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| **Committee:** | Extra Sub-Committee Health and Disability Ethics Committee |
| **Meeting date:** | 08 December 2022 |
| **Zoom details:** | 965 0758 9841 |

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| **Time** | **Review Reference** | **Project Title** | **Coordinating Investigator** | **Lead Reviewers** |
| 11.30am-12.00pm | 2022 FULL 13240 | Improved delivery of topical corticosteroid sprays | Prof Richard Douglas | Dr Cordelia Thomas and Ms Amy Henry |
| 12.00-12.30pm | 2022 FULL 13832 | CLOSE IT (Closed Loop Open SourcE In Type 1 diabetes) trial | Dr Martin de Bock | Dr Leonie Walker and Mr Barry Taylor |
| 12.30-1.00pm | 2022 FULL 13881 | Protocol CNTO1959UCO3004; A Phase 3 Study to Evaluate the Efficacy and Safety of Guselkumab Subcutaneous Induction Therapy in Participants with Moderately to Severely Active Ulcerative Colitis (ASTRO) | Dr Melissa Haines | Dr Cordelia Thomas and Dr Amber Parry-Strong |
| 1.00-1.30pm | 2022 FULL 12900 | HDEC:XL092-303 'STELLAR 303' | Dr Anne O'Donnell | Dr Cordelia Thomas and Mr Barry Taylor |
|  |  | *Break* |  |  |
| 2.00-2.30pm | 2022 FULL 13898 | STRIDE 8 - Safety and Immunogenicity of V116 in Adults With Increased Risk for Pneumococcal Disease | Dr Jackie Kamerbeek | Ms Jessie Lenagh-Glue and Dr Amber Parry-Strong |
| 2.30-3.00pm | 2022 FULL 13875 | 3595-CL-101: A Study Evaluating Daily Oral Doses of TLC-3595 in Participants with Insulin Resistance | Professor Russell Scott | Dr Leonie walker and Ms Amy Henry |
| 3.00-3.30pm | 2022 FULL 13049 | ARCT-032-01: A Study to Evaluate Single Ascending Doses of ARCT-032 in Healthy Participants | Principal Investigator Mark Marshall | Ms Jessie Lenagh-Glue and Mr Barry Taylor |

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| **Member Name**   | **Member Category**   | **Appointed**   | **Term Expires**   | **Apologies?**   |
| Dr Cordelia Thomas  | Lay (the Law) (Acting Chair) | 20/05/2017  | 20/05/2020  | Present  |
| Mr Barry Taylor | Non-Lay (Intervention/Observational Studies) | 13/08/2021 | 16/08/2024 | Present |
| Dr Amber Parry-Strong | Non-Lay (Health/Disability service provision) | 08/07/2022 | 08/07/2025 | Present |
| Ms Amy Henry | Non-lay (Observational studies) | 13/08/2021 | 13/08/2024 | Present |
| Ms Jessie Lenagh-Glue | Lay (Ethical/Moral reasoning) | 22/12/2021 | 22/12/2024 | Present |
| Dr Leonie Walker | Lay (Ethical/Moral reasoning) | 13/08/2021 | 13/08/2024 | Present |

## Welcome

The Secretariat noted that this was a special meeting organised to assist with the extra volume of applications received. Dr Cordelia Thomas was selected to be acting chair for the meeting. All applications approved will be transferred to Northern A for post-approval monitoring.

The Chair opened the meeting at 11.00am and welcomed Committee members co-opted across the HDECs.

The Chair noted that the meeting was quorate.

The Committee noted and agreed the agenda for the meeting.

