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| **Committee:** | Southern Health and Disability Ethics Committee |
| **Meeting date:** | 12 September 2023 |
| **Zoom details:** | https://mohnz.zoom.us/j/9738756003 |

| **Time** | **Review Reference** | **Project Title** | **Coordinating Investigator** | **Lead Reviewers** |
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| 10:30 - 11:00am | 2023 FULL 15571 | Acuity 200™ (fluoroxyfocon A) Orthokeratology Contact Lens Safety and Effectiveness Study | Dr. Jagrut Lallu | Catherine / Barry |
| 11:00-11:30am | 2023 FULL 13080 | CIRCA NZ: Investigation and Research of Patients with Immune Dysfunction | Dr Ignatius Chau | Dominic / Devonie |
| 11:30am - 12:00pm | 2023 FULL 18681 | Disabled People’s Experiences of Abortion Services | Associate Professor Brigit Mirfin-Veitch | Dianne / Nicola |
| 12:00 - 12:20pm | BREAK (20 mins) |  |  |  |
| 12:20 - 12:50pm | 2023 FULL 18565 | M14-658 : Efficacy, Safety, and Pharmacokinetics of Upadacitinib in Paediatric Participants with Moderately to Severely Active Ulcerative Colitis. | Prof. Andrew Day | Dominic / Devonie |
| 12:50 - 1:20pm | 2023 FULL 15478 | Evacuate - Surgical RCT | Dr. Martin Punter | Catherine / Nicola |
| 1:20 - 1:50pm | 2023 FULL 11224 | Digital Twin Dementia Study | Dr Soroush Safaei | Dianne / Barry |
| 1:50 - 2:20pm | BREAK (30 mins) |  |  |  |
| 2:20 - 2:50pm | 2023 FULL 18408 | CO44657: pionERA Breast Cancer | Dr Richard Isaacs | Catherine / Devonie |
| 2:50 - 3:20pm | 2023 FULL 18550 | Phase 3 Study Investigating Sonrotoclax Plus Zanubrutinib Compared With Venetoclax Plus Obinutuzumab in Patients With Newly Diagnosed Chronic Lymphocytic Leukaemia | Doctor Robert Weinkove | Dominic / Barry |
| 3:20 - 3:50pm | 2023 FULL 18646 | Synbiotic Medical Food for RA | Dr. Penelope Jane Montgomery | Dianne / Nicola |
| 3:50 - 4:20pm | 2023 FULL 18467 | Study to investigate efficacy & safety of Secukinumab in patients with giant cell arteritis (GCA) | Doctor Nigel Gilchrist | Dominic / Devonie |

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| **Member Name**   | **Member Category**   | **Appointed**   | **Term Expires**   | **Apologies?**   |
| Dr Devonie Waaka  | Non-lay (Intervention studies)  | 18/07/2016  | 18/07/2019  | Present  |
| Mr Dominic Fitchett  | Lay (the Law)  | 05/07/2019  | 05/07/2022  | Present  |
| Ms Amy Henry | Non-lay (Observational studies) | 13/08/2021 | 13/08/2024 | Apologies |
| Ascc. Prof Nicola Swain | Non-lay (Intervention/Observational studies) | 22/12/2021 | 22/12/2024 | Present |
| Ms Dianne Glenn | Lay (Consumer/Community perspectives) | 08/07/2022 | 08/07/2025 | Present |
| Ms Neta Tomokino | Lay (Consumer/Community perspectives) | 08/07/2022 | 08/07/2025 | Apologies |
| Dr Maree Kirk | Lay (Consumer/Community perspectives) | 03/07/2023 | 02/07/2026 | Present |
| Mr Barry Taylor | Non-lay (Intervention/Observational studies) | 13/08/2021 | 16/08/2024 | Present |
| Dr Carla Strubbia | Non-lay (Intervention studies) | 03/07/2023 | 02/07/2026 | Apologies |
| Ms Catherine Garvey | Lay (the Law) | 19/03/2019 | 19/03/2022 | Present |

## Welcome

The Chair opened the meeting at 10:00 am with a karakia and welcomed Committee members, noting that apologies had been received from Ms Amy Henry, Ms Neta Tomokino and Dr Carla Strubbia.

The Chair noted that it would be necessary to co-opt members of other HDECs in accordance with the Standard Operating Procedures. Mrs Catherine Garvey and Mr Barry Taylor confirmed their eligibility and were co-opted by the Chair as members of the Committee for the duration of the meeting.

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 08 August 2023 were confirmed.

## New applications

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| **1**   | **Ethics ref:**   | **2023 FULL 15571** |
|   | Title:  | Clinical Evaluation of Safety and Effectiveness for Acuity 200™ (fluoroxyfocon A) Orthokeratology Contact Lens for Overnight Wear |
|   | Principal Investigator:  | Dr Jagrut Lallu |
|   | Sponsor:  | Acuity Polymers, Inc. |
|   | Clock Start Date:  | 31 August 2023 |

Dr Jagrut Lallu 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 Researcher confirmed participants would be recruited from people referred to the clinic. The Researcher confirmed the research site was separate from the clinic with a dedicated research team. The Researcher confirmed a study coordinator would do the consenting process separate from the participant’s usual clinical team. The Researcher confirmed a doctor would be available to answer any questions a potential participant may have during the consenting process.
2. The Committee noted the application stated parental consent would be required for participants up to 18 years old and advised this is not applicable in New Zealand. The Committee explained the age of consent in New Zealand was 16 and parental consent would not be required for participants 16 and above. The Committee advised there may also be participants under 16 with sufficient capacity to consent for themselves.
3. The Committee noted the application included detail on how adverse events would be reported but not managed by the site as they arise. The Researcher explained the adverse event would be logged reported and treated. The Researcher stated it would be treated in clinic if appropriate or a referral made if necessary.

