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| **Committee:** | Northern B Health and Disability Ethics Committee |
| **Meeting date:** | 05 July 2016 |
| **Meeting venue:** | Novotel Ellerslie, 72-112 Greenlane Road East, Ellerslie, Auckland |

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| **Time** | **Item of business** |
| 12:00pm | Welcome |
| 12:05pm | Confirmation of minutes of meeting of 07 June 2016 |
| 12:30pm | New applications (see over for details) |
|  | i 16/NTB/121  ii 16/NTB/113  iii 16/NTB/111  iv 16/NTB/115  v 16/NTB/116  vi 16/NTB/119  vii 16/NTB/114  viii 16/NTB/120  ix 16/NTB/117  x 16/NTB/122 |
| 5:05pm | General business:   * Noting section |
| 5:20pm | Meeting ends |

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| **Member Name** | **Member Category** | **Appointed** | **Term Expires** | **Apologies?** |
| Mrs Maliaga Erick | Lay (consumer/community perspectives) | 01/07/2015 | 01/07/2018 | Present |
| Mrs Stephanie Pollard | Non-lay (intervention studies) | 01/07/2015 | 01/07/2018 | Apologies |
| Miss Tangihaere Macfarlane | Lay (consumer/community perspectives) | 19/05/2014 | 19/05/2017 | Present |
| Mrs Phyllis Huitema | Lay (consumer/community perspectives) | 19/05/2014 | 19/05/2017 | Present |
| Mrs Kate O'Connor | Lay (ethical/moral reasoning) | 14/12/2015 | 14/12/2018 | Present |
| Dr Patries Herst | Non-lay (intervention studies) | Co-Opt Central | Co-Opt Central | Present |
| Dr Nora Lynch | Non-lay (health/disability service provision) | 24/07/2015 | 24/07/2018 | Present |
| Mrs Leesa Russell | Non-lay (intervention studies), Non-lay (observational studies) | 14/12/2015 | 14/12/2018 | Apologies |
| Mr John Hancock | Lay (the law) | 14/12/2015 | 14/12/2018 | Present |
| Dr Melissa Cragg | Non-lay (observational studies) | Co-Opt Central | Co-Opt Central | Present |

## Welcome

The Chair opened the meeting at 12:00pm and welcomed Committee members, noting that apologies had been received from Mrs Stephanie Pollard and Mrs Leesa Russell.

The Chair noted that fewer than five appointed members of the Committee were present, and that it would be necessary to co-opt members of other HDECs in accordance with the SOPs. Dr Melissa Cragg and Dr Patries Herst confirmed their eligibility, and were co-opted by the Chair as members of the Committee for the duration of the meeting.

The Chair noted that the meeting was quorate.

The Committee noted and agreed the agenda for the meeting.

## Confirmation of previous minutes

The minutes of the meeting of 07 June 2016 were confirmed.

## New applications

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| **1** | **Ethics ref:** | **16/NTB/121** |
|  | Title: | The CogEx Trial |
|  | Principal Investigator: | Miss Elizabeth Binns |
|  | Sponsor: | Auckland University |
|  | Clock Start Date: | 23 June 2016 |

Miss Elizabeth Binns and Kathy Peri 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 involves participants with mild to moderate dementia.
2. Participants’ level of cognitive impairment will be measured with the Montreal Cognitive Assessment to determine their capacity to provide informed consent. Any potential participants with a score below 15 will be excluded from this study.
3. Some participants with a score higher than 15 will still be unable to provide informed consent, however, participants require enough competency to engage in a meaningful conversation to be included in the study.
4. Because some participants will be unable to provide informed consent the application originally included the provision for proxy consent. However, following discussion with the Secretariat the Researchers agreed to replace the provision for proxy consent with a family and friend consultation form, to ascertain the views of suitable persons when enrolling participants unable to provide informed consent.
5. Consistent with Right 7(4) of the HDC Code of Rights, any participants unable to consent who are recruited in to this study can only be included because participation is deemed to be in their best interests, and the views of suitable persons has been ascertained (where possible) regarding whether the participant would want to be in the study if they were able to provide informed consent.

