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| **Committee:** | Central Health and Disability Ethics Committee |
| **Meeting date:** | 26 March 2024 |
| **Zoom details:** | Zoom details: https://mohnz.zoom.us/j/96507589841 |

| **Time** | **Review Reference** | **Project Title** | **Coordinating Investigator** | **Lead Reviewers** |
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| 12:00PM – 12:30PM | 2024 FULL 19755 | Safety and benefit of the Infinity Figure-8 balloon dilator for improvement of swallowing in patients with swallowing problems | Associate Professor Jacqui Allen | Cordelia Thomas & Patricia Mitchell |
| 12:30PM – 1:00PM | 2024 FULL 17901 | CHOICE UTI Trial | Professor Stuart Dalziel | Jessie Lenagh-Glue & Joan Pettit |
| 1:00PM – 1:30PM | 2024 FULL 19823 | Uplifting the mana of Pacific young people | Ms Rupi Riley | Sandy Gill & Albany Lucas |
| 1:30PM – 2:00PM | 2024 FULL 19699 | M14-671 Crohn's Disease: Efficacy, Safety, and Pharmacokinetics of Upadacitinib in Pediatric Subjects with Moderately to Severely Active Crohn's Disease | Prof. Andrew Day | Cordelia Thomas & Joan Pettit |
|  |  | **BREAK 30 MINUTES** |  |  |
| 2:30PM – 3:00PM | 2024 FULL 19301 | Exploring the effect of dietary intervention in the management of obsessive-compulsive disorder (OCD) | Ms Sophia Dawson | Sandy Gill & Patricia Mitchell |
| 3:00PM – 3:30PM | 2024 FULL 19810 | A study to test long-term treatment with spesolimab in people with a skin condition disease called hidradenitis suppurativa (HS) who took part in a previous study with spesolimab | Dr Marius Rademaker | Jessie Lenagh-Glue & Albany Lucas |
| 3:30PM – 4:00PM | 2024 FULL 19954 | AbbVie M23-703 - Lutikizumab in Ulcerative Colitis | Dr James Brooker | Cordelia Thomas & Joan Pettit |
| 4:00PM – 4:30PM | 2024 FULL 19736 | Pharmacy Research Network Influenza-Like Illness Surveillance Programme | Prof Alex Semprini | Jessie Lenagh-Glue & Patricia Mitchell |

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| **Member Name**   | **Member Category**   | **Appointed**   | **Term Expires**   | **Apologies?**   |
| Mrs Helen Walker  | Lay (Consumer/Community perspectives) (Chair) | 22/12/2020  | 22/12/2024 | Apologies |
| Mrs Sandy Gill  | Lay (Consumer/Community perspectives)  | 22/05/2020  | 22/05/2023  | Present  |
| Dr Patries Herst  | Non-lay (Intervention studies)  | 22/05/2020  | 22/05/2023  | Apologies |
| Dr Cordelia Thomas  | Lay (the Law)  | 22/12/2020  | 22/12/2024 | Present  |
| Mrs Patricia Mitchell  | Non-lay (Health/Disability service provision)  | 08/07/2022 | 08/07/2025 | Present  |
| Mx Albany Lucas | Non-lay (Observational studies) | 22/12/2021 | 22/12/2024 | Present |
| Ms Jessie Lenagh-Glue | Lay (Ethical/Moral reasoning) | 22/12/2021 | 22/12/2024 | Present |
| Ms Joan Pettit | Non-Lay (Intervention Studies) | 08/07/2022 | 08/07/2025 | Present |

## Welcome

The Chair opened the meeting at 11:30am and welcomed Committee members, noting that apologies had been received from Mrs Helen Walker and Dr Patries Herst.

The Chair noted that it would be necessary to co-opt members of other HDECs in accordance with the Standard Operating Procedures. Ms Joan Petit confirmed their eligibility and were co-opted by the Chair as a member of the Committee for the duration of the meeting. Dr Cordelia Thomas was acting chair for this meeting as Mrs Helen Walker was an apology.

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 27 February 2024 were confirmed.

## New applications

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| **1**   | **Ethics ref:**   | **2024 FULL 19755** |
|   | Title:  | Safety and Efficacy of the Infinity Figure 8 balloon dilator for Improvement of Swallowing in Patients with Upper esophageal sphincter obstruction |
|   | Principal Investigator:  | Dr Jacqueline Allen |
|   | Sponsor:  | Hope Medical Incorporated |
|   | Clock Start Date:  | 14 March 2024 |

Dr Jacqueline Allen was present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of resolved ethical issues.