Summary of outstanding ethical issues

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

1. The Committee noted the submitted documents were for an American study population and would need to be adapted for a New Zealand context to meet the requirements in the [National Ethical Standards for Health and Disability Research.](https://neac.health.govt.nz/national-ethical-standards/)
2. The Committee noted the application did not indicate a therapeutic benefit to participants and queried whether a paediatric study was appropriate in the absence of potential therapeutic benefit. The Researcher explained orthokeratology lenses have established safety and efficacy in paediatric patients, and the study lens is a superior material to what is currently available under FDA approval. The Researcher stated this trial was being conducted to support FDA approval for the alternative lens material. The Committee requested the Researcher supply information confirming the safety profile of the lens in paediatric participants. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 6.19)*
3. The Committee advised any advertisements used, including social media advertising, would require HDEC approval.
4. The Committee requested the advertisement be amended to state that the study lens is experimental.
5. The Committee noted the answer to D8 in the form was incorrect as it is possible some participants will not give informed consent (i.e. children).
6. The Committee advised that in order to enrol child participants the study would need to provide age-appropriate information on the trial to obtain their assent to participate. The Committee recommended having two assent forms for child participants, one for older children which is more verbal and one for younger children that is simpler and includes pictures. The Committee recommended adapting the [assent templates available on the HDEC website.](https://ethics.health.govt.nz/guides-templates-and-forms/participant-information-sheet-templates/) *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 6.22).*
7. The Committee requested the Researcher supply a PIS for the parent / guardian of a child participant to give consent on their behalf for their participation.
8. The Committee noted E9.2 (“Does your intervention study involve trialling an investigational or approved item?”) was incorrectly answered no and follow-up questions were not generated in the form. The Committee requested this answer be changed to ‘yes’ and the follow-up questions answered in the resubmission.
9. The Committee noted the trial is commercially sponsored and evidence of ACC-equivalent insurance would be required. The Committee requested that a Sponsor Certificate of Insurance be submitted for review. *(HDEC Standard Operating Procedure Para 39.4.7).*
10. The Committee requested the Researcher supply evidence of professional indemnity for the Coordinating Investigator. *(HDEC Standard Operating Procedure Para 39.4.7).*
11. The Committee noted the answer to C5 in the form discussed Pasifika participants and requested an answer pertinent to issues that may arise for Māori.
12. The Committee advised Māori consultation would be required and requested information on this be included on the resubmission. The Committee advised this was so mana whenua could review the study and ensure proper tikanga was in place and any cultural issues in the application are identified and addressed. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 3.7).*
13. The Committee noted the response to C11 in the form was a duplicate to C6 and requested this answer is revised on the resubmission to address Pacific consultation.
14. The Committee requested New Zealand ethnicity data be collected at New Zealand sites for the final report to HDEC.
15. The Committee noted participant numbers on page 4 of the PIS differ from what is stated in the application form and requested this is reconciled in the resubmission.
16. The Committee noted authorisation from the Sponsor and study locality would be required in the resubmission. *(HDEC Standard Operating Procedure Para 176).*
17. The Committee recommended the Researcher adapt the [HDEC data management plan template](https://ethics.health.govt.nz/assets/Uploads/HDEC/templates/HDEC-data-only-management-template-Nov2022.docx) to comply with [Chapter 12 of the National Ethical Standards](https://neac.health.govt.nz/national-ethical-standards/part-two/12-health-data/).
18. The Committee recommended the Researcher adapt the [HDEC participant information sheet template](https://ethics.health.govt.nz/guides-templates-and-forms/participant-information-sheet-templates/).

The Committee requested the following changes to the Participant Information Sheet and Consent Form (PIS/CF) *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17)*:

1. Please refer to study participants as participants and not subjects.
2. Please include the section on compensation for injury in a commercial trial available from the HDEC template.
3. Please include information on how study data will be deidentified and stored.
4. Please include information on the sub-study and whether this is optional.
5. Please delete duplicated information throughout the sheet.
6. Please ensure terminology is suitable for a New Zealand context (e.g. remove references to federal or state law).
7. Please remove the information on a legally authorised representative as this is not applicable in New Zealand.
8. Please clarify whether the participant will be identifiable in the video/photo referenced on page 7.
9. Please include information on reimbursements for travel and parking expenses on page 9 as participants should not incur costs for their participation.
10. Please include frequencies in the risk section (e.g. more than 1 in 10 people) for 'common', 'uncommon' and 'rare' risks.
11. The Committee requested the resubmission include a cover letter responding to each point in the decline letter.

**Decision**

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

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| **2**   | **Ethics ref:**   | **2023 FULL 13080** |
|   | Title:  | CIRCA NZ: Investigation and Research of Patients with Immune Dysfunction |
|   | Principal Investigator:  | Dr Ignatius Chau |
|   | Sponsor:  |  |
|   | Clock Start Date:  | 31 August 2023 |

Dr Ignatius Chau and Dr Karen Enthoven were present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of resolved ethical issues

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

1. The Committee stated it would provisionally approve the application for consenting adults only, as no parent / guardian information sheet or assent forms for children were included with the application. The Committee advised the inclusion of minors unable to provide independent informed consent can be submitted via the amendment pathway once the study has been granted approval.
2. The Committee noted the protocol states parental consent would be required for participants up to 18 years old and advised this is not applicable in New Zealand. The Committee explained the age of consent in New Zealand was 16 and parental consent would not be required for participants 16 and above. The Committee advised there may also be participants under 16 with sufficient capacity to consent for themselves.
3. The Committee queried the legal agreement referenced at the end of the application. The Researcher stated it was a material and data transfer agreement. The Committee advised that this was a site-level issue that did not require HDEC oversight and would defer to the Coordinating Investigator to manage this.