## New applications

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| **1**   | **Ethics ref:**   | **2022 FULL 13240** |
|   | Title:  | Improved delivery of topical corticosteroid sprays |
|   | Principal Investigator:  | Professor Richard Douglas |
|   | Sponsor:  |  |
|   | Clock Start Date:  | 25 November 2022 |

Professor Richard Douglas and Dr Kristi Biswas 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 asked about the steroid spray and if there is any commercial interest. The Researcher explained that they have investigated it and have concluded there is no commercial interest as there is a better version out there and that is where all the commercial interest is. The Researchers confirmed that the study design cannot be patented and lacks commercial interest.
2. The Committee asked about the koha and why there are different monetary payments. The Researcher explained that the different koha was for different arms across the study and the 20 dollar was for the fuel voucher. The Researcher explained that they will standardise the payments to the same amount throughout by using a petrol voucher.
3. The Committee asked about the study protocol and the randomizing of part 2 and how it will be conducted. The Researcher explained that they had a randomized part 2 through a computer programme.
4. The Committee asked if any images will be taken of the participants. The Researcher confirmed that they will be taking photos of the participants’ sinuses during the study and will include this in the participant information sheet and will confirm that the images will not be identifiable.
5. The Committee asked if any genetic testing will be conducted. The Researcher confirmed that there will be no genetic testing taking place.

Summary of outstanding ethical issues

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

1. The Committee requested that on section C5 of the application form, please amend the cultural issues important to Māori by including information such as taonga and the head being tapu and include a cultural statement in the participant information sheet. An example of this can be found on the [HDEC template](https://ethics.health.govt.nz/guides-templates-and-forms/participant-information-sheet-templates/).
2. The Committee requested an amendment to the data management plan by noting that de-identified is not the same as anonymised. Participants have the right to request to have any information about them corrected. The Committee noted that the data management plan also needs a plan for data breach, withdrawal of data and tissue, and recommended use of the [HDEC template](https://ethics.health.govt.nz/guides-templates-and-forms/data-and-tissue-management-plan-templates/) as a guideline.

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

1. Please amend the participant information sheet by using the same font throughout and using lay language where possible.
2. If images of participants are to be taken, please let participants know.
3. Data must be stored for 10 years. Please remove the tick box.
4. Please note that the shopping vouchers as koha are taxable, participants must be informed of this.
5. Please remove the option to inform the GP as this is mandatory for participation.
6. Please add page numbers.
7. Please correct "Health and District" Ethics Committee.
8. Please put the acronym for ORL in full first time it is mentioned.
9. Please change "should be excluded" to "will be excluded"
10. It was noted that "Participation will not affect care in any way" is incorrect, there will be additional calls. Please amend.
11. Please include the 6 month follow up that is in the protocol into the participant information sheet.

**Decision**

This application was *approved with non-standard conditions* 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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| **2**   | **Ethics ref:**   | **2022 FULL 13832** |
|   | Title:  | Randomised open label clinical trial examining the safety and efficacy of the Android Artificial Pancreas System (AAPS) with advanced bolus-free features in adults with type 1 diabetes |
|   | Principal Investigator:  | Dr Martin de Bock |
|   | Sponsor:  | University of Otago |
|   | Clock Start Date:  | 25 November 2022 |

Dr Martin De Bock and Dr Tom Wilkinson 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 asked about access to the cell phones for participants. The Researcher explained that they can supply the cell phones to participants if that is required.
2. The Committee asked about the insulin and the switching of insulin and if there are any concerns. The Researcher explained that they do this regularly and there are no concerns, and that patients have no issues with the switching of insulin.

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 was assured of the CI’s indemnity coverage, but requested this is uploaded for filing as this was missing from the submission.
2. The Committee noted that it is essential that those with limited data or Wi-Fi access are not discriminated against through exclusion of the study.

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

1. Please remove the measurement reference of tablespoons replace with mLs.
2. Please include Māori cultural statement regarding the use of data and use of blood tissue, state if karakia will be available on the disposal. An example of this is available on the [HDEC template](https://ethics.health.govt.nz/guides-templates-and-forms/participant-information-sheet-templates/). Questions of whakamā, information as taonga and participation and consultation with whānau should be addressed.
3. Please use lay language where applicable throughout.
4. Please check for general grammar and typos.

