***Minutes***



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| **Committee:** |  | Central Health and Disability Ethics Committee |
| **Meeting date:** |  | 25 June 2019 |
| **Meeting venue:** |  | Room GC.3, Ground Floor, Ministry of Health, 133 Molesworth Street, Wellington |

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| **Time** | **Item of business** |
| 12:00 | Welcome  Confirmation of minutes of meeting of 26 April 2019 |
| 12:30 | New applications (see over for details) |
| 12:30 – 12:55  12:55 – 1:20  1:20 – 1:45  1:45 – 2:10  2:10 – 2:35  2:35 – 3:00  3:00 – 3:25 | i 19/CEN/93 ii 19/CEN/103 iii 19/CEN/100 iv 19/CEN/101 v 19/CEN/102 vi 19/CEN/196 vii 19/CEN/95 |
| 3:25 | General business |
| 3:30 | Meeting ends |

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| **Member Name** | **Member Category** | **Appointed** | **Term Expires** | **Apologies?** |
| Mrs Helen Walker | Lay (consumer/community perspectives) | 01/07/2015 | 01/07/2018 | Present |
| Mrs Sandy Gill | Lay (consumer/community perspectives) | 30/07/2015 | 30/07/2018 | Present |
| Dr Patries Herst | Non-lay (intervention studies) | 27/10/2015 | 27/10/2018 | Present |
| Dr Dean Quinn | Non-lay (intervention studies) | 27/10/2015 | 27/10/2018 | Apologies |
| Dr Cordelia Thomas | Lay (the law) | 20/05/2017 | 20/05/2020 | Present |
| Dr Peter Gallagher | Non-lay (health/disability service provision) | 30/07/2015 | 30/07/2018 | Present |
| Ms Helen Davidson | Lay (ethical/moral reasoning) | 06/12/2018 | 06/12/2021 | Apologies |

# Welcome

The Chair opened the meeting at 12:00 and welcomed Committee members, noting that apologies had been received from Dr Dean Quinn and Ms Helen Davidson.

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 26 April 2019 were confirmed.

# New applications

**1**  **Ethics ref:**  **19/CEN/93**

Title: ALXN1840 in Patients with Wilson Disease

Principal Investigator: Prof Ed Gane

Sponsor: INC Research New Zealand Limited

Clock Start Date: 06 June 2019

Professor Ed Gane was present by teleconference for discussion of this application.

## Potential conflicts of interest

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

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

## Summary of Study

1. This Phase III clinical trial for patients with Wilson’s Disease (WD) tests the safety and efficacy of the Investigational Product (IP) ALXN1840 compared to Standard of Care (SoC) which includes oral medications Trientine, Penicillamine and Zinc. Approx 180 patients will be enrolled internationally, of which 3 will be enrolled in NZ.
2. The primary objective is to compare copper (Cu) control in patients taking the IP vs SoC by laboratory testing. Safety and tolerability of ALXN1840 will be evaluated through review of AEs, lab testing, neurological testing, physical exam findings, ECG and vital signs. Hepatic status, disability status, neurological status, clinical symptoms and nonceruloplasmin-bound Cu will be evaluated.
3. Patients will be screened for eligibility and if eligible, randomised to a 2 IP:1 SoC ratio. Cohort 1 patients will received IP and Cohort2 patients will receives SoC.
4. IP treatment involves IP in a dose range from 15mg every other day to 60mg once daily. Patients in the SoC arm will continue their SoC regimen or start a new SoC regimen if they are treatment naive The treatment period is for 48 weeks. There are 9 on-treatment visits in which safety and efficacy testing will be performed as per protocol and 4 scheduled phone assessments.
5. Finally, follow-up visit 4 weeks after the last dose for patients who do not elect to continue in the Extension Period. Extension Period will be offered to patients who complete this study and fulfil certain criteria, which involves treatment up to 60-months with IP.

