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| **Committee:** | Northern B Health and Disability Ethics Committee |
| **Meeting date:** | 05 September 2023 |
| **Zoom details:** | 965 0758 9841 |

| **Time** | **Review Reference** | **Project Title** | **Coordinating Investigator** | **Lead Reviewers** |
| --- | --- | --- | --- | --- |
| 11.30am-12.00pm | 2023 FULL 18386 | PCR assay for the detection of Group A Streptococcus in throat swabs. | Dr Rebecca Lucas-Roxburgh | Maakere / Barry |
| 12.00-12.30pm | 2023 FULL 18459 | CRSP-CVD-400: A Study to Evaluate the Safety and Tolerability of a Lipid Nanoparticle Formulation Called CTX310 for the Treatment of Dyslipidaemias | Professor Russell Scott | Maakere / Amber |
| 12:30 - 1:00pm | 2023 FULL 16745 | Safety and Tolerability of NeuroDirect Noribogaine in Healthy Individuals | Dr Paul Glue | Kate / Leesa |
| 1:00 - 1:30pm | 2023 FULL 14008 | Single Maintenance And Reliever Therapy in Children's Anti-inflammatory REliever (SMARTCARE) study | Professor Stuart Dalziel | Alice / Barry |
| 1:30 - 2:00pm | 2023 FULL 18323 | Enhancing automated chyme reinfusion therapy with The Insides System | Professor Ian Bissett | Kate / Joan |
|  | *Break (30)* |  |  |  |
| 2:30 - 3:00pm | 2023 FULL 18526 | Exploring rider engagement within therapeutic horse riding | Dr Rachelle Martin | Ewe Leong / Joan |
| 3:00 - 3:30pm | 2023 FULL 18589 | Comparison of two iron polymaltose tablets under fed conditions with diet control | Dr Noelyn Hung | Alice / Amber |
| 3:30 - 4:00pm | 2023 FULL 18108 | A study of warm and humidified carbon dioxide delivery during laparoscopic colorectal surgery | Dr Ryan Salter | Ewe Leong / Leesa |

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| **Member Name**   | **Member Category**   | **Appointed**   | **Term Expires**   | **Apologies?**   |
| Ms Kate O’Connor  | Lay (Ethical/Moral reasoning) (Chair) | 13/08/2021 | 16/08/2024 | Present |
| Mrs Leesa Russell | Non-Lay (Intervention/Observational Studies) | 13/08/2021 | 16/08/2024 | Present  |
| Mr Barry Taylor | Non-Lay (Intervention/Observational Studies) | 13/08/2021 | 16/08/2024 | Apology |
| Ms Alice McCarthy | Lay (the Law) | 22/12/2021 | 22/12/2024 | Present |
| Ms Joan Pettit | Non-Lay (Intervention Studies) | 08/07/2022 | 08/07/2025 | Present |
| Dr Amber Parry-Strong | Non-Lay (Health/Disability service provision) | 08/07/2022 | 08/07/2025 | Present |
| Mr Ewe Leong Lim | Lay (Consumer/Community perspectives) | 08/07/2022 | 08/07/2025 | Present |
| Ms Maakere Marr | Lay (Consumer/Community perspectives) | 08/07/2022 | 08/07/2025 | Present |

## Welcome

The Chair opened the meeting at 11.00am and welcomed Committee members, noting that apologies had been received from Mr Barry Taylor

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 01 August 2023 were confirmed.

## New applications

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| **1**   | **Ethics ref:**   | **2023 FULL 18386** |
|   | Title:  | Validation of an extraction free qPCR assay for the detection of Group A Streptococcus in throat swabs. |
|   | Principal Investigator:  | Dr Rebecca Lucas-Roxburgh |
|   | Sponsor:  |  |
|   | Clock Start Date:  | 24 August 2023 |

Dr Rebecca Lucas-Roxburgh 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 confirmed that adequate consultation has occurred.
2. The Committee confirmed that there are good data and tissue management strategies in place.
3. The Committee confirmed the samples will be destroyed following use for this additional use.
4. The Committee commended the Researcher on the quality of their application and the thoughtful consideration for the waiver of consent laid out in the application and to the Committee. The Committee were satisfied of sufficient justification for a waiver.
5. The Committee confirmed there was no commercial benefit for the researchers.

**Decision**

This application was *approved* by consensus.