Summary of outstanding ethical issues

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

1. The Committee requested the Researcher supply an independent peer review from New Zealand. The Committee strongly recommends using the [HDEC peer review template.](https://ethics.health.govt.nz/assets/Uploads/HDEC/hdec-peer-review-template-june-2021.docx)
2. The Committee queried the conflict of interest between research and clinical roles and how this would be managed. The Committee noted patients arriving for their clinical visit with no knowledge of the study and being asked to sign up on the same day may create undue pressure to participate. The Committee requested information about the study be sent to potential participants in advance of their clinical visit and the recruitment process is undertaken at least in part by a study coordinator instead of the participant’s clinical provider.
3. The Committee noted the response to question C11 in the application form discussed Māori consultation only. The Committee requested this answer be completed to discuss any Pacific consultation.
4. The Committee requested New Zealand ethnicity data be collected at a site level for final reporting to HDEC.
5. The Committee noted the application stated withdrawal of consent must be written and advised withdrawal in New Zealand may be verbal. The Committee requested any references to withdrawing consent are updated to reflect this.
6. The Committee requested that initials or full date of birth are not included on tissue samples. The Committee advised that a participant ID number and partial birth date are acceptable. The Committee requested the data and tissue management plan be updated to reflect this.
7. The Committee noted that Researchers outside the local team should not have access to identifiable data other than on-site review for monitoring or audit purposes. The Committee advised re-identification could be undertaken by the local site if required. The Committee requested that page 7 of the protocol and several sections of the data management plan be updated accordingly.
8. The Committee requested the Researcher update the protocol so participants in New Zealand are informed of any clinically actionable results as a mandatory component of study participation. The Committee advised that participants opting-out of receiving significant but not clinically actionable results is permissible. The Committee requested information explaining the difference be included in the information sheet.
9. The Committee requested the New Zealand based Coordinating Investigator authorise the study in the EthicsRM system.

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

1. Please correct the typographical error in the first sentence (page 1).
2. Please delete the final sentence of 'what is the purpose of the study' (page 2).
3. Please delete references to genetic variants and testing from the document.
4. Please state clearly that there may be no benefits to study participation (page 3).
5. Please state that withdrawal of consent can be provided verbally (page 4).
6. Please address return of clinically actionable versus non-actionable results in the information sheet and consent form, as noted above.
7. Please include a Māori data and tissue statement (an example may be found on the HDEC template)
8. Please more clearly describe data management, including who has access to identifiable and de-identified data; potential future uses of data; data retention time; and risk of privacy breach.
9. Please remove ‘yes / no’ tick boxes unless agreement is an optional component of study participation (i.e. the participant can answer ‘no’ and still participate).
10. Please include a statement advising participants that samples will not be returned and a karakia will not be available at the time of discussion.

**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).
4. Please obtain a New Zealand based independent scientific peer review of the study protocol. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.29).*
5. 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).*
6. Please supply tracked-changes versions of revised documents when responding to the provisional approval.

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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| **3**   | **Ethics ref:**   | **2023 FULL 18681** |
|   | Title:  | Abortion is a Human Right and Health Issue: Disabled People’s Experiences of Abortion Services in Aotearoa New Zealand |
|   | Principal Investigator:  | Associate Professor Brigit Mirfin-Veitch |
|   | Sponsor:  |  |
|   | Clock Start Date:  | 31 August 2023 |

Associate Professor Brigit Mirfin-Veitch, Dr Robbie Francis Watene, Ms Umi Asaka and Ms Lydie Schmidt were present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of resolved ethical issues

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

1. The Committee commended the Researchers on their respectful approach to their community of interest and a thoughtful application.
2. The Researcher confirmed koha would be offered to participants who engage in the interview phase and a payment would be made to advisory committee members. The Researcher confirmed no payment would be offered for identifying potential participants to the study.
3. The Committee queried whether 20 interviews would be representative of the wider group of disabled people in New Zealand. The Researcher stated the approach was an in-depth qualitative approach and was not intended to be a representative or generalisable but to gain an in-depth understanding of a particular sample. The Researcher stated they would be careful and purposeful around sampling to get a diverse and intersectional range of views but the study would not be presented as representative of all disabled people, only those taking part in the study.
4. The Committee queried whether a snowballing approach may limit the diversity of participants. The Researcher stated information collected from the survey would allow the study team to be specific on who they sample for and most participants will come through that process. The Researcher stated the snowballing approach can be amended and will be looking for participants who may not always have their voice heard in research. The Researcher stated snowballing can be effective to identify people who have accessed a service when it is a sensitive subject and the protocol contains maximum variation sampling to ensure there is an intersectional lens applied.

Summary of outstanding ethical issues

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

1. The Committee requested removal of “Unless the participant is under the age of 16” from section 6.1 of the data management plan as this would not be applicable.
2. The Committee requested the Researcher obtain locality authorisation from the Donald Beasley Institute in the EthicsRM system.
3. The Committee noted the response to E1 in the application form indicated a key risk of participation is the potential for emotional distress and recommended incorporating a follow-up appointment/call to support participants who would benefit from this.
4. The Committee noted a discrepancy between the consent forms with one stating to tick a consent box and the other to circle. The Committee requested this be amended for consistency.