## 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 the study was only open to adults. Professor Gane stated that the present study is part of a wider international study which is open to adults and ages 12 to 18 years. However, the New Zealand-based research unit did not at this stage plan to recruit anyone below the age of 18. Professor Gane confirmed that if any potential participants under 18 were identified, the appropriate amendments would be made and submitted to HDEC for review.
2. The Committee queried that if a participants’ partner became pregnant during the study, would the researchers gather data from the baby postnatally, as separate consent is needed for this. Professor Gane confirmed that in the event of a participant’s partner becoming pregnant, the appropriate amendments would be made to the Participant Information Sheet (PIS) and submitted to HDEC for review.
3. The Committee queried that if a participant became pregnant during the study, would the researchers gather data on the baby once they are born, as separate consent is needed for this. Professor Gane confirmed that in the event of a participant becoming pregnant, the appropriate amendments would be made to the Participant Information Sheet and submitted to HDEC for review.
4. The Committee queried the purpose of video recording of participants. Professor Gane stated that the videos are used exclusively for diagnostic purposes by the research team and would not be used in conference presentations or publications, nor would the sponsor be granted access to these videos.
5. The Committee queried the data retention statement in the PIS, in which samples and data are stated to be retained for no longer than ten years. Professor Gane confirmed this was in error, and just only refer to samples rather than samples and data.
6. The Committee queried the expiry date on the insurance certificate, which stated that the insurance was due to expire before the end of the study. Professor Gane confirmed that a renewed certificate will be provided and submitted to HDEC.
7. The Committee queried whether the research is of potential benefit to Māori. Professor Gane stated that there are currently no known cases of this hereditary disease in Māori, however that does not rule out the possibility of it occurring
8. Pregnant partner PIS: information going overseas to be added to PIS

The Committee requested the following changes to the Participant Information Sheet and Consent Form:

1. Please reword the paragraph under the heading “Extension Period” on page three of the PIS to remove technical language and include more lay-language.
2. Please correct page 18, in which the disease is incorrectly named as liver cancer, rather than Wilson’s Disease.
3. Please remove the statement on page 19 regarding specialist Māori advocates, as they are not available through HDC.
4. Pregnant partner consent sheet needs to be amended to state that pregnant partner’s data will be going overseas.

## Decision

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

* Rewording to paragraph under the heading “Extension Period” on page three of the PIS to remove technical language and include more lay-language.
* Correction to page 18, in which the disease is incorrectly named as liver cancer, rather than Wilson’s Disease.
* Removal of statement on page 19 regarding specialist Māori advocates, as they are not available through HDC.  Pregnant partner consent sheet needs to be amended to state that pregnant partner’s data will be going overseas.

**2**  **Ethics ref:**  **19/CEN/103**

Title: 3% Kanuka Oil Serum for the Topical Treatment of Acne

Principal Investigator: Dr Alex Semprini

Sponsor: Hikurangi Bioactives Limited Partnership

Clock Start Date: 13 June 2019

Mr Nick Shortt and Dr Alex Semprini were present by teleconference for discussion of this application.

## Potential conflicts of interest

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

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

## Summary of Study

1. This study will assess the efficacy of 3% Kanuka Oil serum in the treatment of acne. In order to investigate this we have designed a single blind, randomised, vehicle controlled feasibility study.
2. 30 participants will be recruited via pharmacies throughout New Zealand and will be randomised 1:1 to receive either 3% Kanuka Oil serum or vehicle control.
3. Participants will be recruited from community pharmacies by pharmacy staff. Pharmacy staff will be trained as investigators by a MRINZ investigator. The baseline visit will consist of screening, consent, demographics, acne scoring, photograph of the face, randomisation and supply of study medication. Participants will be instructed to apply their treatment twice daily for 12 weeks.
4. The participants will complete a weekly electronic diary for 10 weeks (skipping week 6 and week 12). The electronic diaries will capture quality of life scores, treatment compliance, and adverse events. A paper diary will be offered as a back-up if participants are unable to complete the electronic diary. The paper diary will be returned at the final study visit.
5. The participants will return to the pharmacy at the end of week six for a follow up study visit. This visit will consist of acne scoring, photo of the face, adverse event collection, and concomitant medication collection. The participant will be resupplied their assigned study medication.
6. The participants will return to the pharmacy at the end of week 12 for a final study visit. This visit will consist of acne scoring, photo of the face, treatment acceptability, adverse event collection, and concomitant medication collection.
7. A follow up survey will be conducted at week 14 to assess adverse events post study.
8. The primary outcome for this study is improvement in patient reported quality of life at 12 weeks. Secondary outcomes include improvement in objective symptoms, treatment acceptability, and inter-rater validity of IGA and lesion counting

