability-research-and-quality-improvement/part-two/12-health).
8. The Committee noted the PIS infers that the Sponsor and any subcontracted companies will keep identified information for up to 15 years. The Researcher clarified it would not be identified and would be labelled with the study code only. The Committee requested the sheet be revised to explain participants’ data would not be stored under their name but with their study code and that this is potentially identifiable.
9. The committee requested section 6.4 of the PIS be edited using headings, to clearly explain the use of identifiable and de-identified data
10. The Committee noted an unclear statement that if pregnant partners withdraw from the study the doctor will not receive data from the pregnancy except for safety data. The Committee queried what this safety data would be. The Researcher agreed it was confusing and agreed to revise the section.
11. The Committee requested a thorough simplification of the pregnancy PIS as it contained a lot of technical language and would benefit from a lay-friendly revision.
12. The Committee noted page 14 of the PIS referred to genetic studies and queried whether this study would involve genetic research. The Researcher stated this was an error and agreed to remove it.
13. The Committee noted the study contact card only has Dr. Schwabe’s contact information and unless he is available 24/7 requested an alternative number for participants or medical personnel to use to contact a member of the study team.
14. The Committee requested a general revision of the main PIS to check for formatting inconsistencies.

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 a data governance plan to ensure the safety and integrity of participant data

*National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15).*

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

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| **7** | **Ethics ref:** | **20/STH/92** |  |
|  | Title: | Zoster Eye Disease Study (ZEDS) |  |
|  | Principal Investigator: | Dr Jay Meyer |  |
|  | Sponsor: | NYU Grossman School of Medicine |  |
|  | Clock Start Date: | 28 May 2020 |  |

Ms Mee Lee was present 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 ethical issues

The main ethical issues considered by the Committee were as follows.

1. The Committee queried whether this was an approved medicine being used for a new indication. The Researcher state it was approved in New Zealand for the treatment of herpes zoster and normally used for 7 – 10 days. The Researcher stated they are trying to use a lower dose for a longer period to see if it may prevent recurrence. The Committee requested information explaining this be added to the PIS as it is currently unclear.
2. The Committee queried whether the study involved any use of human tissue. The Researcher confirmed they would be taking blood samples. The Committee noted the application had answered that tissue would not be used and as a result some questions had not appeared. The Committee requested answers to the following questions:

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| Future use of human tissue | |
| Will any human tissue collected or otherwise obtained from participants in this study but not used in it be made available for use in future research, for instance by being stored in a tissue bank?  yes  no  not applicable | |
| *You should explain this clearly to potential participants.*  Will consent for future unspecified use of human tissue be obtained separately from consent to participate in your study?  yes  no | |
| *You must obtain consent for future unspecified use of human tissue separately from consent to participate in the study.* | |
| Please briefly describe the possible future uses for human tissue collected in your study.  [<200 words] | |
| Will any human tissue collected or otherwise obtained from participants in this study but not used in it be stored or sent overseas?  yes  no | |
| *You should explain this clearly to potential participants.* | |
|  | |
| **r.3** | **Risks associated with the use of human tissue** | |
| r.3.1 | *The use of human tissue in New Zealand is regulated by the* [*Human Tissue Act 2008*](http://www.legislation.govt.nz/act/public/2008/0028/latest/DLM1152940.html) *and the* [*Code of Health and Disability Services Consumers’ Rights 1996*](http://www.hdc.org.nz/the-act--code/the-code-of-rights)*.*  Will human tissue be collected and/or used in your study?  yes  no | |
| r.3.2 | What types of human tissue will be collected and/or used in your study?  [<100 words] | |
| r.3.3 | Will your study involve:  human tissue collected from participants?  existing stored human tissue samples? | |
| r.3.4 | How and from where will you obtain these existing stored human tissue samples?  [<100 words] | |
| r.3.5 | Will any human tissue samples used in your study be imported from outside New Zealand?  yes  no | |
| r.3.5.1 | Please briefly explain why it is appropriate to use imported human tissue in your study.  [<100 words] | |
| r.3.6 | Will donors of existing stored human tissue samples used in your study be able to be identified by you or your research team?  yes  no | |
| r.3.6.1 | Please briefly explain why the use of existing stored human tissue samples in a form that may allow the donor(s) to be identified is necessary in your study.  [<100 words] | |
|  | Access to human tissue during the study | |
| r.3.7 | Please briefly explain how human tissue samples will be stored during your study, and how the privacy of donors and participants will be protected.  [<100 words] | |
| r.3.8 | Will human tissue collected in New Zealand be sent overseas as part of your study?  yes  no | |
| r.3.8.1 | *You should explain this clearly to participants.*  Please briefly explain why it is necessary and appropriate that human tissue samples be sent overseas as part of your study.  [<100 words] | |
|  | Use of human tissue without consent | |
| r.3.9 | Will the use of all human tissue in your study be in accordance with the informed consent (including consent to [future unspecified research](http://www.moh.govt.nz/moh.nsf/indexmh/guidelines-use-human-tissue)) that has been or will be obtained from participants, donors of existing stored human tissue, or other persons entitled to give informed consent under the [Human Tissue Act 2008](http://www.legislation.govt.nz/act/public/2008/0028/latest/DLM1152940.html)?  yes  no | |
| r.3.9.1 | Insofar as your study involves the storage, preservation or use of human tissue without informed consent, does a statutory exemption to the need to obtain such consent apply?  *Statutory exemptions are set out at section 20(f) of the* [*Human Tissue Act 2008*](http://www.legislation.govt.nz/act/public/2008/0028/latest/DLM1152940.html) *and Right 7(10)(c) of the* [*HDC Code of Rights*](http://www.hdc.org.nz/the-act--code/the-code-of-rights)*.*  yes  no | |
| r.3.9.1.1 | *Under section 20(e) of the* [*Human Tissue Act 2008*](http://www.legislation.govt.nz/act/public/2008/0028/latest/DLM1152940.html) *and Right 7(10)(b) of the* [*HDC Code of Rights*](http://www.hdc.org.nz/the-act--code/the-code-of-rights)*, HDECs may approve the use of human tissue without consent in research. Approval may be given where it is not practicable to obtain informed consent, and/or where the benefits of the research outweigh the very strong need to protect an individual’s right to consent.*  Please briefly justify the storage, preservation or use of human tissue without consent in your study.  [<300 words] | |
|  | Tests and analyses of human tissue | |
| r.3.10 | What types of tests or analyses will be carried out on human tissue as part of your study?  [<100 words] | |
|  | Storage and use of human tissue after the study | |
| r.3.11 | What will happen to human tissue at the end of your study, or if participants withdraw consent for its use in this study?  disposal  return to donor, whānau, or family member  return to current holder of existing stored human tissue (e.g. a tissue bank)  transfer to another tissue bank  storage by the research team for use in another study  storage by the research team as part of a new tissue bank  other | |
| r.3.12 | Please briefly explain your answer above.  [<100 words] | |