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

1. The Committee asked if the study is research for a new device or whether it’s an alternative to current standard of care and asked for the researchers’ thoughts. The Researcher explained that the standard of care is currently balloon dilation made by two main prop companies explaining the balloon dilation aspect is not new, what is new is the shape of the balloon being used in this study that the manufacturers have created. The Researcher explained they do not see it as a new device but more of an update. The Committee further explained that because this device is not available in New Zealand, HDEC would classify the device as a new device.
2. The Committee asked about the study design sentence: "In no way will nonparticipants be impacted, in fact, choosing the traditional balloon shape would allow us a convenient comparison cohort". The Committee commented if a comparison cohort is needed why is it not part of the study. The Researcher explained that this study does not require a cohort and has a historical cohort of many participants who have already received round balloons that can be used for comparisons if needed.

Summary of outstanding ethical issues

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

1. The Committee all agreed that the study device should be submitted as a new device as it is not available in New Zealand rather than an alternative to standard of care.
2. Please amend the study start date.
3. The incorrect WDHB logo is used on all documents, please amend.
4. Please amend the incorrect protocol title front page: 'Platelet rich plasma injections for vocal fold atrophy and scarring'.
5. Please include who is funding the study in documentation.
6. Please upload ACC information.
7. The Committee stated more information around data management is required than what is available in the study documentation satisfy the Committee that privacy and confidentiality is protected and that Standard 12.15a is met. Use of the HDEC template from the HDEC website is not mandatory but is encouraged to be adapted or used as a guide/starting point.
8. Please include who is manufacturing the investigational device.
9. Please amend the last page of the protocol, it seems to be incomplete.
10. Please remove the exclusion criteria of pregnant women.

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

1. Please include that this device is new and not approved for use in New Zealand, and that the device is commercially available in other countries such as Australia.
2. The Committee noted there are missing sections of the participant information sheet to obtain fully informed consent. The Committee recommended the Researcher adapt the PIS template available on the HDEC website.
3. Please include a table detailing visits and interventions, this would assist in participants understanding what is required of the study.
4. Please use lay language throughout, please define what is barium swallow and other technical references.
5. Please include the risks and alternatives available to participants to fully inform potential participants, this is not for the risks of the treatment it’s the risks of the research aspect and participating.
6. Submission and PIS lay title are different, please amend.
7. Please include a Māori cultural statement and the tapu of the head should be addressed.
8. No discussion of GP being informed; Consent form needs to include acknowledgement that GP/usual provider will be contacted.
9. No discussion of risks or alternatives to participating in the study. Please add.
10. Need Māori and Ethics support contact information. Please add.
11. Please explain how the participants will be completing the Eating Assessment Tool and what is required of the participant.
12. Please include whether the balloon will be removed if the participant withdraws, or just that data will no longer be collected.
13. HDEC recommends the participant are provided expenses such as travel to be paid for and provided with a koha.
14. The Committee explained that the data of participants who have had the round balloon used previously will need give their consent to be a part of this research as research is different from treatment. Currently in the participant information sheet it is stated this study is being done to compare the figure 8 balloon to the round balloon. Either recruit a group of participants who have/had the round balloon and then require these participants to consent their data to be used in the research. If the participant does consent the data cannot be used.
15. Please include a separate PIS/CF for participants using the round balloon as currently it only mentions the round balloon participants briefly and is difficult to understand how these participants will be involved in the study.

**Decision**

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

1. Please address all outstanding ethical issues raised by the Committee.
2. Please update the Participant Information Sheet and Consent Form, taking into account the feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17).*
3. 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).*
4. Please update the data management plan, taking into account the feedback provided by the Committee. (National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15a).

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| **2**   | **Ethics ref:**   | **2024 FULL 17901** |
|   | Title:  | Clinical efficacy of single dose (daily) IV antibiotics followed by two days oral antibiotics compared to three doses (daily) IV antibiotics for children with complicated urinary tract infections: a multicentre randomised trial |
|   | Principal Investigator:  | Professor Stuart Dalziel |
|   | Sponsor:  | NHMRC Medical Research Future Fund |
|   | Clock Start Date:  | 14 March 2024 |

Professor Stuart Dalziel was present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of resolved ethical issues.