## 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 practical aspects of collecting data for this study. Mr Shortt stated that an iPad will be issued to directly upload participant data to the study database.
2. The Committee queried how potential participants will be identified. Mr Shortt stated that participants will self-identify upon presentation to the pharmacy, or in response to advertising. Alternatively, if potential participants are known to the pharmacists as customers, then they may be approached by the pharmacist.
3. The Committee queried the status of the advertisements that will be used for recruitment. Mr Shortt responded that they are yet to be finalised, and will be submitted to HDEC once they are completed.
4. The Committee queried what will happen to participant photos after they have been assessed by the study dermatologist. Mr Shortt stated that the photos will be archived with study data.

## 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 why participant photographs need to include participants’ initials on the backs of them. Mr Shortt stated that typically three points of identification are used and initials are one of them. The Committee stated that only two were described and this should be corrected in the PIS.

The Committee requested the following changes to the Participant Information Sheet and Consent Form:

1. The Committee stated that the first paragraph of the PIS should be reworded to replace technical language with lay-language where possible.
2. The Committee requested that any ambiguous language regarding storage of information offshore should be removed from the PIS and Consent Form, and that the location of the data storage will be included (e.g., Sydney, Australia).
3. The Committee requested that the consent form and PIS be amended to include a statement that says only the New Zealand-based study team can access this data, despite the server’s physical location being in Sydney, Australia.
4. The Committee requested that a grid, table or flow chart could be included in the PIS in addition to existing wording, to indicate to participants the time frame and intervals between participants and researchers to improve clarity.
5. The Committee stated that the consent form should be amended to explicitly state that participants will have their photograph taken, and what will happen with that photograph.
6. The Committee requested that page three of the PIS should be amended, as it suggests that each participant will be receiving both treatments, when they will each only be receiving the singular treatment that they have been allocated.
7. The Committee requested greater detail on page six of the PIS, in particular the inclusion of groups or persons that may be able to access stored study data (e.g. regulatory bodies), needs to be more explicit.
8. The Committee requested the removal of the statement on page three of the PIS that suggests participants would be able to smell the difference between the two treatments.
9. The Committee requested the correction of wording around “filling in questionnaires” versus “answering questions” on page three of the PIS.

## Decision

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

* Please correct the PIS to state that three points of identification will be used for photographs, and what those points of identification are.
* Please reword the first paragraph of the PIS where possible to replace technical language with lay-language.
* Please remove any ambiguous language regarding storage of information offshore from the PIS and Consent Form.
* Please include in the PIS and Consent Form the location of servers for data storage (e.g., Sydney, Australia).
* Please amend the consent form and PIS to include a statement that says only the New Zealand-based study team can access this data, despite the servers’ physical location being in Sydney, Australia.
* Please include a grid, table or flow chart in the PIS in addition to existing wording, to indicate to participants the time frame and intervals between participants and researchers to improve clarity.
* Please amend the consent form to explicitly state that participants will have their photograph taken, and what will happen with that photograph.
* Please amend page three of the PIS, as it currently suggests that each participant will be receiving both treatments, when they will each only be receiving the singular treatment that they have been allocated.
* Please include greater detail on page six of the PIS, in particular the inclusion of groups or persons that may be able to access stored study data (e.g. regulatory bodies), needs to be more explicit.
* Please remove the statement on page three of the PIS that suggests participants would be able to smell the difference between the two treatments.  The Committee requested the correction of wording around “filling in questionnaires” versus “answering questions” on page three of the PIS.

After receipt of the information requested by the Committee, a final decision on the application will be made by Dr Peter Gallagher and Mrs Helen Walker.

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| **3** | **Ethics ref:** | **19/CEN/100** (CLOSED) |
|  | Title: | Phase 3 Study of Pembrolizumab/Placebo plus Enzalutamide in mCRPC |
|  | Principal Investigator: | Dr Anthony Rahman |
|  | Sponsor: | MSD |
|  | Clock Start Date: | 13 June 2019 |

Mrs Katharine Moore and Dr Anthony Rahman were present by teleconference for discussion of this application.