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| **2**   | **Ethics ref:**   | **2023 FULL 18459** |
|   | Title:  | A Phase 1 Open-label, Multicenter, First-in-human, Ascending Single-dose Study Evaluating the Safety and Tolerability of a LipidNanoparticle Formulation of CRISPR–Guide RNA–Cas9 Nuclease (CTX310) for In Vivo Editing of the Angiopoietin-like 3 (ANGPTL3)Gene in Subjects With Refractory Dyslipidemias |
|   | Principal Investigator:  | Professor Russell Scott |
|   | Sponsor:  | CRISPR Therapeutics AG |
|   | Clock Start Date:  | 24 August 2023 |

Professor Russell Scott, Dr Jane Kerr, Courtney Rowse, Julia O’Sullivan and Holly Thirlwall 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 confirmed that patients to be enrolled are those who will have exhausted all therapeutic options to prevent further events.
2. The Committee asked the Researcher to comment on potential hereditability of the technology. The Researchers commented that there is no chance to transmit or inherit this trait as there is no entry into the reproductive system.
3. The Committee were assured of appropriate intervals between participant dosing to monitor changes per cohort.
4. The Committee requested, if possible, in future, to be provided the peer review correspondence between GTAC for their own learning and understanding of the 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 queried the exclusion of those with child-bearing potential. The Researcher noted that all previous studies had excluded this population, however after more safety data was obtained, protocol amendments have been submitted to include this population. There is potential for that to occur for this study. It is the preference of the Committee that once it is deemed safe, this population should be included.
2. Further to the point above, the Committee noted requirement for pregnancy test despite excluding those who could get pregnant, and that it may be futile or offensive. Please re-consider its inclusion.
3. The Committee noted the advertisement brochure which includes in bold “looking for potential option to lower your cholesterol?”. There are also repeated references to therapy which is overstated benefit. The Committee wondered if it would even be used here given that recruitment via New Zealand will be known patients who could receive potential benefit, not wider public. After discussion with the Researcher, please either resolve these with the Sponsor, or do not use in New Zealand given the target population.

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

1. Please make it clear that participation is a long-term exclusion from donation of organs etc, and any other restrictions in the light on the extended follow-up. .

**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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| **3**   | **Ethics ref:**   | **2023 FULL 16745** |
|   | Title:  | A Phase 1, Single Centre, Randomised, Double-Blind, Placebo-Controlled, Single Ascending Dose Study to Evaluate the Safety,Tolerability, and Pharmacokinetics of NeuroDirect Noribogaine in Healthy Adult Volunteers |
|   | Principal Investigator:  | Dr Paul Glue |
|   | Sponsor:  | Psycheceutical, Inc |
|   | Clock Start Date:  | 24 August 2023 |

Dr Paul Glue, Chad Harman, and Aric Logsdon 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 Researcher assured the Committee that Noribogaine doesn’t appear to have potential to become abusable.
2. The Committee noted the side effects in previous work by the Principal Investigator of this study had minimal side effects, but others had several. They queried what this study is doing to keep the participants safe. The Researcher responded that they have a lot of data of dosing healthy people up to a certain threshold and it is well tolerated. However, in the patient cohort, a lot of side effects could be attributed to withdrawal symptoms experienced. Overseas, they are also using bigger doses. The Researcher noted there are adequate monitoring in place for any changes in QTc. The Committee were satisfied with this approach for participant safety.
3. The Committee queried what contingency planning has taken place for participants who develop significant side effects (cardiac-related) or experiencing psychological effects that put themselves or others at risk. After discussion, the Committee were assured that the research team were suitable qualified to recognise and manage it as participants will be monitored closely.