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

1. The Committee raised the peer review submitted and agreed that the funding approval letter provided is sufficient peer review for this study.
2. The Committee asked about the protocol outlining standard treatment and how long the antibiotics should be used for. The Researcher explained in previous studies antibiotics were used for 10-15 days however with new evidence those days can be reduced, the researchers feel confident that the first dose for UTI’s should be 7 days for a complicated UTI. Further explaining that many participants are getting put on 7 days to begin with.
3. The Committee asked if the children being included presented through the Emergency Department (ED). The Researcher explained all children will be coming through the ED and the informed consent process will be in the ED setting.
4. The Committee asked about the quality of life (QoL) questionnaires and that the questions are not relevant to the study. The Researcher explained it is a standard paediatric QoL measure that is included in the economic assessment of the study, it is mainly for Australia however is not needed in New Zealand. Further explaining it allows for data comparison between the Australian sites and New Zealand sites.
5. The Researcher explained that the study is already underway in 5 sites in Australia so the protocol is very fixed and will relay to the study teams in Australia that the fixed questionnaire will not be used in New Zealand but will take some time to set up.

Summary of outstanding ethical issues

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

1. Ages on the assent form should be avoided and just be older or younger as some children may not be able to understand the older child assent form even if they are between 12 and 15.
2. Please note that data is kept for 10 years after the youngest participant turns 16, not 18.
3. Please amend the GP being informed as this should be mandatory, not optional.
4. Please remove references to postcodes being collected.
5. Please amend section D8 of the application, typo.
6. Under the study design section please amend the sentence explaining how many hospitals and countries are involved with this study.

Protocol:

1. Please include how the study drugs will be dispensed and tracked to ensure they will not be mixed up with clinical care drugs.
2. One of the study objectives is to test whether a 7 day antibiotic course is effective, as opposed to 10 or 14 days, but the protocol does not explicitly address that research question, please amend.
3. Please add if pregnant minors are included.
4. On page 4 please explain what the IV line not being accessible means.
5. On page 25 there are two statements that are inconsistent. One says that if duration of IV differs from the study requirements, there is a "protocol violation". The other sentence says that that antibiotic timing may be modified if clinically appropriate. Please amend.
6. Please include if the parents can keep the thermometers or not.
7. On page 34: The definition of "protocol violation" seems to include Adverse Events. A Protocol Violation is often thought of as a departure from the approved protocol in a way that suggests non-compliance and could adversely affect participants and/or study integrity. Protocol deviations are departures from the protocol that are not under the control of the study team - for example, a parent failing to give the child the study drug as prescribed. These terms need to be clear as they have recording, analytic, and reporting implications.

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

1. Please make clear that the study is testing whether a 7 day course of antibiotics will be effective.
2. If any data is being collected by the parents, the parents will need a separate participant information sheet and consent form as the parents at that stage are now becoming a part of the research.
3. Please clarify that after 7 days, all decisions about treatment will be the responsibility of the child's treating clinician.
4. The paragraph under "How is study designed" virtually duplicates the language of the last paragraph of the previous section, please amend.
5. Please check for typos and grammatically incorrect sentences throughout.
6. Please add an explanation about why a child may be taken out of the study.
7. On page 4 it asks participants/parents to "record any extra costs" incurred during hospital admission (such as parking and food) "to find out how much a hospital admission costs to families". However, there is no mention of reimbursement for participants, please either include a reimbursement for participants or remove this sentence.
8. Please include what tissue and samples are being sent overseas.
9. Please include that it is not only the parent that needs to agree to the child’s participation, but also the child’s choice (as is stated in the assent form).
10. Please remove duplicate statements.
11. The Committee noted the inclusion of questionnaires that ask after the participant’s mental health. The Committee requested further information around how quickly the scores are seen and what is done to provide support to those whose answers flag concerns for depression or anxiety.
12. The Committee requested the inclusion of a cultural tissue statement to the PIS. The Committee recommended the following statement: *“You may hold beliefs about a sacred and shared value of all or any tissue samples removed. The cultural issues associated with sending your samples overseas and/or storing your tissue should be discussed with your family/ whānau as appropriate. There are a range of views held by Māori around these issues; some iwi disagree with storage of samples citing whakapapa and advise their people to consult before participating in research where this occurs. However, it is acknowledged that individuals have the right to choose.”*
13. Please include the risks into the participant information sheets.

**Decision**

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

1. Please address all outstanding ethical issues, providing the information requested by the Committee.
2. 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).*
3. Please update the study protocol, taking into account the feedback provided by the Committee. (National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.7).