## Potential conflicts of interest

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

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

## Decision

This application was *provisionally approved* by consensus.

**4 19/CEN/101**

Drug screening trauma patients in Emergency Departments

Principal Investigator: Ms Siobhan Isles

Sponsor:

Clock Start Date: 13 June 2019

Ms Siobhan Isles and Dr Helen Poulsen were present in person 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 Study

1. This study aims to understand the association between drug use (all drugs) and injury. The study involves the inclusion of a blood test in the trauma blood series which is taken on all trauma calls in the Emergency Department at two DHBs. The drug blood samples will be sent to ESR for testing. The findings will include analysis of the presence of drugs by injury type (e.g. road traffic crash, fall, assault etc), and the type of drugs found.

## 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 why consent cannot be sought when blood samples are taken. Ms Isles stated that it may not be possible to do so for patients who die. The committee stated that if patients die then consent is not required.
2. The Committee queried why consent cannot be obtained after the blood samples have been taken but before they are analysed. Ms Isles stated that it may not be possible to do so for patients who are in a prolonged state of unconsciousness. The Committee stated that if blood samples (leftover from that which was taken for the purposes of treatment) were stored and not tested until these patients were able to give consent, then it would comply with the law.
3. The Committee queried whether ethnicity statistics would be collected. Ms Isles stated that they would not be collecting ethnicity data, due to the small sample size and possibly stigmatising results.
4. The Committee queried the decision to recruit severe trauma patients. The Researcher stated that it is the most objective criteria they could identify that would not introduce bias into the recruiting 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 stated that if consent cannot be obtained to take blood samples solely for the purposes of research, then it is in breach of Right 7.4 of the Code of Health and Disability Services Consumers’ Rights as there is no benefit to the individual patient, so enrolment in the research is not in their “best interests”.
2. The committee stated if consent were to be sought from patients, it must be prospective, rather than retrospective, as retrospective consent does not give participants opportunity to choose not to participate in the study.
3. The Committee stated that if researchers wish to use samples from patients who are transferred out of research sites, a system must be put in place in which consent can still be obtained from those patients.
4. The Committee stated that if leftover samples are used, the samples will need to be deidentified before they are tested, so that participant test results are protected.
5. The Committee stated that, to comply with the Code, testing of blood samples that were originally collected for treatment purposes must not occur until the patient is able to give consent, after which point the samples could be de-identified and sent for testing.
6. The Committee stated that the research must take great care to communicate in any publications that their findings are correlational, not causational, so that causal relationships between some substances and injuries are not incorrectly identified.

## Decision

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

* Informed consent could not be obtained.
* Right 7.4 of the Code of Health and Disability Services Consumers’ Rights not complied with, as the research is not in the best interests of individual participants.

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| **5** |  | **19/CEN/102** |
|  |  | Comparison of the blood levels of two forms of levothyroxine tablets. |
|  | Principal Investigator: | Dr Noelyn Hung |
|  | Sponsor: | Southern Cross Pharma Pty Ltd |
|  | Clock Start Date: | 13 June 2019 |

## 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 Study

1. This study is comparing the blood levels of the test formulation, 3 x 200 mcg levothyroxine tablets (Southern Cross, Australia) against that of the reference formulation, 3 x 200 mcg Eutroxsig® (Aspen, Australia) following oral administration to healthy male and female subjects under fasting conditions.

1. To assure the good health of subjects, pre-study physical examinations, vital signs, ECG and clinical laboratory tests will be performed. Pre-dose laboratory tests will also be performed before dosing in Periods 2, 3 and 4. Post-study exit procedures will be carried out and subjects will be monitored for AEs throughout the study.

1. During each treatment period, each of the enrolled and randomised healthy male and female subjects will receive a single dose of three (3) tablets of either formulation. Subjects will receive the test formulation twice and the reference formulation twice all under fasting conditions. There will be at least 42 days (6 weeks) washout between each dosing period.

1. Subjects will be recruited within 3 weeks (21 days) prior to the study commencing. One hundred and thirty (130) days (18-19 weeks) will be required for sample collection. This includes the washout periods. The reason for the length of the study, is that the levothyroxine is eliminated from the body over a long period of time so we need to make sure there is no residue remaining when each of the doses are administered.