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 governance and suggested University of Otago should be onboarded as local Sponsor or at least seek their guidance on requirements.
2. The Committee requested more precise language in the flyer advertisement that this is an investigational product for treating addiction.
3. The Committee noted that quotation for insurance has been provided in place of evidence of insurance (such as an insurance certificate). The Committee cannot approve the study until receive evidence that insurance is in place. Please provide this.
4. The Committee queried if there are any iatrogenic harms from the Columbia Suicide Scale given it details potential suicide methods. The Researcher clarified that the Food and Drug Administration (FDA) demands that any medicine that affect psychological functioning need to have suicidality specifically addressed and this scale is their preferred tool. Part of screening would identify significant anxiety or depression and they would not be included. There’s no evidence use of this scale has caused an increase in suicide. Response to results of this will be appropriate based on the severity of answers. The Committee were satisfied there is no increased risk, however the participant information sheet and protocol should document what the expected response will be to answers of concern.
5. The Committee raised the following about the Data and Tissue Management Plan:
	1. It is currently unclear if the study is doing Future Unspecified Research (FUR). It is not mentioned elsewhere, but the section on FUR in the DTMP template has been left in.
	2. The DTMP indicates there is no data linking, but the participant information sheet on page 20 suggests data linking will occur. Please reconcile which is correct. If there is to be linkage, then participants must be advised of what is being linked to what.
6. Committee queried whether to exclude those with neck tattoos given the photographs taken of the administrative spot on the neck, and a tattoo would be indirectly identifiable as well as not giving the amount of visibility needed.

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

1. Please use University of Otago logo on PIS.
2. On page 2, please state approval status of both oral and topical form of drug and briefly describe its registration status.
3. Remove the word treatment wherever it appears as its not a treatment until its proven. “Investigational product” is more appropriate.
4. Please review the PIS for clarity and technical language. It is currently quite dense.
5. For section 20, please use [HDEC template](https://ethics.health.govt.nz/guides-templates-and-forms/participant-information-sheet-templates/) wording as it is more succinct:

*This study has been approved by an independent group of people called a Health and Disability Ethics Committee (HDEC), who check that studies meet established ethical standards. The [insert Committee name] has approved this study.*

*The scientific aspects of this study have been approved by the Standing Committee on Therapeutic Trials (SCOTT), which is part of Medsafe.*

1. Please clarify what confinement involves, hooked up to a holter monitor, etc.
2. Please clarify if the participant can drive themselves home, or what alternate travel arrangements will be made for them.
3. There is mention of obligation of disclosure of drug use, but this may be a hangover of an international template. Please remove.
4. The PIS suggests a consent for FUR with data, but this is not provided in the consent section. Either make it mandatory or include optional consent item.

**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 evidence of ACC-equivalent compensation available to all participants in the event of injury during the study. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 17.1).*
5. Please update the advertisements, taking into account the feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 11.12).*
6. Please update the data and tissue 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, 14.16&14.17).*

After receipt of the information requested by the Committee, a final decision on the application will be made by Ms Kate O’Connor and Mrs Leesa Russell.

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| **4**   | **Ethics ref:**   | **2023 FULL 14008** |
|   | Title:  | An open-label Randomised Controlled Trial of budesonide-formoterol as single maintenance and reliever therapy vs prescribed maintenance asthma therapy and salbutamol as reliever therapy in moderate to severe childhood asthma |
|   | Principal Investigator:  | Professor Stuart Dalziel |
|   | Sponsor:  | University of Auckland |
|   | Clock Start Date:  | 24 August 2023 |

Professor Stuart Dalziel and Libby Haskell 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 was assured that the use of approach of research nurse will help mitigate any conflict of interest and white coat bias.
2. The application states that it will be accessible to disabled children but doesn't give any details of steps taken to ensure accessibility. The Researcher responded that staff involved are qualified in addressing disability and accessibility needs in standard care, and are able to recognise what needs cannot be met.

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 Principal Investigator has signed off on behalf of the local university sponsor. Please ensure the university’s research office signs the study off.
2. The Māori consultation undertaken noted that there is no reference to how Māori data will be protected in the study documentation. The Committee stated that this doesn't appear to be in the data management plan either. The Researcher responded that there is a Māori investigator whose role is partly having oversight to ensure sovereignty. The Committee recommended documenting that oversight at least in the data management plan.

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

1. Please ensure University logos are on the information sheets.
2. Please revisit the language on the young PIS such as "feel poorly", "your grown-up", and "no one will be angry with you". These are likely able to be written more plainly.
3. The Committee noted that there is no clear potential benefit stated of participation in the older/Parent PIS for those who may not have access to these drug arms outside of the study. It was noted by the Researcher that this is usually covered as part of the verbal discussion, however the Committee requested that this is still highlighted in the PIS.
4. The PIS should also make it clear that the alternative to participation in this study is to say on Standard of Care inhaler with the standard medication.