After receipt of the information requested by the Committee, a final decision on the application will be made by Ms Jessie Lenagh-Glue and Ms Joan Pettit.

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| **3**   | **Ethics ref:**   | **2024 FULL 19823** |
|   | Title:  | Uplifting the mana of Pacific young people in Ōtepoti |
|   | Principal Investigator:  | Ms Rupi Riley |
|   | Sponsor:  |  |
|   | Clock Start Date:  | 14 March 2024 |

Ms Rupi Riley was present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of outstanding ethical issues

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

1. HDEC are concerned about the use of schools as other students will know the participants have been taken out of class and parents may feel obliged to encourage children to be involved if the teachers have recommended them.
2. Section D13 of the application form answer is incorrect. There may be adults (16 and 17 year old) who could be incompetent. Some participants may turn 16 before research completed of who will need to reconsent. Please amend.
3. There should be koha available for participants, and aimed at the children at least provision of snacks during the focus groups etc.
4. Asking for gender may be problematic for non-binary young people, please amend.
5. Please use gender neutral language where possible.
6. The peer review submitted doesn’t meet HDEC requirements of being independent from the study. Please provide an independent peer review. The HDEC peer review template can be used *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.26).*
7. Please explain how the researcher aims to manage peer pressure amongst the students to either participate or not to participate. Will they be excused from class during the interview period or will this be extra-curricular (eg in lunch break or after school) please include the plan.
8. Please use healthy refreshments (not soda for example) for the participants.
9. HDEC recommend sharing the results with wider Pacific communities in Dunedin (e.g. fono), not just peer-reviewed journals.
10. Please amend the interview guides, they need to be adapted for gender-diverse and queer participants; current iterations are very heteronormative (e.g. why would a gay Pacific boy care what girls thought about his body?)
11. Please include if participants will be provided with the whole transcript or just their contributions.
12. Please amend the figure rating scale it could be embarrassing/shameful if a participant’s body type is not represented on the scale. Please include larger body types if possible.
13. The Committee note the selection of these two schools from which to recruit potential participants seems to be convenient for the investigator but will not produce a representative sample. The conclusions the investigator makes will reflect upon the students from these schools only. The Committee recommended to recruit participants from the community, instead. Could use existing local Pacific services (e.g. Pacific Trust Otago) to facilitate and spread word also.
14. The Committee note the investigator has obtained the permission of the school to conduct this study with this student population and on the school grounds, but that fact alone should not suggest to parents or students that they should consider participating. There is a risk that school permission will be equated with approval and could provide an undue influence for these students and their families to consent.
15. Please include how many Māori/Pacifica students are eligible to participate in each sub-group, as having such a small number of participants per age group and school, and having the research occur at the schools, means that it's possible the identity of the participants will be known to others. Please review and amend the sub-groups to avoid participants knowing each other.
16. Please include if the use of direct quotes will be used in publications, if about issues of body image, the quotes could identify the source, which could cause harm/embarrassment.
17. Please explain and include how the report generated will protect the group of student-participants from "group harm".
18. The Committee explained the researchers will have to understand group discussions amongst peers who know one another will not be confidential. While the investigator says only researchers will have access to the study data, all participants in each group will know who said what.
19. The study documents contain several typos and spelling errors, please amend.
20. The Committee noted the inclusion of questionnaires that ask after the participant’s mental health. The Committee requested further information around how quickly the scores are seen and what is done to provide support to those whose answers flag concerns for depression or anxiety, please explain the safety plan.

Assent Form:

1. The Committee noted the inclusion of questionnaires that ask after the participant’s mental health. The Committee requested further information around how quickly the scores are seen and what is done to provide support to those whose answers flag concerns for depression or anxiety.
2. Please include other contact numbers, eg advocacy, cultural support.
3. Please note the focus groups cannot be confidential.
4. The Committee stated more information around data management is required than what is available in the study documentation satisfy the Committee that privacy and confidentiality is protected and that Standard 12.15a is met. Use of the HDEC template from the HDEC website is not mandatory but is encouraged to be adapted or used as a guide/starting point.
5. Please supply an ACC statement.

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

Parents:

1. Currently this parent PIS Indicates parents are attending the focus groups and what the parent says will be used in the study, please amend this.
2. The Committee noted there are missing sections of the participant information sheet in order to obtain fully informed consent. The Committee recommended the Researcher adapt the PIS template available on the HDEC website.