**Decision**

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

* please update the Participant Information Sheet and Consent Form, taking into account the feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17).*
* please obtain locality authorisation on the EthicsRM system (*HDEC Standard Operating Procedure, para 176*)
* please update the data management plan *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15a).*

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| **4**   | **Ethics ref:**   | **2023 FULL 18565** |
|   | 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 Paediatric Subjects with Moderately to Severely Active Ulcerative Colitis and Inadequate Response, Intolerance, or Medical Contraindications to Corticosteroids, Immunosuppressants, and/or Biologic Therapy. |
|   | Principal Investigator:  | Prof. Andrew Day |
|   | Sponsor:  | AbbVie Ltd |
|   | Clock Start Date:  | 31 August 2023 |

Katherine Denton 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 Researcher confirmed that part of the recruitment process would be undertaken by someone who is not the participant’s usual clinical provider.
2. The Committee noted age is not a sole determinant of capacity to provide informed consent. At the age of 16 there is the presumption of capacity and anyone under 16 should be assessed for their capacity to provide informed consent. If they have capacity to provide informed consent, they should do so. Otherwise assent and parental consent should be obtained. The Researcher confirmed this was their standard process.
3. The Researcher confirmed the X-rays were standard practice for any child starting a biological agent similar to that used in the study. The Researcher confirmed the study would involve one extra X-ray and the Coordinating Investigator did not consider it to be high risk.
4. The Committee noted the PIS states karakia may be available whereas the response to Question F7 in the application form states it will not be available at the time of tissue destruction. The researcher explained that karakia may be available at the time of tissue donation but not destruction.

Summary of outstanding ethical issues

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

1. The Committee requested an independent scientific peer review of the submitted protocol and recommended using the [HDEC peer review template.](https://ethics.health.govt.nz/assets/Uploads/HDEC/hdec-peer-review-template-june-2021.docx)
2. The Committee requested New Zealand ethnicity data be collected at a site level for final reporting to HDEC.
3. The Committee noted that G6 of the application form states no further information will be collected should a participant withdraw from the study, while the data management plan states that certain health information may continue to be collected post study withdrawal. Please clarify what is intended and amend study documentation accordingly.

**Data Management Plan**

1. The Committee requested the Researcher ensure section 4 of the Data Management Plan aligns with the approach to informed consent.
2. The Committee requested section 6.1 be amended to state participants will be informed of any privacy breach, not just a notifiable breach.
3. The Committee requested the reference to tissue in section 8.4 be removed as it is not applicable in this study.
4. The Committee requested an amendment to section 9.1 to state data will be retained for at least 10 years after the youngest participant turns 16.
5. The Committee requested removal of the final sentence in section 13 as the study will not involve future unspecified research on tissue.

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

Main PIS / parent guardian:

1. Please include a lay title.
2. Please update the first paragraph to align with the discussion on informed consent above.
3. Please simplify the PIS to remove repetition.
4. Please simplify the information presented in “What is the purpose of the study” to be lay-friendly.
5. Please reword the ‘Who can take part in this study’ to address participants providing initial consent as it currently states the participant is already participating and has turned 16.
6. Please explain what HCV (page 8) and Tanner stage (page 11 and 15) are.
7. Please remove the reference to “AIDS Virus”.
8. Please add the paragraph on home visits in the parent/guardian PIS to the main PIS.
9. Please remove the paragraph on SCOTT approval on page 35.
10. Please include contact details for Māori cultural support.
11. Please remove the ‘yes / no’ option for informing the participants GP as this should be mandatory. Please include a paragraph in the body of the PIS explaining this.
12. Please reword the paragraph on informing the child’s GP in the parent guardian PIS to remove “with your permission”.
13. Please remove the box referencing a legally authorised representative on page 38 as this is not applicable in New Zealand.
14. Please correct the text in 'study information' (p3).
15. Please explain 'mandatory' the first time it is used (p3).
16. Please delete information about notifiable diseases from the general blood test statement, information is provided on p19. Note that active TB is also a notifiable disease, and that only new cases of HBV / HCV are reportable.
17. Please delete forms of TB testing not relevant to NZ sites - this may be done at a site level if some sites are still using PPD testing.
18. Please delete information regarding optional PK samples on page 8 if the optional PK PISCF is retained.
19. Please delete repeated explanations about assessments under 'Study procedures' (p8), remove / simplify unnecessary detail, and simplify table of assessments (e.g. 'systolic and diastolic', 'Japan only', 'subjects', 'your child', 'adverse events'....).
20. Please clarify that the data discussed in para 1 under 'how will my personal data be protected' pertains to identifiable information.
21. Please delete the risks of named blood tests (p20).
22. Please re-write the information in the first paragraph of page 21 as staff cannot take anthropological or vital sign measurements remotely.
23. Please replace 'subjects' with 'participants' throughout.
24. Please simplify the reproductive risks section which currently contains significant unnecessary detail. Use lay language to describe contraceptive options with common New Zealand examples.
25. Please delete repeated information about new information (p27/p30).
26. Please amend 'may' to 'will' for study doctor sharing lay summary of study results (p35).
27. Please add an optional tick box for receiving lay summary of study results from study doctor (p38).
28. Please amend the sentence on page 34 that states a participant may be removed from the trial at any time for any reason as halting a trial for commercial reasons is not permissible in New Zealand

Optional PK / Parent PK PIS:

1. Please include applicable points above from the main sheets (e.g. include a lay title, remove the legally authorised representative box).
2. Please remove the ‘yes / no’ option for blood samples on the consent form for the optional PK study as these are mandatory to participate.
3. The Committee noted that the optional PK sub-study involves 4 additional blood samples at Week 2 and could readily be dealt with as an optional paragraph and tick-box in the main PISCF.