1. The Committee note the recruitment material seemed to be a copy used in New York and queried whether there was a New Zealand specific version. The Researcher stated it was a copy of the advertisement used in the US and Canada but if there needed to be a country-specific one they can amend it to a local context. The Committee stated the concern was the poster referred to American institutions and requested a version with the appropriate New Zealand ones.
2. The Committee requested the removal of the words ‘important’ and ‘very important’ when promoting research and to use neutral language instead.
3. The Committee noted the information about participant payment amounts and the phone script do not match and contain information that is not applicable to New Zealand (e.g. insurance billing). The Committee requested this be amended to a New Zealand context.
4. The Committee requested an independent peer review and recommended the Researcher use the [scientific peer review template available on the HDEC website.](https://ethics.health.govt.nz/system/files/documents/pages/HDEC-Peer-Review-Template.docx)
5. The Committee requested the Researcher supply a data management plan that complies with [Chapter 12 of the National Ethical Standards for Health and Disability Research and Quality Improvement](https://neac.health.govt.nz/national-ethical-standards-health-and-disability-research-and-quality-improvement/part-two/12-health).
6. The Committee queried the mention of providing participant information to the Sponsor before they consent. The Researcher stated it would be redacted and only to ensure participants are eligible for the study. The Committee stated this was not acceptable in a New Zealand context and instead researchers obtain participant consent and do a proper screening procedure.
7. The Committee requested that a lay title be used as the main heading for the PIS.
8. The Committee requested a general revision to simplify the information sheet and make it lay friendly.
9. The Committee requested the Researcher adapt the [Reproductive Risks template.](https://ethics.health.govt.nz/system/files/documents/pages/participant-information-sheet-consent-form-template-reproductive-risks-17apr20.docx)
10. The Committee queried whether the Researcher had a PIS for the scenario of a participant or their partner becoming pregnant. The Researcher stated they would submit an amendment with the sheet ad hoc if this occurred.
11. The Committee noted the PIS mentions side effects are possible but does not explain what they may be. The Committee requested a list of all potential side effects be included.
12. The Committee noted a statement on page 5 of the PIS indicating if a participant’s kidney is worsened while on the study they will be removed from the trial and transferred to their GP care and the study would not pay for the treatment. The Committee queried why the study would not cover a participant potentially made worse by the drug when this is what insurance is for. The Committee queried whether this was a commercially sponsored trial. The Researcher stated it was not. The Committee stated if it is not a commercial trial then ACC will apply, but the welfare of participants on a trial is still the responsibility of the site.
13. The Committee queried whether study results or a deidentified dataset may be shared with other researchers. The Researcher stated it would be deidentified aggregated data and there was no intention to share the dataset. The Committee requested this phrase in the PIS be removed. The Committee noted journals frequently require a deidentified dataset to publish an article and recommended the Researcher check publishing requirements.
14. The Committee requested informing the participant’s GP be mandatory and for any abnormal findings that may be discovered to be communicated. The Committee requested information in the PIS explaining this.

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 an independent peer review of the study protocol. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.26).*
* Please supply a data governance plan to ensure the safety and integrity of participant data

*National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15).*

* Please update the advertisements, taking into account the feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 11.12).*

After receipt of the information requested by the Committee, a final decision on the application will be made by Mr Dominic Fitchett and Associate Professor Mira Harrison-Woolrych

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| **8** | **Ethics ref:** | **20/STH/93** |  |
|  | Title: | MANA: Meaning, Agency & Nurturing Autonomy |  |
|  | Principal Investigator: | Dr Fiona Graham |  |
|  | Sponsor: | University of Otago |  |
|  | Clock Start Date: | 28 May 2020 |  |

Dr Fiona Graham was present for discussion of this application.

Potential conflicts of interest

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

Jean Hay-Smith declared a conflict of interest, relinquished voting rights and agreed not to participate in the discussion but would remain in the room as an observer.

Summary of ethical issues

The main ethical issues considered by the Committee were as follows.