**Decision**

This application was *approved with non-standard conditions* 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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| **3**   | **Ethics ref:**   | **2022 FULL 13881** |
|   | Title:  | A Phase 3, Randomized, Double-blind, Placebo-controlled, Parallel-group, Multicenter Study to Evaluate the Efficacy and Safety of Guselkumab Subcutaneous Induction Therapy in Participants with Moderately to Severely Active Ulcerative Colitis |
|   | Principal Investigator:  | Dr Melissa Haines |
|   | Sponsor:  | Janssen-Cilag New Zealand Ltd |
|   | Clock Start Date:  | 25 November 2022 |

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.

Jessie Glue declared a conflict of interest as one of the PI’s is a friend and gastroenterologist.

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 a safety plan for suicidality rating scale. The submission shows that the co-ordinating investigator will be evaluating, and appropriate action taken, so please elaborate on what that action will be and if the results will be read in real time. Please also explain if there is a mental health professional on site or included in the study and ensure potential participants are made aware of this.
2. In Section 7.5 of the Data and Tissue Management Plan, please clarify what is part of the main study and what is future research.
3. The Committee noted that C4 of application not answered properly and does not currently identify how common ulcerative colitis is in Māori which is what that question seeks to explore. The Committee further stated that there are cultural issues due to whakamā, which is not mentioned.
4. The Committee requested clarity in the answer on section E8 of the application form, noting discontinuation cannot be for commercial reasons.
5. The Committee noted that the current insurance expires March 2023 and requested this be extended with proof submitted to the HDEC once it has been renewed.
6. The Committee requested that proof of indemnity for the coordinating investigator is required to be uploaded.
7. The Committee requested amendment of the term “washroom” from questionnaires as this is not commonly used in New Zealand and may be confusing to participants.
8. On page 3 of the participant information sheet, it was unclear the rationale for receiving the placebo at some visits. Please provide this.
9. The Committee noted that if advertisements are anticipated on being used, please ensure they are uploaded.

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

1. Please include a Māori cultural statement. The [HDEC template](https://ethics.health.govt.nz/guides-templates-and-forms/participant-information-sheet-templates/) provides an example of one that can be used.
2. There are incomplete sections of the PIS with template statements, please ensure the final version is submitted.
3. Please provide a lay title.
4. On page 1, the box about confidential information to not discuss with anyone is contradictory with the advice to discuss research with whānau etc. Please clarify this for participants.
5. Please include information about the number of questionnaires and nature of these, as well as approximately how long these will take. Please also include that the questionnaires ask sensitive questions around bowel habits.
6. On page 2, please amend “must" sign consent to "will be asked to".
7. On page 5, please note that HDEC only approves ethical aspects of the study.
8. Please remove gendered language throughout (i.e. ‘if you can get pregnant’ instead of ‘if you are woman who can…’)
9. The Committee noted that vaginal contraception rings are not available methods of contraception in New Zealand anymore and should be removed.
10. On page 16, please complete the conflict-of-interest section.
11. On page 16, please remove prompts from participant information sheet, and complete highlighted sections.
12. On page 19, the Committee noted that participants in New Zealand have the right to access, review and correct their information at any time.
13. On page 20, please amend to make it clear that participants do not have to withdraw in writing.
14. On page 20, participants should be able to withdraw permission to share health information verbally or by electronic means and not just by writing to a postal address.
15. On page 24, please remove the box for participants unable to consent for themselves. As per the submission, all participants will be able to consent. Further, a representative cannot consent in New Zealand. This is also in the future research PIS section, please amend both to reflect the New Zealand context.