Children:

1. Please explain exactly what type of topics will be discussed and safety plan if child becomes distressed.
2. The Committee noted there are missing sections of the participant information sheet in order to obtain fully informed consent. The Committee recommended the Researcher adapt the PIS template available on the HDEC website.
3. Please explain why the child was selected and that parent/guardian must consent and child give assent, either can withdraw at any time.
4. Please include a full participant information sheet and consent form for young people aged 16 and 17 as they can consent for themselves.
5. The Committee requested the inclusion of a cultural tissue statement to the PIS. The Committee recommended the following statement: *“You may hold beliefs about a sacred and shared value of all or any tissue samples removed. The cultural issues associated with sending your samples overseas and/or storing your tissue should be discussed with your family/ whānau as appropriate. There are a range of views held by Māori around these issues; some iwi disagree with storage of samples citing whakapapa and advise their people to consult before participating in research where this occurs. However, it is acknowledged that individuals have the right to choose.”*

**Decision**

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

1. please address all outstanding ethical issues raised by the Committee
2. please update the Participant Information Sheet and Consent Form, taking into account the feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17).*
3. 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).*
4. please update the data management plan, taking into account the feedback provided by the Committee. (National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15a).
5. Please supply a more detailed data management plan to ensure the safety and integrity of participant data. This can be a standalone document or incorporated as part of the protocol *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15a).*
6. Please supply evidence of ACC-equivalent compensation available to all participants in the event of injury during the study. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 17.1).*
7. 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).

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| **4**  | **Ethics ref:**   | **2024 FULL 19699** |
|   | Title:  | A Phase 3 Multicenter Study to Evaluate Efficacy, Safety, and Pharmacokinetics of Upadacitinib with Open-Label Induction, Randomized, Double-Blind Maintenance and Open-Label Long-Term Extension in Pediatric Subjects with Moderately to Severely Active Crohn's Disease and Inadequate Response, Intolerance, or Medical Contraindications to Corticosteroids, Immunosuppressants, and/or Biologic Therapy |
|   | Principal Investigator:  | Professor Andrew Day |
|   | Sponsor:  | AbbVie |
|   | Clock Start Date:  | 14 March 2024 |

Tao Wong was present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of resolved ethical issues.

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

1. The Committee asked if the study would establish the sexual activity of minor participants in a way that protects their privacy. The Researcher explained that the discussions will occur in transition clinics and participants can choose to have their parents there or not. The Research team will have the minor’s privacy protected as much as possible.
2. The Committee asked about the optional blood sample for biological blood medicine levels and asked for clarification. The Researcher explained that if a participant was already on a biological agent to treat Crohn’s disease instead of waiting for the wash out period of 12 weeks, what can be done instead is be tested for the levels of previous treatment that is left over and if the blood shows low levels or previous treatment the participant can be included in this study, however will be excluded if previous treatment levels are found to be high.

Summary of outstanding ethical issues

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

1. Please amend the submission section and uncheck healthy volunteers at S4.
2. Please note the protocol should explain that minors reaching age of majority while in the study will be reconsented.
3. The Committee suggest gender-matching for Tanner exam with a support person present to protect the child.
4. The Committee advised the Researcher that relevant Māori cultural issues for this research would include blood samples as tapu, information as a taonga and the potential for whakamā in participants. The Committee requested the Researcher become familiar with these concepts and be mindful of this for future applications.
5. Please provide koha for the child participants, they should be given something age appropriate as an acknowledgement of their contribution.

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

Assent Forms:

1. Please change the wording of "feel bad" to "feel sick".
2. Please do not say "no one will be upset with you if you say no", cannot guarantee that.
3. Please change feel good to feel well.
4. Please amend the mature child assent form where it says doctors will look at whole body, please include that the participant will have to take off clothes and whether they can have a support person or not.
5. Please include that travel expenses will be covered.

Main PIS:

1. The main participant information sheet needs to be clear that the parent is consenting for the child, so if either parent or child refuse, neither of them can be involved.
2. On page 3: if you meet study requirements you can be in study, please amend to "your child".
3. Please include how many New Zealand participants are involved.
4. On page 4 if a participant turns 16 while in study, that participant must consent for themselves.
5. On page 5, if protocol is amended written consent will be required, not verbal consent.
6. Please change Local health department to Medical Officer of Health.
7. On page 6 please delete references to federal or state.
8. Will the parents or child not be told the results of testing if they want to know, that bullet needs to be expanded and explained or removed.
9. Please note the child must sign new consent form once 16 years old.
10. On page 7 questionnaires there is no mention of questions about how adults have been affected, please include these.
11. The Committee suggest moving description of "Study Medicine" to the Purpose section following paragraph beginning "Medications, drugs, devices....”
12. Please check for repeated titles and sentences throughout.
13. Please check for grammatical errors and typos throughout.
14. Please include if the children who receive a phone to record the electronic diary be allowed to keep it at the end of the study or not.