1. Subjects will be housed at the Zenith Clinical Site 12 hours before dosing until approximately 24 hours after dosing. Blood samples will be collected at baseline and at specified times up to 72 hours after dosing. All PK blood collection up until 24 hours post dosing will be completed at the Zenith Clinical Site. Subsequent samples at 36, 48, and 72 hours post dosing will be collected at Zenith Technology Corporation Limited. The serum will be assayed for levothyroxine, using a fully validated LC-MS/MS method.

The Committee requested the following changes to the Participant Information Sheet and Consent Form:

1. Please amend page four of the PIS, relating to history of alcohol and drug abuse, to include more objective language that is appropriate to the population, i.e. how much use amounts to abuse.
2. Page five of the PIS where it is stated that participants should take care performing activities should be amended to be more specific about what this means.
3. Please clarify the statement on page five of the PIS “you may consume various things” so that it is clearer as to whether participants should or should not be consuming certain things during the course of the study.

## Decision

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

* Please amend page four of the PIS, relating to history of alcohol and drug abuse, to include more specific references to the meaning of abuse that is appropriate to the population.
* Page five of the PIS where it is stated that participants should take care performing activities should be amended to be more specific about what this means.
* Please clarify the statement on page five of the PIS “you may consume various things” so that it is clearer as to whether participants should or should not be consuming certain things during the course of the study.

**6 19/CEN/96**

Norovirus molecular typing in children

Principal Investigator: Dr Joanne Hewitt

Sponsor: ESR Ltd

Clock Start Date: 13 June 2019

Dr Joanne Hewitt was present in person 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 Study

1. The study is sentinel surveillance for determining the genotypes of norovirus among children under 5 years of age. Norovirus positive samples will be collected from a New Zealand hospital in Auckland. This study will gather information on norovirus genotypes circulating, supporting the ongoing public health surveillance of norovirus associated with outbreaks.
2. Norovirus genotyping will be performed on norovirus-positive specimens taken from either children who present at hospital with acute gastroenteritis, or who have been diagnosed with gastroenteritis while in hospital. Samples will have been tested for norovirus by the hospital laboratory as part of the usual diagnostic practice. Only norovirus-positive faecal specimens will be sent to ESR and the norovirus will be genotyped by sequencing.

## 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 where the researcher will be collecting samples from. The Researcher stated that samples are collected for diagnostic purposes by the healthcare provider; standard practice is for them to then destroy the positive samples, but in this instance the researchers will be collecting the samples to perform genotype testing.
2. The Committee queried the identifiability of the samples received by the researcher. The researcher stated that the only information attached to each sample is a study code, the patient’s age and the patient’s sex. Additionally, the only geographical identifier would be that all samples are from Auckland, New Zealand.

## 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 stated that, as there is no way of knowing the ethnicity of patients from which samples are taken, evidence of external Māori consultation will be necessary.
2. The Committee requested the inclusion of external scientific peer-review that comments on the scientific validity of the study’s protocol and methodology, from a professional who is familiar with genetic testing and who is also independent from the proposed study.

## Decision

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

* Additional independent peer review that comments on the scientific merit of the study’s protocol and methodology, from a professional who is familiar with genetic testing and who is also independent from the proposed study.
* Evidence of Māori consultation, such as a letter from the organisation that as consulted.

After receipt of the information requested by the Committee, a final decision on the application will be made by Peter Gallagher and Helen Walker.

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| **7** |  | **19/CEN/95** |
|  |  | Warm humidified insufflation study in acute surgical unit |
|  | Principal Investigator: | Professor John Windsor |
|  | Sponsor: | University of Auckland |
|  | Clock Start Date: | 13 June 2019 |

## 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 Study

1. A randomised controlled single-blind study will be performed at Auckland District Health Board. The overall aim of this trial is to investigate the impact of warm humidified insufflation (administered using the HumiGard medical device developed by Fisher and Paykel Healthcare) on post-operative ileus in patients undergoing acute general surgical laparotomy. Specifically, the trial aims to determine whether warm humidified insufflation during surgery will reduce the length (in days) of post-operative ileus as defined by clinical markers of return to bowel function, improved gut dysfunction, and improved quality of life.