Assent forms:

1. The Committee noted many explanations in the mature assent form could be used in the main PIS.
2. Please state that the GP will be told about study participation, that some people outside the study will have access to information to check the study is being done correctly, and that only coded information will be sent away from the research centre.
3. Please simplify the study title on the mature child assent form and include age-appropriate lay titles on each sheet.
4. Please amend the definition of ethics committees on page 2 as not all members are scientists.
5. Please include contact details for Māori cultural support.
6. Please simplify the header tables.
7. Please increase the font size in the consent form to match the information sheet.

**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 obtain an independent scientific peer review of the protocol. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 9.29).*
4. Please update the data management plan. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15a).*
5. Please supply tracked-changes versions of revised documents when responding to the provisional approval.

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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| **5**   | **Ethics ref:**   | **2023 FULL 15478** |
|   | Title:  | Ultra-Early, minimally inVAsive intraCerebral haemorrhage evacUATion versus standard trEatment (EVACUATE) |
|   | Principal Investigator:  | Dr Martin Punter |
|   | Sponsor:  | The University of Melbourne |
|   | Clock Start Date:  | 31 August 2023 |

Dr Martin Punter, Dr Sana Oladi and Dr Timothy Kleinig were present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of resolved ethical issues

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

1. The Committee noted some participants would be enrolled under Right 7(4) of the Code of Health and Disability Consumers’ Rights. The Researcher confirmed they would always attempt to contact whānau to determine the best interests of a potential participant prior to their enrolment and a second opinion would be sought from a clinician who is not involved with the study.
2. The Researcher confirmed proxy consent on behalf of the participant would not be sought and participants who could not provide informed consent would be enrolled under Right 7(4) of the code.
3. The Committee queried why participants could not request results of follow-up assessments as this information could be reidentified. The Researcher stated they would be able to provide these on request.
4. The Committee queried whether participants would be reimbursed for their expenses attending the additional face-to-face study visit. The Researcher stated they would cover any parking or travel costs.

Summary of outstanding ethical issues

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

1. The Committee queried the scenario of a participant death and noted it would be better to disclose the enrolment with the participant’s whānau for reasons of transparency, so they do not learn of the study through other means. The Committee requested the Consent Scenarios document be amended accordingly.
2. The Committee queried why the first five participants would not be randomised, and asked if this was 5 participants per site or across the study. The Researcher confirmed it was per site as a way to upskill site staff so they are well experienced in the surgical technique before randomisation, and this would allow a fair comparison between the technique and standard of care. The Researcher confirmed data from the first five participants would not be included in the comparative analysis. The Committee requested information explaining this be included in the participant information sheet.
3. The Committee noted follow-up would be done from the international lead site and this has privacy and data security issues. The Researcher stated this was an error in the form and confirmed Wellington Hospital would be the lead site that would manage follow-up in New Zealand. The Researcher stated the rationale was to reduce variation in follow-up. The Committee queried the process if the lead site identified an issue that required clinical follow-up at another site. The Researcher stated they would liaise with the local treating team. The Committee requested this process be formally documented in the data management plan.
4. The Committee noted a discrepancy in the documentation where the data management plan and information sheet state data from a participant who withdraws from the study will continue to be used, whereas the consent scenario states this would occur only with consent for ongoing use. The Researcher stated their intention was to continue to use any data that had been collected up to that point to reduce bias. The Committee queried the process for if a participant requested their data be withdrawn, as they did not initially consent to its use if they were enrolled under Right 7(4). The Researcher stated if a participant requested their data withdrawn they would do so. The Committee requested the data management plan and information sheets are updated to address this.
5. The Committee requested that references to blood samples in the data management plan are removed, as the study does not involve collection or analysis of blood samples.

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

Short PIS:

1. The Committee suggested the information sheet could be simplified by splitting the information into bullet points and reducing the length.
2. The Committee requested information advising approximately how many people have had this procedure be inserted into the sheet.
3. The Committee requested a statement disclosing it is unknown at this time whether the surgical technique under study is better or worse than standard medical care.
4. The Committee noted it was unclear whether the follow-up component of the study was for all participants or only those randomised to the surgery. The Committee requested this be clarified to state all participants will have follow-up.
5. The Committee noted the use of information section was lengthy and could be simplified. The Committee suggested summarising who could see identifiable information and advising how information will be coded.
6. The Committee noted that a number of the consent clauses reference information not provided in the body of the PIS. Please review and delete.
7. The Committee requested a statement advising that if the participant is one of the first five participants they will receive the surgical technique, and that their doctor will advise them if this is the case.

Long PIS and Interested Persons Information Sheet:

1. The Committee requested information advising approximately how many people have had this procedure be inserted into the sheet.
2. The Committee requested information explaining why each site will perform five procedures before moving onto the randomisation phase.

Long PIS only:

1. The Committee requested any ‘yes / no’ tick boxes are removed from the consent form unless they are truly optional (i.e. the participant can answer ‘NO’ and still participate).
2. The Committee requested options on the consent form for participants to participants to consent to remaining in the study, decline participation but allow the use of already collected data and to decline participation and withdraw any collected data.