Master ICF:

1. Please review the master ICF for typos and grammar errors throughout.
2. On page 6 please change receiving the low maintenance dose and stop responding rather than "lose response".
3. Please either include main inclusion/exclusion criteria or delete the bullet point.
4. On page 7 please remove reference to Medical Officer of Health.
5. On page 8 second bullet please explain in lay language.

**Decision**

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

1. Please address all outstanding ethical issues, providing the information requested by the Committee.
2. 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).*
3. Please update the study protocol, taking into account the feedback provided by the Committee. (National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.7).

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

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| **5**   | **Ethics ref:**   | **2024 FULL 19301** |
|   | Title:  | A whole-food diet and obsessive-compulsive disorder: a pilot study |
|   | Principal Investigator:  | Ms Sophia Dawson |
|   | Sponsor:  |  |
|   | Clock Start Date:  | 14 March 2024 |

Sopha Dawson and Julia Rucklidge was present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of resolved ethical issues.

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

1. The Committee suggested that the costs of purchasing the likely groceries that participants are required to eat is going to be prohibitive for many individuals who would potentially benefit from the intervention. The koha stated is for participation in the study and not to cover expenses participants will incur as being part of the study. The Researcher explained that would require more funds of which they do not have as a PhD student. Further explaining the researchers want to give the participants knowledge on how to prepare and cook healthy foods, providing pre-prepared meals stops that.
2. The Committee asked if the study is a feasibility study and asked for an overall explanation of the study. The Researcher explained the study is a feasibility study with all participants entering the first dietary intervention and some will enter the second intervention, but it is a feasibility study in the sense this study/literature has not been done before.
3. The Committee asked about the cultural advice the Researchers had requested regarding the food and dietary changes with its effects on a cultural perspective. The Researchers explained the advice they received explained the importance of knowing a difference in lens regarding food and that food is approached in different cultural groups, the Researchers are taking this advice into the study to hopefully, better understand the participants and the food they consume.

Summary of outstanding ethical issues

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

1. GP notification should not be optional, nor should the review of relevant medical records by HDEC or regulatory authorities, please amend.
2. Please state that what will happen to blood samples and whether karakia will be available.
3. "As part of the study, you will be required to buy supermarket groceries that align with each dietary intervention. To support you with the cost of this, you will be provided with a $50 New World voucher at the beginning of each dietary intervention (thus, a total of $100) in recognition of your participation". Please include if the money for the food is required to buy groceries or participation.
4. Please state what foods the participant will be required to buy.
5. Please include more information regarding the additional funding; being sourced from third party organizations. Please state what/who and where.
6. Please remove the word rarely and change may to will in the following statement: "Rarely, it may be necessary for the research coordinator 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".
7. Given the nature of the research, the Committee suggest internet costs should be reimbursed.
8. The protocol does not specifically address the risks and benefits of the proposal, please include.
9. The Committee noted the inclusion of questionnaires that ask after the participant’s mental health. The Committee requested further information around how quickly the scores are seen and what is done to provide support to those whose answers flag concerns for depression or anxiety.

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

1. Please lower the reading level of the document. It needs to be simplified, and to add more details about things like randomization and what the glucose monitor looks like, please include photos for reference.
2. Please include how much participating in the study may cost the participant. This will allow the participant to be fully informed of the pricing and can decide whether to be included in the research. Explain that being in this research, that the costs incurred may be over and above the stipend provided by the researcher.
3. Please provide more details about what kinds of foods these two diets include.
4. The Committee note that x2 photos weekly will be insufficient to verify the diet and suggest asking for more photos.
5. Please include that any information up until withdrawal will remain in the research.
6. Participants will be asked not to take any new treatment or make any new lifestyle changes over the course of the study, please give example of what these might be.
7. Please include a diagram of the timeline of the study and the various phases.
8. Please include where the blood sample collection will occur and if the results will be provided to the participants with an explanation about these tests.
9. The paragraph on future use of data says "coded". Please explain what that means and that the data will be provided as a complete set with no identifiers associated with any individual's information.
10. Please include the purpose of the surveys and the time it is expected to undertake them all in the PIS.
11. For the future use section, there is no place in the PIS for the participant to provide specific consent to future use. Please include this.
12. Please remove all Yes/No checkbox unless truly optional.