1. The Committee queried if the primary outcome will be the child’s participation as it seemed most of the review is to be done with the parent rather than the child. The Researcher stated the mechanism for change is the caregiver and how they can set up a developmentally supportive environment, so the intervention is largely given to the caregiver. The Researcher explained that many of the children in the study would not have the cognitive or physical ability to verbalise and may not be present in any of the sessions. The Researcher explained the intervention itself directs the caregiver to be collaborative with the child and involve them in identifying situations of concern and finding solutions to problems.
2. The Committee stated its role is to ensure things are not done to children without consent, or that will have adverse effects. The Committee queried whether an additional evaluation from the child (e.g. a simple quality of life measure) would be possible. The Researcher stated they could potentially do this with some children that had the cognitive and communicative ability.
3. The Committee queried whether the caregiver and child would be treated as a combined participant. The Researcher confirmed they would be a joint participant.
4. The Committee stated the rationale for not seeking consent for an audit of clinical practice that has been delivered does not apply to a prospective intervention to answer a research question. The Committee queried why the Researcher could not simply obtain consent to access peoples files. The Researcher stated it was important to have a complete dataset as part of a sample can introduce biases. The Committee stated it did not believe there was an overwhelming case for not informing participants as this was being done for research and that consent should be obtained.
5. The Committee advised that if the study recruits any children then their health information must be retained for 10 years after they turn 16.
6. The Committee queried whether the audio transcription file would be deleted. The Researcher stated the local copy on the tablet would be deleted and a copy of the file and transcript can be kept on the secure University server. The Committee queried whether identifying information would be redacted. The Researcher stated the automated transcription does need some manual checking which would be done by a research assistant and any identifying information can be removed. The Committee requested information explaining all of this be added to the PIS.
7. The Committee requested the statement “If you say yes your family will get two $50 gift vouchers” be removed from the assent form as this may be an inducement.
8. The Committee requested the assent form be split into levels of competency (e.g. 7 – 11, 12 – 15) and recommended the Researcher adopt an easy-read approach to simplify the information.
9. The Committee noted the rebuttal to the HRC review comments had been supplied but not the actual HRC peer review. The Committee requested it be provided with a copy of this.
10. The Committee requested the Researcher devise some sort of assessment from the child (e.g. something simple such as a selection of smiley faces to choose before/after). The Committee stated it was important to have some sort of evaluation of the child so it can be reassured the child is included in the research.
11. The Committee noted the assent form should be returned from the child and not verbally via the parent.
12. The Committee requested the Researcher supply a data management plan that complies with [Chapter 12 of the National Ethical Standards for Health and Disability Research and Quality Improvement](https://neac.health.govt.nz/national-ethical-standards-health-and-disability-research-and-quality-improvement/part-two/12-health).
13. The Committee requested a disclaimer in the main PIS advising that if the therapist withdraws from the study the participant would need to withdraw as well.

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 revise the study protocol to include an assessment by the child of the study
* Please supply a data governance plan to ensure the safety and integrity of participant data

*National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15).*

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

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| **9** | **Ethics ref:** | **20/STH/94** |  |
|  | Title: | Service user and clinician experiences of self-harm services |  |
|  | Principal Investigator: | Dr Sarah Fortune |  |
|  | Sponsor: |  |  |
|  | Clock Start Date: | 28 May 2020 |  |

Ms Linda Hobbs was present 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 ethical issues

The main ethical issues considered by the Committee were as follows.

1. The Committee queried whether visual recordings would be destroyed after transcription. The Researcher confirmed they would.
2. The Committee noted P.2.1. in the application form implied participants would consent over Zoom. The Committee explained digital consent is permissible but only as long as participants have had a chance to read the material first. The Committee advised that if the Researcher is going to obtain digital consent they would need to record that consent was obtained, in writing, to comply with [Chapter 7 of the National Ethical Standards for Health and Disability Research and Quality Improvement.](https://neac.health.govt.nz/national-ethical-standards-health-and-disability-research-and-quality-improvement/part-two/7)
3. The Committee queried why the visual recording would be undertaken. The Researcher stated it was designed during the time when an increased Covid alert level may have meant an in-person meeting was not possible and a visual recording is preferable to telephone.
4. The Committee queried whether the information could be sufficient to identify anyone (e.g. ethnicity, age and gender could potentially identify an individual). The Researcher stated if it looked like the data could show that they would collapse it down into broader categories.
5. The Committee queried the possibility of a participant experiencing or displaying signs of distress during an interview. The Researcher stated although the interview was about the service some participants may want to talk about their own health and they could be referred through regular clinical pathways. The Committee stated it was satisfied the study team is an expert in this area and could manage any participants experiencing distress or suicidal ideation.
6. The Committee noted the study information would be anonymous, but participants would be required to enter an email address and be contactable for the interview. The Committee requested clarification on how data will be managed to allow for this.
7. The Committee requested the Researcher supply a data management plan that complies with [Chapter 12 of the National Ethical Standards for Health and Disability Research and Quality Improvement](https://neac.health.govt.nz/national-ethical-standards-health-and-disability-research-and-quality-improvement/part-two/12-health).
8. The Committee queried how the Researcher could ensure the security of transmission and access to the recordings sent to the transcription service. The Researcher stated they were unaware of the specifics and only that it was a secure service. The Researcher agreed to provide clarification.
9. The Committee recommended the Researcher check whether the University has a policy around use of the word ‘gift’ as it may only allow ‘reimbursement’ to be used.
10. The Committee noted the PIS for those who tried to commit suicide contains technical language and requested a revision to simplify it for a lay audience. The Committee recommended asking a layperson to proof-read it.
11. The Committee requested a statement in the PIS advising that any recordings will be destroyed once transcribed.