**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).*
* please update the data management plan *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15a).*

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| **6**   | **Ethics ref:**   | **2023 FULL 11224** |
|   | Title:  | Advanced MRI for Characterisation of Hemodynamic Changes in Brain Associated with Early Stages of Dementia |
|   | Principal Investigator:  | Dr Soroush Safaei |
|   | Sponsor:  | The University of Auckland |
|   | Clock Start Date:  | 31 August 2023 |

Dr Soroush Safaei 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 queried whether normative MRI data was available and if the Researcher could use this instead of collecting from the control group. The Researcher stated this data was available but the study protocol has been designed to cover every aspect of brain function as available datasets have parts missing so the preference would be for a comprehensive control. The Committee accepted this justification.
2. The Committee queried whether the Researcher would undertake Pacific consultation as the response in the form was the same response for Māori consultation. The Researcher stated this was being undertaken through consultation with Iwi United.
3. The Committee noted inconsistency in the application which indicated participants will not give informed consent in S5 which conflicts with the inclusion criteria in D1 which states participants must be able to give informed or supported consent. The Researcher confirmed that the response in D1 is correct.
4. The Committee noted that the Researcher should have included the maximum amount of $100 reimbursement in the application form.
5. The Committee noted the response to the cultural questions in the application form would have benefitted from including discussion of Māori data sovereignty and requested the Researcher be mindful of this for future applications.

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 expressed concern at the submitted advertising which states “help prevent dementia” and “we will help keep afflicted people stronger and with their whānau longer” as these claims may be overstating the benefit of participation. The Committee requested the advertising is revised and recommended stating “Participate in research that aims to..”.
2. The Committee noted the peer review had identified issues with the protocol and recommended a major revision. The Committee queried whether the protocol was revised and if a response had been submitted to the peer reviewer. The Researcher stated the revisions had been made but the protocol had not been sent back. The Committee requested the Researcher obtain confirmation from the peer reviewer that their concerns have been addressed as scientific review is not within HDEC’s scope.
3. The Committee noted the eligibility criteria for the healthy control group in the protocol does not include suitable parameters for healthy volunteers (e.g. there is no exclusion of participants with a history of cognitive dysfunction or significant cardiovascular disease). The Researcher stated the design is to include people who are prone to develop dementia rather than completely healthy people. The Committee requested the Researcher define inclusion and exclusion criteria for the control group more clearly in the protocol to properly explain who can participate.

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

1. Please undertake a revision to make the language more lay-friendly by simplifying or explaining any technical terms.
2. Please include a statement advising that orthodontics/dental work is safe for an MRI.
3. Please include more detail about the option to receive abnormal findings that are not clinically significant.
4. Please include examples of how abnormal findings may affect a participant’s profession/employment.
5. Please revise the statement “Your name will only appear on the consent form” to “Your name will appear only on the consent form”.
6. Please revise the future research clause on the consent form to be opt-in rather than opt-out.
7. Please revise the risks section to separate the information on MRI risks, ACC cover, privacy breaches and whakamā.
8. Please include information on available counselling in the information sheet.
9. Please revise the spacing on the consent form for greater readability.

**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*).
4. Please supply tracked-changes versions of revised documents when responding to the provisional approval.

After receipt of the information requested by the Committee, a final decision on the application will be made by Ms Dianne Glenn and Mr Barry Taylor.

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| **7** | **Ethics ref:**   | **2023 FULL 18408** |
|   | Title:  | A Phase III, Randomized, Open-Label Study Evaluating Efficacy and Safety of Giredestrant Compared with Fulvestrant, Both Combined with a CDK4/6 Inhibitor, in Patients with Estrogen Receptor-Positive, HER2-Negative Advanced Breast Cancer with Resistance to Prior Adjuvant Endocrine Therapy |
|   | Principal Investigator:  | Dr Richard Isaacs |
|   | Sponsor:  | Roche Products (New Zealand) Ltd.  |
|   | Clock Start Date:  | 31 August 2023 |

Ms Susan Newlands and Dr Navin Wewala were present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of resolved ethical issues

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

1. The Committee commended the Researcher on the high-quality application.

Summary of outstanding ethical issues

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

1. The Committee requested New Zealand ethnicity data is collected at a site level for final reporting to HDEC.
2. The Committee queried the process if the leftover sample for optional research was the last of the available tumour sample for future clinical testing. The Researcher agreed to alert participants if that was the case and offer participants a choice on whether to donate the rest of their sample to the RBR.

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

Main PIS:

1. The Committee noted the biomarker statement in the information sheet is too broad to be mandatory as written. On page 23 it states mandatory genetic analyses will be used to look at breast cancer and also other diseases, possible links among diseases, genome variations and how they might affect a disease or a person’s response to treatment and new avenues to drug development and personalised therapies. The Committee requested this be revised to state clearly that mandatory genetic analysis will be restricted to analysis directly related to the disease area and drugs under study.
2. Please correct the typographical error on page 26 that refers to “Hepatitis X”. The Committee advised that only new cases of HCV and Hepatitis B are notifiable.
3. The Committee queried the statement on page 26 that Roche would be able to link de-identified study data with 'other data collected from you', when the Sponsor should only have access to participant data collected for the purpose of the study. The Researcher agreed to revise the wording.
4. Please add 'coded' to the sentence regarding the use and sharing of personal information, and clarify that this is restricted to information required for or generated by the study.
5. Please clarify the data sharing statement on page 27 to clarify that the Sponsor will share coded data.
6. Please move the statement on page 28 advising that samples may be analysed in any country in the world to the sample storage section, as it is currently under the data risks section.