1. Study: Patients undergoing acute general surgical laparotomy admitted to the Acute Surgical Unit at Auckland City Hospital, will be screened for eligibility. Upon obtaining informed consent, patients will be randomised to one of two groups: those receiving warm humidified insufflation or those not receiving warm humidified insufflation. Patients will be followed up every 12 hours during their hospital stay to determine their return to bowel function and administer quality of life questionnaires. Patients will then be followed up with a phone call at 30 days after discharge to determine quality of life and gut function. During the surgery, 4 tissue punch biopsies (5-6 mm) will be taken at each time point (at start of surgery, 1 and 2-hours into the surgery, and just before closure) for peritoneal inflammation measurement - interim analysis of 40 patients.

1. Return to bowel function will be determined based on time from surgery to tolerance of a solid diet. Improved gut function will be determined based on GCSI score. Quality of life will be determined based on GIQLI score. Peritoneal inflammation will also be measured using rtqPCR of 5-6 mm peritoneal tissue punch biopsy at initiation, 1-hour, 2-hour, and just before closure during the surgery.

## 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 standard of care, which is stated in the protocol to be doing nothing.
2. HDEC queried used of punch biopsies; unclear if FUR (PIS CF inconsistency), and this should go to SCOTT.
3. NTA should be changed to CEN.
4. PIS should state information about access to data, where is it stored and who has access
5. Application form: haven’t said F & P are the sponsor.
6. Independent peer review needs to state what organisation they are from, so unclear if truly independent.
7. How much of a time gap between first approach from researcher and actual surgical procedure

## 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 stated that the researchers need to clarify the timeframe between participants being approached and when they undergo the surgery.
2. The Committee stated that information around the sponsor should be clarified, as there are discrepancies between documents as to whether Fisher and Paykel or the DHB are the primary sponsor for this study
3. The Committee stated that standard of care should be clarified in the protocols, as in its current form it is unclear as to whether standard of care of is to not insufflate at all, or to insufflate with cold air.
4. The Committee stated that SCOTT should be approached for review, as the insufflation device is being used internally in the body.
5. The Committee stated that the use of punch biopsies should be clarified in the protocol.
6. The Committee stated that the researchers need to provide the name of the organisation from which their independent peer review came.

The Committee requested the following changes to the Participant Information Sheet and Consent Form:

1. The Committee stated that the PIS and Consent Form should be amended to more clearly state whether samples will be stored for future unspecified research.
2. The Committee stated that the PIS and Consent Form should be more specific about tissue storage, such as duration of storage and whether further analysis pertains to the current study or to other unspecified research.
3. The Committee stated that references to the NTA HDEC in the PIS and Consent Forms should be amended to reference the CEN HDEC.
4. The Committee requested changes to page five of the PIS regarding storage of data to more closely resemble the HDEC template; e.g. where data is stored and who can access it.

## Decision

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

* Please clarify the process and timeframe between patients being approached fro participation and when they undergo the surgery.
* Please amend documentation to clarify study sponsorship, as there are discrepancies between documents as to whether Fisher and Paykel or the DHB are the primary sponsor for this study
* Standard of care should be clarified in the protocol, as in its current form it is unclear as to whether standard of care of is to not insufflate at all, or to insufflate with cold air.
* Please confirm whether SCOTT has been approached for review, as the insufflation device is being used internally.
* Please give more information in the PIS and protocol regarding the use of punch biopsies.
* Please provide the name of the organisation from which their independent peer review came.
* Please amend the PIS and Consent Form to more clearly state whether samples will be stored for future unspecified research.
* Please amend the PIS and Consent Form to be be more specific about tissue storage, such as duration of storage and whether further analysis pertains to the current study or to other unspecified research.
* Please amend references to the NTA HDEC in the PIS and Consent Forms, to instead reference the CEN HDEC.
* Please make changes to page five of the PIS regarding storage of data to more closely resemble the HDEC template; e.g. where data is stored and who can access it.

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

# General business

1. The Committee noted the content of the “noting section” of the agenda.

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

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| **Meeting date:** | TBD |
| **Meeting venue:** | TBD |

1. **Problem with Last Minutes**

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

1. **Matters Arising**

1. **Other business**

1. **Other business for information**

1. **Any other business**

The meeting closed at 3:25pm.