**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 Alice McCarthy and Dr Amber Parry-Strong.

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| **5**   | **Ethics ref:**   | **2023 FULL 18323**  |
|   | Title:  | Enhancing automated chyme reinfusion therapy with The Insides System |
|   | Principal Investigator:  | Professor Ian Bissett |
|   | Sponsor:  | The Insides Company |
|   | Clock Start Date:  | 24 August 2023 |

Emma Ludlow 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.

Mr Ewe Leong declared a potential conflict of interest and the Committee decided to recuse him from discussion and decision.

**Summary of resolved ethical issues**

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

1. The Committee clarified that the visits with participants to ensure they are getting the guidance they need per the device use would be done per clinical need rather than on a set schedule.
2. The Committee clarified that no potential participants would be using the already available version of this device prior to participation.

**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 conflict of interest of the investigators who are employed by the Company and/or who own shares in the company being linked to all advertisements, conducting all recruitment, obtaining informed consent, and performing data analysis. The study needs a robust Conflict of Interest management plan to preserve the autonomy of the potential participants, remove possible undue influence, and protect the integrity of the study. The Committee noted that there needs to be an alternative, unconflicted, person to conduct the recruitment and to obtain consent.
2. ’The Committee requested clarification on the determination about the relatedness of adverse events to the study procedures. The criteria should be very clear and an unconflicted person should make the determination to ensure objectivity. Please clarify this in the protocol and PISCF.
3. The Committee noted the protocol mentions a Data Safety Monitoring Committee. Please specify who will be on it and what is its charge is, including how data will be monitored, frequency of monitoring etc. This committee should be comprised of non-conflicted clinicians with appropriate expertise. The Committee requested assurance that the relatedness assessments be conducted in a consistent manner to ensure that the risk of the device is accurately assessed.
4. The Committee queried whether the currently described “substudy” should be incorporated into the main study as the new feeding tube is an essential part of the investigational device and there is no plan to consent people for this activity. The potential benefits and risks of the new tube should be clearly outlined in the protocol.
5. The Committee noted that no insurance certificate has been provided. Please provide this for review.
6. The Committee requested that the researcher provide the university’s safety plan for home visits and detail this in the PISCF for participants.
7. The Committee clarified that the visits with participants to ensure they are getting the guidance they need per the device use would be done per clinical need rather than on a set schedule.
8. The Committee noted that there was a lack of comprehensive Data Management Plan (DMP). Please refer to the [HDEC template](https://ethics.health.govt.nz/assets/Uploads/HDEC/templates/HDEC-data-tissue-management-template-Nov2022.docx) for guidance and submit to the Committee for review.

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

1. Please disclose the financial conflicts of interest and how they will be managed.
2. Please include an additional optional section to the PISCF around the sub study. This should include the risks of the sub study, the aims to investigate and compare the feeding tubes and any other information that may be required for the participants to understand what is being asked of them. If this is optional, indicate so with an option to consent or not in the consent form. If this is a mandatory part of participation, then no tick box would be necessary.
3. Please add a company logo to the start of the PISCF.
4. Please make it clear that the device under study is an investigational version of a commercially available device.
5. Please include information about how many people have been given the existing device.
6. Please include information as to how the extension phase will operate in terms of home visits and provision of devices.
7. Please refer to the [HDEC PISCF template](https://ethics.health.govt.nz/assets/Uploads/HDEC/templates/participant-information-sheet-consent-form-template-v5.0april2023.doc) for the section regarding the approval of the study.
8. Please clarify and expand upon the information about the driver and the monitoring device. This should include how are they powered, if they need re-charging, if the driver will send data over the internet, or if is it being stored on the device. This information will also need to be included in the DMP.
9. Please identify the "Insides Badge" per patient questionnaire.
10. Please note that alerting of the general practitioner (GP) to participation should not be optional. Please remove the tick box for 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).*
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 a detailed data management plan to ensure the safety and integrity of participant data. This can be a standalone document or incorporated as part of the protocol *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15).*
5. Please update the advertisements, taking into account the feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 11.12).*
6. Please provide a researcher safety plan addressing the concerns raised by the Committee *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 11.62).*
7. Please supply evidence of ACC-equivalent compensation available to all participants in the event of injury during the study. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 17.1).*

After receipt of the information requested by the Committee, a final decision on the application will be made by Ms Kate O’Connor and Ms Joan Pettit.