**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 Dr Amber Parry Strong and Dr Cordelia Thomas.

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| **4**   | **Ethics ref:**   | **2022 FULL 12900** |
|   | Title:  | A Randomized Open-Label Phase 3 Study of XL092 + Atezolizumab vs Regorafenib in Subjects with Metastatic Colorectal Cancer |
|   | Principal Investigator:  | Dr Anne O’Donnell |
|   | Sponsor:  | Exelixis Inc. |
|   | Clock Start Date:  | 25 November 2022 |

Dr Anne O’Donnell and Dr Rachel Cahir were present via videoconference for discussion of this application.

Potential conflicts of interest

Mr Barry Taylor declared a potential conflict of interest and the Committee decided it would not impact his ability to review this application and the member was still able to participate in the discussion.

Summary of outstanding ethical issues

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

1. The Committee noted that recruitment should not be done by the patient’s oncologist to avoid undue influence of patients wanting to please their doctor. After discussion, it was acceptable for participants to be identified in the clinical setting, but a research nurse, co-ordinator or not their direct clinician should be the one directly consenting them.
2. It was noted that consultation with Māori has not yet been undertaken. The Committee reminded the Researchers that because the study is an international clinical trial which was designed outside of New Zealand, this does not mean that early consultation should not be undertaken, and a more informed consultation should be taken before submitting an ethics application and not just before commencing study as part of locality authorisation. No data was provided of prevalence in Māori and Pacific Islanders in the application. If Māori are over-represented, then it is essential that the trial process is more than a cut and paste in ethics submission.
3. The Committee queried how soon the Researchers would know emotional or mental distress has been indicated in the questionnaires. After discussion, the Committee was assured there were appropriate measures in place but requested that this is indicated in the participant information sheet as a general statement that the research team will discuss any distress with the participant and help them get support.

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

1. The wording is currently very long and technical and should be simplified lay-language.
2. The Committee noted that the schematic in the protocol is very clear and suggested this could be included in the PIS.
3. Headings should be white on blue background for readability.
4. The Committee suggested an appendix outlining all the side effects as a separate and comprehensive piece of information, with the PIS referring potential participants to the appendix. The addition of a line in the CF that they have read this would be appropriate.
5. On page 18, it is indicated that if someone withdraws, information will still be gathered from their GP. The Committee noted that this should be done with their consent, so if that consent is also withdrawn, it cannot be accessed anymore.
6. It is not clear who “usual doctor” refers to, whether that is their oncologist, GP, etc. Please clarify this.

**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 Dr Cordelia Thomas and Mr Barry Taylor.

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| **5**   | **Ethics ref:**   | **2022 FULL 13898** |
|   | Title:  | A Phase 3, Randomized, Double-blind, Active Comparator-controlled Clinical Study to Evaluate the Safety, Tolerability, andImmunogenicity of V116 in Pneumococcal Vaccine-naïve Adults 18 to 64 years of Age With Increased Risk for Pneumococcal Disease |
|   | Principal Investigator:  | Dr Jackie Kamerbeek |
|   | Sponsor:  | Merck Sharp & Dohme (New Zealand) Limited (MSD) |
|   | Clock Start Date:  | 25 November 2022 |

Dr Richard Stubbs, Deanna Watson and Agathe Fudym 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 outstanding ethical issues

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

1. The Committee suggested using more lay-friendly language in the advertisement and participant information to define streptococcus pneumoniae. The Committee also requested that serotype is defined, and drug or alcohol abuse should be defined with an intake variable. The Researcher commented that the drug or alcohol abuse is often determined at the discretion of the Researcher and is pre-screened for via a questionnaire.
2. The Committee noted that while reimbursement is not taxable, payments for visits and phone calls are taxable. If possible, please deduct withholding tax and file on behalf of participants, otherwise please indicate to them that this is taxable and they are responsible for this. Please also clarify whether the $200 is inclusive of travel expenses.
3. The Committee noted that the insurance expires mid-2023 and to ensure this is renewed and the Committee notified via a post-approval form in a timely manner.
4. The Committee requested that it is included in the protocol to prompt any participants who withdraw to check if they wish to also remain in future biomedical research (FBR).
5. In section 8.5 of the Data and Tissue Management Plan, please clarify what is related to the FBR and what is part of the main study