Optional RBR PIS:

1. Please address the points above regarding use of data in this sheet also.

Optional Biopsy PIS:

1. Please increase the font size of the table or remove the information from a table and outline them in text.

**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).*

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| **8** | **Ethics ref:**   | **2023 FULL 18550** |
|   | Title:  | A Phase 3, Open-Label, Randomized Study of Sonrotoclax (BGB-11417) Plus Zanubrutinib (BGB-3111) Compared With Venetoclax Plus Obinutuzumab in Patients With Previously Untreated Chronic Lymphocytic Leukemia |
|   | Principal Investigator:  | Dr Robert Weinkove |
|   | Sponsor:  | Beigene |
|   | Clock Start Date:  | 31 August 2023 |

Dr Robert Weinkove, Helen Gower, Maureen Blakemore, Andrea Chu and Dr Xia (Summer) Zhao were present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of resolved ethical issues

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

1. The Committee queried how potential participants would be approached with information regarding the study. The Researcher confirmed their clinical provider would offer information about the study and then refer them to a study coordinator if they are interested so a potential participant would have the option to say no to someone who is not their clinical provider. The Researcher stated local feedback indicated participants prefer the consenting process to be completed by their clinician they have an established relationship with. The Committee stated this approach was acceptable as anyone who did not wish to participate would have the option of declining with the study coordinator.
2. The Committee noted the application form stated that the study would involve an internal Data Safety Monitoring Committee and queried whether this was appropriate in a Phase 3 multi-national trial. The Researcher clarified that this was likely an oversight from the previous trial and confirmed the study would involve an independent Data Safety Monitoring Committee.

Summary of outstanding ethical issues

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

1. The Committee requested the Researcher ensure the trial is registered in a WHO-approved clinical trial registry before commencement.
2. The Committee requested New Zealand ethnicity data is collected at a site level for final reporting to HDEC.
3. The Committee noted the response to F8 in the application form states participants can request tissue is destroyed, whereas the data tissue management plan indicates tissue will continue to be used. The Committee requested this is addressed for consistency and ensure the information sheet aligns with the data and tissue management plan.

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

1. Please include a simple lay title above the formal protocol title on all information sheets.
2. Please state that Zanubrutinib is not approved for use in any indication in New Zealand.
3. Please explain what biomarkers are in lay language on page 4.
4. Please remove bone marrow aspirate and biopsy bullet points from the screening procedures section, as they are to be undertaken post treatment or if complete response / progression (p4). Auckland City Hospital text should also be removed from the top of p5. Alternatively, make it clear that the described tests relate to tests performed at any time during the study, not only at screening.
5. Please undertake a general revision for lay-friendly language to replace or define any technical or medical terms and acronyms.
6. Please delete formal questionnaire names from the schedule of assessments table and instead describe in lay language, for example “a number of questionnaires that look at quality of life and pain”.
7. Please remove “also known as the AIDS virus” on page 22.
8. Please state what Hepatitis viruses will be tested for.
9. Please remove the paragraph regarding inspection of medical records on page 26 as this repeats information on page 25.
10. Please remove the information under study results on page 27 that repeats information provided under ‘identifiable information’.
11. Please advise that karakia will not be available on destruction of tissue samples on page 22.
12. Please move the heading “Common Side Effects Reported in at Least 1 Out of 20 (5% or more) Patients While Taking Sonrotoclax Alone” on page 15 above the table.
13. The Committee noted the bulk of the Auckland site cultural tissue statement on page 26 repeats information on page 22 under ‘What will happen to my test samples’ and recommended revising this to remove repetition.

**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).*
* Please ensure the trial is registered in a WHO-approved registry prior to commencement. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 11.2).*

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| **9**   | **Ethics ref:**   | **2023 FULL 18646** |
|   | Title:  | A randomised, double blind placebo-controlled trial evaluating the medical food synbiotic SBD121, versus placebo for the clinical dietary management of early Rheumatoid Arthritis |
|   | Principal Investigator:  | Dr. Penelope Jane Montgomery |
|   | Sponsor:  | Solarea Bio |
|   | Clock Start Date:  | 31 August 2023 |

Dr Penny Montgomery, Eric Schott, and Kshemina Mhaksar were present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of resolved ethical issues

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

1. The Committee queried the term ‘medical food’. The Researcher clarified this was a requirement from the FDA as the investigational product is regulated as a medical food which is a distinct category between dietary supplements and pharmaceutical drugs.
2. The Researcher confirmed ACC-equivalent insurance would be available. The Researcher confirmed the five listed ACC entitlements (rehabilitation, first week compensation, weekly compensation, lump sum compensation for permanent impairment, and funeral/survivor grants and weekly compensation for spouse/partner/children/dependents) would be available.
3. The Committee noted the requirement to discuss any rescue medication such as ibuprofen with a study doctor. The Researcher confirmed participants would have access to 24-hour care and this would be discussed during the consenting process.

Summary of outstanding ethical issues

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

1. The Committee noted the video on the landing page discusses Australian sites only. The Researcher stated they were unsure if this video would be used in New Zealand and would discuss with the Sponsor.
2. The Committee requested New Zealand ethnicity data is collected at a site level for final reporting to HDEC.
3. The Committee queried how participants who are methotrexate-naïve would be managed. The Researcher confirmed they would not commence any participants on methotrexate as this is not within scope of the research team. The Researcher confirmed any participants would require methotrexate prescribed by a specialist prior to enrolling in the study. The Committee requested the Researcher ensure the study advertisement makes this clear.
4. The Committee requested the Sponsor authorise the study in the EthicsRM system.