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| **6**   | **Ethics ref:**   | **2023 FULL 18526** |
|   | Title:  | Exploring how rider engagement within the therapeutic horse riding landscape can be optimised: a participatory action researchapproach |
|   | Principal Investigator:  | Dr Rachelle Martin |
|   | Sponsor:  | University of Otago |
|   | Clock Start Date:  | 24 August 2023 |

Lena Aewerdieck and Dr Fiona Graham 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 acknowledged that there are parts of the study that are unknown due to the methodology of the collaborative study design.
2. The Committee discussed the intention of the design and the study. While on a technicality, this kind of study can be in scope for the HDEC, after clarity and discussion surrounding the particulars of the study, it was determined that the study would be better suited to sit with the University’s ethics committee over HDEC to best meet the needs of the study and the student.
3. The Committee noted for the Researcher to consider with development of their study to include criteria of engagement to primarily look for, such as amount of time in the saddle, how long the teacher is attentive for, how they are communicating, etc. This is in addition to the recommendations made from previous review. The committee suggested that an Observation Framework be drafted that outlines the kind of factors contributing to ‘engagement’ that could be ‘optimised’.

**Decision**

This application was determined to be Out of Scope by consensus of the Committee and recommended submission to the institutional committee.

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| **7**   | **Ethics ref:**   | **2023 FULL 18589** |
|   | Title:  | A single dose, double-blind, balanced, randomised, two-treatment, two period, two sequence, two-way crossover bioavailability studycomparing 1 x 370 mg Iron Polymaltose tablet (equivalent to 100 mg of elemental iron) with 1 x 370 mg Maltofer® tablet (equivalent to 100 mg of elemental iron) in iron deficient participants under fed conditions with diet control. |
|   | Principal Investigator:  | Dr Noelyn Hung |
|   | Sponsor:  | Nova Chem Australasia Pty Ltd |
|   | Clock Start Date:  | 24 August 2023 |

Dr Noelyn Hung and Linda Folland 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 if there was any clinical reason for why someone who already was on low iron should be on a low iron diet for participation. The Researchers clarified they limited the lower haemoglobin so that the participant wouldn’t be dangerously low. Once they finish the trial, they will be referred to the GP with all test results.
2. The Committee were assured that the food is laid out by a dietician and is prepared and sealed according to food safety standards.
3. The Committee were assured there was no risk to participants if they didn’t adhere to the diet, it would only affect study results.

Summary of outstanding ethical issues

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

1. The Committee noted that the insurance certificate expires end of the month. Please supply an updated one.

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

1. There are many restrictions on participants aside from diet, including having to remain elevated for 4 hours after taking study drug, having someone accompany you to the toilet, forgoing prescription drugs, OTC, and dietary supplements. The consent process needs to be thorough about all the requirements. Please check all of these are mentioned in the PIS.

**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 Alice McCarthy and Dr Amber Parry-Strong.

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| **8**   | **Ethics ref:**   | **2023 FULL 18108** |
|   | Title:  | A pilot safety study of warm and humidified carbon dioxide delivery in patients undergoing laparoscopic colorectal surgery |
|   | Principal Investigator:  | Dr Ryan Salter |
|   | Sponsor:  | Fisher & Paykel Healthcare |
|   | Clock Start Date:  | 24 August 2023 |

Dr Ryan Salter, Rebecca Hu and Chris Colquhoun 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 progress on the engagement with the surgical team and whether they have COI with the company. The Researchers responded that they have been engaging with them from the start and it’s a small team, but there is no financial conflict of interest with the company.
2. The Committee queried why this is not being trialled with other types of laproscopic surgery because of the risk to cancer patients. The Researchers elaborated that this is an efficacy and safety study, the surgery really needs to be long enough to demonstrate there is a thermal benefit to utilizing the device. All equipment being used for the procedures are single use. The main risks are linked to two factors; surgical technique to not disturb the tumours, and damage caused by cold-dry seal tube. With the investigational system, the surgical technique is not being impacted, and the system has a filter and is constantly removing the gas and will remove free-floating cancer cells and won’t go back to patient. For risk-assessment, they are optimistic this device might reduce existing risks. The Committee were satisfied with this.
3. The Committee were assured that if device becomes too warm, it will be turned off.
4. The Researchers noted that all safety monitoring is as per standard of care with no interference or negative impact from the research team, but any adverse events are still logged as per study procedure in case this was caused by the device.

**Decision**

This application was *approved* by consensus.

## General business

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

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| **Meeting date:** | 03 October 2023 |
| **Zoom details:** | To be determined |

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