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

1. Please include a lay-title.
2. The Committee recommended the statement of “It takes lots of people… to advance medical science…” on page 1 is removed as it can be coercive.
3. On page 5, under “what will happen to my samples”, please explain the difference between local testing and overseas testing as it is currently slightly contradictory.
4. Please include a statement reassuring participants that it is expected that the terms of conditions is read, but data will not be shared with a third-party.
5. The Committee noted the information under the genetic testing header that outlines the storage of samples is not related to this header and should be under the one above it.
6. “Most new vaccines need testing…” Given that all new vaccines require testing, please amend.
7. Please ensure risk of anaphylaxis is stated in explicit terms.
8. Please make it clear that there is no guarantee this trial can offer them protection as a result of participation.
9. On page 15, there is reference to family doctor, usual doctor, and later GP. Please be consistent with terminology.
10. Please check for typos, i.e. “common site effects”, “pain in extremity”
11. Please include a statement after the side-effects to reassure participants of the follow-up provided if these do occur.
12. The Committee noted that vaginal contraception rings are not available methods of contraception in New Zealand anymore and should be removed.
13. Please explain to participants who had received a placebo that they would not be protected against pneumonia, and to participants who had received the vaccine that there was no guarantee that they were immunised – so if they were concerned, they should talk to their GP about receiving the existing vaccine

**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 Ms Jessie Lenagh-Glue and Dr Amber Parry-Strong.

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| **6**   | **Ethics ref:**   | **2022 FULL 13875** |
|   | Title:  | A Phase 2a Study Evaluating the Safety, Tolerability, and Efficacy of TLC-3595 in Subjects with Insulin Resistance |
|   | Principal Investigator:  | Professor Russell Scott |
|   | Sponsor:  | OrsoBio Inc |
|   | Clock Start Date:  | 25 November 2022 |

Dr Paul Hamilton, Holly Thirlwall, and Courtney Rowse 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 were assured that no one in the public health system would be impacted for accessing MRIs.
2. The Committee clarified with the Researcher that no advertisement is being used for this study but would submit it as an amendment if so.

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 approach letter comes from the GP.
2. The Committee noted that B5 of the application form and the participant information sheet refers to 3 tablets, but it is 2 in D19. Please correct the documentation for consistency to 2.
3. The Committee noted currently that the taxable amount of $100 for the PK future research currently is inadequate and requested revision of this amount to be at least the equivalent of minimum wage.

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

1. On page 7 of the Main PIS, please clarify that travel reimbursement is in addition to the $100 per visit.
2. On page 14 of the Main PIS, future unspecified research is discussed but is not explained that its subject to a separate consent form and optional.
3. The Committee noted that vaginal contraception rings are not available methods of contraception in New Zealand anymore and should be removed.
4. Please state ‘Hep’ as Hepatitis.

**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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| **7**   | **Ethics ref:**   | **2022 FULL 13049** |
|   | Title:  | A Phase 1 Randomized, Double Blinded, Placebo Controlled, Ascending Dose Study to Assess the Safety, Tolerability, andPharmacokinetics of Single Doses of ARCT-032 in Healthy Adult Subjects |
|   | Principal Investigator:  | Dr Mark Marshall |
|   | Sponsor:  | Arcturus Therapeutics, Inc. |
|   | Clock Start Date:  | 25 November 2022 |

Holly Thirlwall and Courtney Rowse 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 outstanding ethical issues

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

1. Please clarify that travel reimbursement is in addition to the $100 per visit. Page 10 is missing the word “You” at the start of sentence about sperm donation.
2. Medical officer of health will be informed of a positive covid test
3. The Committee noted that vaginal contraception rings are not available methods of contraception in New Zealand anymore and should be removed.
4. Please mention requirement for contraception use with an already-pregnant partner.

**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).*

## General business

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

The meeting closed at 3.00pm