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

1. Please undertake a general revision for lay-friendly language to replace or define any technical or medical terms and acronyms.
2. Please state whether an interpreter is available at the beginning of the PIS.
3. Please change the reference to ‘each test arm’ on page 2 to state ‘each test group’ for consistency.
4. Please include more information on taking methotrexate in combination with the food.
5. Please revise the eligibility criteria to be less technical (e.g. ‘blood pressure within normal range’).
6. Please remove repetition of “(experimental medical food or placebo)” after each reference to the capsules as this only needs to be stated once.
7. Please revise the statement on page 15 that that the study tests 'will not produce the type of results that will have any useful meaning that would affect your health or treatment', as many of the study assessments may produce clinically relevant findings.
8. Please revise the contraception section to use lay-friendly language.
9. Please clarify that reimbursements are per visit and the $650 is not a lump sum upfront.

**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 obtain Sponsor authorisation in the EthicsRM system
4. Please supply tracked-changes versions of revised documents when responding to the provisional approval.

After receipt of the information requested by the Committee, a final decision on the application will be made by Ms Dianne Glenn and Associate Professor Nicola Swain.

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| **10**   | **Ethics ref:**   | **2023 FULL 18467** |
|   | Title:  | A randomized, parallel-group, double-blind, placebo controlled, multicenter Phase III trial to investigate the efficacy and safety of secukinumab 300 mg and 150 mg administered subcutaneously versus placebo, in combination with a glucocorticoid taper regimen, inpatients with giant cell arteritis (GCA) (GCAptAIN) |
|   | Principal Investigator:  | Dr Nigel Gilchrist |
|   | Sponsor:  | Novartis Pharmaceuticals Australia Pty Limited |
|   | Clock Start Date:  | 31 August 2023 |

Dr Nigel Gilchrist and Deidre Thompson were present via videoconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of resolved ethical issues

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

1. The Committee queried the process for identifying and consenting participants. The Researcher stated eligible participants would be referred to the study by the ophthalmology department or would be identified through an existing research database. The Researcher confirmed the consenting process would be undertaken by the Coordinating Investigator who is not their usual clinical provider.
2. The Committee requested the ethical rationale for a placebo design in a study of this nature with a patient population. The Researcher stated participants would be on prednisone which is standard of care.
3. The Committee queried the response to F8 in the application form which indicated participants can withdraw tissue from the study and continue to participate. The Researcher confirmed this was an error in the form.

Summary of outstanding ethical issues

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

1. The Committee noted the data management plan was incomplete with highlighted sections missing. The Committee requested this is completed.
2. The Committee queried the arrangements for the independent Data Safety Monitoring Committee. The Researcher stated they would clarify with the Sponsor.

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

Main PIS:

1. Please revise the page numbering as it currently resets.
2. Please undertake a general revision for lay-friendly language to replace or define any technical or medical terms. Please replace ‘efficacy’ from the short title and throughout the document.
3. Please delete “who are similar to you” from the description of who can take part on page 3.
4. Please revise the description of dosing groups and options as it is difficult to follow. The Committee suggested a simplified flow diagram would ease understanding. Please remove acronyms and remove repetition.
5. Please amend the phrase ‘placebo …. to sekinumab’ as it reads as if a participant will switch from placebo to the active drug.
6. Please simplify the study assessment table.
7. Please remove references to spoon measurements for blood samples.
8. Please revise the statement on quality-of-life questionnaires to state they will be reviewed by study staff on completion.
9. Please explain what oesophageal candidiasis is in lay language.
10. Please remove repeated information on allergic reactions.
11. Please remove information on safety concerns in animal studies and only include information on humans.
12. Please remove imaging risks information from the main sheet as these are covered in the optional MRI sheet.
13. Please revise the contraception information to use lay language and use New Zealand examples.
14. Please remove the final section on contraception about not agreeing with certain methods.
15. Please clarify in the optional consent section that no additional tests will be done on samples.
16. Please specify the city tissue samples will be sent to as well as the country.

Optional MRI PIS:

1. Please undertake a general revision for lay-friendly language to replace or define any technical or medical terms.
2. Please include more detail under ‘what will my participation involve’. Please explain what an MRI/MRA is, how long the procedure itself is expected to take, and provide an approximate total visit length. For each site please state where the imaging will happen.
3. Please separate the risks section under a risks subheading.
4. Please simplify the contrast risks and rewrite in lay language.
5. Please state whether there are any individual benefits to sub-study participation .
6. Please revise the bullet points under the identifiable information section as some do not apply to the sub-study.
7. Please remove consent clauses that do not apply to the sub-study.

Optional Genetic PIS:

1. Please undertake a general revision for lay-friendly language to replace or define any technical or medical terms.
2. Please state whether individual results will be available or not. If they will not please state the tests are exploratory and will not have an impact on the participant’s health.
3. Please include information regarding withdrawal of consent for ongoing use of tissue as per the main PIS.
4. Please include the city and country samples will be sent to.

**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 complete the data management plan *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15a).*
4. Please confirm the arrangements for data safety monitoring *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 11.25).*
5. Please supply tracked-changes versions of revised documents when responding to the provisional approval.

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.

## General business

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

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| **Meeting date:** | 10 October 2023 |
| **Zoom details:** | To be determined |

 The following members tendered apologies for this meeting.

* Mr Dominic Fitchett
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 4:00pm with a karakia.