**Decision**

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

1. Please address all outstanding ethical issues, providing the information requested by the Committee.
2. 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).*
3. Please update the study protocol, taking into account the feedback provided by the Committee. (National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.7).

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

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| **6**   | **Ethics ref:**   | **2024 FULL 19810** |
|   | Title:  | Lunsayil LTE: An extension trial assessing long-term spesolimab treatment in patients with Hidradenitis Suppurativa (HS) |
|   | Principal Investigator:  | Dr Marius Rademaker |
|   | Sponsor:  | Boehringer Ingelheim |
|   | Clock Start Date:  | 14 March 2024 |

Dr Marius Rademaker was present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of resolved ethical issues.

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

1. The Committee note SCOTT approval applied for, no need for peer review to be submitted.

Summary of outstanding ethical issues

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

1. The participant’s GP or usual doctor being informed if incidental finding occurs should not be optional, please amend.
2. The Committee strongly suggest that if participants are doing well under the active drug, the sponsor should ensure they will continue to have access to it on a compassionate basis after the trial is finished.
3. The Committee stated more information around data management is required than what is available in the study documentation satisfy the Committee that privacy and confidentiality is protected and that Standard 12.15a is met. Use of the HDEC template from the HDEC website is not mandatory but is encouraged to be adapted or used as a guide/starting point.
4. Data management plan section 11.1 discussion regarding karakia, but there is no mention of this in the PIS please amend.
5. Data management plan says that a participant’s usual doctor will be notified regarding an incidental finding, but in the PIS, it is optional, please amend.
6. Section C4 of the application answer is not adequate, prevalence in Māori, please amend.
7. Section C7 of the application answer is not adequate, prevalence in Pacific people, please amend.

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

1. The PIS states that this is a randomized controlled trial, however all participants will resume the doses from the previous studies, there's no additional randomization. Please revise the participant information sheet to clarify that there is no new randomization.
2. Please amend the alternatives section it states that the participants may obtain study drugs outside the study. The investigational drug is only available to participants in the study.
3. Please provide koha for study participation.
4. Change wording of: “It is important that your personal doctor is aware that you are in a research project because you may be taking a treatment that could affect your health. With your permission, we will notify him/her that you are taking part in this research project” – notification of GP should be required for people to participate.
5. The Committee noted the inclusion of questionnaires that ask after the participant’s mental health. The Committee requested further information around how quickly the scores are seen and what is done to provide support to those whose answers flag concerns for depression or anxiety.
6. It is not Northern A, it is Central HDEC, please amend.
7. The PIS states 4 months however the protocol states 16 weeks. These could be interpreted differently (calendar months vs 4 weeks). Please clarify and make sure the PIS is reflecting the accurate number.
8. Participants should be reimbursed for any costs associated with trial participation.
9. Please state the countries/locations where samples will be sent (not just BI subsidiaries).
10. The Committee request a more complete explanation of Māori taonga than the minimal one used in the PIS.
11. Please amend the pregnancy statement, the study doctor may only contact the participant and monitor their health with their permission.
12. Please explain what will happen to participants receiving placebo in previous study.
13. On page 10 please explain if this will be a stipend or will they have to retain receipts. The Committee strongly suggest this be a stipend as retaining receipts is quite onerous for participants.
14. On page 14 physical exam, please include if participants will have to remove clothing and if the participant can bring a support person.
15. On page 16 follow up baby with consent.
16. On page 17 please explain if the drug can be in sperm and should males' partners be informed of risk.
17. On page 20 "justifiable efforts" does this mean "reasonable efforts" please clarify and amend if needed.
18. Privacy Commissioner not "local data protection authority" please amend.
19. Please check the participant information sheet for typos and grammar errors.
20. Please use gender-neutral wording throughout PIS, esp. when discussing pregnancy/contraception.
21. Please amend the visit schedule table as it is even more confusing with the icons in place of the procedures. Suggest using words instead of icons and using a landscape orientation (as the columns will be wider).
22. Please remove reference to 'AIDS' as this language is stigmatising.
23. The paragraphs after the HIV/Hepatitis paragraph don’t seem to relate to infectious disease testing but are under that heading for some reason (page 12-13). Coded data is mentioned again on page 19. Suggest using HDEC template wording instead.
24. Please don’t combine study procedures and risks sections. Risks should be its own section. Study procedures should be described before or immediately after visit schedule table.
25. Please use HDEC template for contraception (birth control) section.
26. Karakia is not mentioned in PIS please include.