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 a data governance plan to ensure the safety and integrity of participant data

*National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15).*

* Please provide clarification of the security for the transcription service.

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

## Substantial amendments

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| **1** | **Ethics ref:** | **19/STH/7/AM03** |  |
|  | Title: | Centre for Brain Research Neurogenetic Research Cl |  |
|  | Principal Investigator: | A/Prof Richard Roxburgh |  |
|  | Sponsor: |  |  |
|  | Clock Start Date: | 27 April 2020 |  |

Associate Professor Richard Roxburgh was present for discussion of this amendment.

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 ethical issues

The main ethical issues considered by the Committee were as follows.

1. The Committee queried whether this was a registry for neurogenetic conditions. The Researcher stated it was not and was a longitudinal study of patients.
2. The Committee stated the PIS was vague and queried what data the study would ask of participants. The Researcher stated they are interested in observational data of neurological function e.g. ultrasound of nerves, walk tests, how fast participants can do a 9-peg hole test. The Researcher confirmed they were non-invasive tests.
3. The Committee expressed concern at the vagueness of the form as it was ambiguous what participants were agreeing to. The Committee requested the Researcher revise the information sheet to include all this information as participants need to know exactly what it is they will be doing before they consent into the study.
4. The Researcher stated the study would be monitoring over 50 neurological conditions and it was not practical to create over 50 unique forms. The Committee stated it can accept generic forms for healthy volunteers but when a study involves cognitive assessments the information sheet needs to explain what sort of tests are required and what data the Researcher is interested in.
5. The Committee stated the sheets do not need to list every single test by name but would need to give enough examples to obtain informed consent and so participants are aware of what will be expected of them in advance.
6. The Committee queried what the genetic tests would involve. The Researcher stated they wish to compare genetic data of those with the gene and the disease and those with the disease but not the gene. The Researcher stated an objective is to define the phenotype and what is normal and abnormal and in knowing the genotype is necessary for this in some cases. The Committee queried whether the Researcher would need genetic data from a control group. The Researcher stated yes, when this is available.
7. The Committee stated the information sheet would need adequate information about what genetic testing and analysis would be done on participant samples, who the sample and data would be provided to, whether any future unspecified research may be done on it and whether there would be any involvement of third parties.
8. The Committee requested the Researcher supply a data management plan that complies with [Chapter 12 of the National Ethical Standards for Health and Disability Research and Quality Improvement](https://neac.health.govt.nz/national-ethical-standards-health-and-disability-research-and-quality-improvement/part-two/12-health).
9. The Committee requested a lay title be used as the main heading on the PIS.
10. The Committee requested a general revision of the sheet to make it more lay friendly and to explain technical language (e.g. ‘neurogenetic’).
11. The Committee requested the Researcher create three separate information sheets, one for adult participants, one for children, and one for the control group. The Committee advised that each sheet would have to contain enough information so all participants are aware of how much data they are giving and for what purpose, and that it may be shared with other researchers (specify if known) and for what purpose.

Decision

This amendment was *declined* by consensus, as the Committee did not consider that the amendment would meet the following ethical standards.

* Participants need to know exactly what they are signing up for in order to provide informed consent. 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 a data governance plan to ensure the safety and integrity of participant data

*National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15).*

## 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:** | 14 July 2020, 11:45 AM |
| **Meeting venue:** | Zoom Meeting ID: 367 426 700 |

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.

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

The meeting closed at 4:00 pm.