**Decision**

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

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

After receipt of the information requested by the Committee, a final decision on the application will be made by Mx Albany Lucas and Ms Jessie Lenagh-Glue.

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| **7**   | **Ethics ref:**   | **2024 FULL 19954** |
|   | Title:  | A Multicenter, Randomized Study to Evaluate the Safety and Efficacy of Lutikizumab for Induction and Maintenance Therapy in Subjects with Moderately to Severely Active Ulcerative Colitis |
|   | Principal Investigator:  | Dr James Brooker |
|   | Sponsor:  | AbbVie |
|   | Clock Start Date:  | 14 March 2024 |

No Researcher was present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of resolved ethical issues.

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

Summary of outstanding ethical issues

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

1. “You will sign and date a study specific independent ethics committee (IEC)/institutional review board (IRB) informed consent form.” Please amend this wording as this makes it sound as though HDEC have created the consent form, HDEC have approved it.

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

1. On page 3 "if you decide to take part in the study, your doctor will determine if you meet the study requirements..." please amend to study doctor.
2. Please use gender-neutral wording ("females of childbearing potential" etc) throughout document.
3. Please provide details of the physical exam (is undressing required? Can they bring a support person?).
4. Please clearly explain when a placebo product would be given to a participant; it is clear why a placebo is needed to preserve the blind, but it would be helpful to be more explicit when explaining the three groups who would get a placebo and when.
5. Please remove reference to 'AIDS virus' as this language is stigmatising.
6. Please explain and include if there are no risks passed on in sperm and why are there no contraception responsibilities for those assigned male at birth.
7. Will those who are assigned male at birth need to use contraceptive means as well, please include in the PIS.
8. On page 16 "are planning to take a street drug" would this exclude them from study, please clarify.
9. Keeping receipts for reimbursement is too burdensome, please remove.
10. Please include if a karakia is available at the time of collection of samples.
11. Māori cultural support, not health support.

**Decision**

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

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

After receipt of the information requested by the Committee, a final decision on the application will be made by Mx Albany Lucas and Ms Joan Pettit.

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| **8**  | **Ethics ref:**   | **2024 FULL 19736** |
|   | Title:  | Addressing gaps in the surveillance and response to influenza-like illness: A community pharmacy-based feasibility study |
|   | Principal Investigator:  | Professor Alex Semprini |
|   | Sponsor:  | Te Niwha |
|   | Clock Start Date:  | 14 March 2024 |

Professor Alex Semprini was present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of resolved ethical issues

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

1. The Committee asked about the inclusion criteria and whether being registered with a General Practitioner to be involved. The Researcher explained that because the study is being done looking at the feasibility point of view and how to swap the swab result from ESR back to the GP and continuity of care, the researchers thought it would be best to stick with just the GP registered participants at this stage, the original plan was once the main data was captured to then look at the un-registered participants. The Researcher wanted to include the un-registered participants however, resource wise cannot and instead is capturing the registered participants for base-line data and the study is surveillance not diagnostic.

Summary of outstanding ethical issues

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

1. Please refer the HDEC as Central HDEC.
2. Please review the lay title "surveillance" suggest using other word(s) to describe surveillance.
3. Please remove the generalised sentence: "people with these symptoms often prefer to see their pharmacist for advice because not everyone with these symptoms is able to, or needs, to see a doctor".

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

1. Māori and Pasifika Cultural support, not health, please amend.
2. Please check for grammar errors throughout.
3. Please review te Reo spelling throughout.
4. Please remove the following sentence: "This study follows the same process that GPs use to swab people with the symptoms of an influenza-like-illness as part of the Sentinel General Practice Respiratory Virus Surveillance programme." as this sentence is not relevant to the participant of the study.
5. Please change the photo of screening location to a pharmacy, it is currently looks like a hospital.

**Decision**

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

* Please address all outstanding ethical issues raised by the Committee.
* Please update the Participant Information Sheet and Consent Form, taking into account the feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17).*

## General business

1. The Chair reminded the Committee of the date and time of its next scheduled meeting:

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| --- | --- |
| **Meeting date:** | 23 April 2024. |
| **Zoom details:** | TBD |

1. **Review of Last Minutes**

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

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

The meeting closed at 4:30PM.