Summary of ethical issues (resolved)

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

1. The Committee noted that in New Zealand, proxy consent for research is only legally acceptable in cases where the medical experiment would save the person’s life or prevent serious damage to the person’s health. Because of this, they understood that the researchers had replaced proxy consent forms with a form for the participant’s representative that will only be used to gauge views of relatives/ friends/ EPOA of potential participants involved that are unable to consent for themselves.
2. The Committee noted that as this study involves some participants unable to provide their own informed consent they must be assured that participation is in each individual participant’s best interests to approve the study. It is not possible for HDECs to approve an application unless it is consistent with New Zealand law, including the right not to be subjected to medical or scientific experimentation without that person's consent (section 10 of the New Zealand Bill of Rights Act 1990). Research involving participants who are not competent to consent is inconsistent with the Bill of Rights unless it is undertaken in accordance with Right 7 (4) of the of the Code of Health and Disability Services Consumers’ Rights.
3. Right 7(4) of the Code requires that any health services provided without the informed consent of the consumer must be in the best interests of the consumer, and where possible the views of the consumer and other suitable persons must be obtained. This means that there must be some benefit, or potential benefit, to the participant beyond what they would receive if they were not participating in the research.
4. The Researchers explained that this study combines Cognitive Stimulation Therapy with an exercise component aimed at reducing fall risk. The Researcher explained that there is a wealth of literature that strongly supports Cognitive Stimulation Therapy and demonstrates a benefit from it for patients with cognitive impairment. Cognitive Stimulation Therapy is currently considered the best available care for this patient group. Because of this, the Researcher stated that the Cognitive Stimulation Therapy aspect of the study is clearly in the best interests of the participants and can be expected to provide each participant with a benefit directly.
5. The Researcher assured the Committee that it is their clinical judgement that the exercise component is also in the best interest of the participants as exercise is beneficial for everyone. Further, for older adults with cognitive impairment falls pose a significant risk, and there is evidence to suggest that this kind of exercise aimed at improving balance can help to reduce the risk of falls.
6. The Committee agreed that there seems to be sufficient evidence that participation is in the best interest of each participant as both the Cognitive Stimulation Therapy and the exercise intervention can be expected to provide a benefit.
7. The Committee noted that they would not approve a study in people who cannot consent if the study could be done adequately with only participants able to provide informed consent being included. The Committee asked whether the study could be able to be done if only participants able to provide informed consent were included. The Researchers explained that although they want to focus on people with only mild to moderate dementia that some of these participants may still be unable to consent, including some with only mild dementia. Because of this the Researchers stated that in order to proceed with the study in this population group at least some participants will not be able to provide informed consent and this cannot be avoided. The Committee agreed that it seems necessary to include participants unable to consent.
8. Based on the information provided by the Researchers, the Committee agreed that participation appears to be in the best interest of each individual participant, and the views of other suitable persons will be obtained where possible, in line with Right 7(4) of the HDC Code of Rights. Further, this study requires participants who cannot provide informed consent due to the population group being studied, and the results of this study stand to prove important and beneficial. Because of these reasons the Committee agreed that they had enough information to approve the inclusion of participants unable to provide their own informed consent, as participation is deemed to be in their best interests by the Researchers and this will be attested to by the enrolling clinician for each participant.
9. The Researcher also stated that although some participants may not have the cognitive capacity to provide fully informed consent they will need to be willing to participate. If participants do not want to participate in the interventions the researchers cannot, and will not, force their participation. The kinds of interventions involved in this study require voluntary active engagement of the participant. The Committee noted that it is comforting to know that participants will only be involved if they want to participate, even if they are unable to provide fully informed consent.
10. The Committee questioned whether the time allocated for Cognitive Stimulation Therapy is reduced to allow time for the exercise component and could mean that the benefits from this therapy are reduced. The Researcher explained that the time engaged in the Cognitive Stimulation Therapy is not reduced by the addition of the exercise component.
11. The Committee questioned how potential participants will be screened and identified. The Researcher explained that they will discuss the study with the Alzheimer’s Foundation and consider the results of previous tests to identify patients who are potentially suitable participants.
12. The Committee asked the researchers how participants’ safety would be ensured during the physical intervention, especially with the risk of falls. The Researcher explained that everyone running the intervention and assessments will be suitably trained by one of the lead researchers. Further, the ratio of participants to researchers in the interventions is quite low and this will help to ensure the safety of participants.
13. The Committee questioned why the baseline assessment does not mention musculoskeletal conditions, such as arthritis. The Researcher stated this is a mistake and they will ensure this is added before it is used.
14. The Committee questioned where the study sessions are conducted. The Researcher explained that for participants living in the community the study sessions will be held at a community hall, and for participants living in rest homes the study sessions will be held at the rest home.
15. The Committee questioned whether participants would be reimbursed for travel costs associated with attending study sessions in the community. The Researcher stated that although this is not currently included they could add this. The Committee requested that this is added as participants should not incur any additional costs to be involved in a study.

Summary of ethical issues (outstanding)

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

1. Please ensure that the form for obtaining the views of the participant’s family and friends is clearly in line with the requirements of Right 7(4) and makes it clear what these people are being asked to do. This means that the forms should not involve language whereby the relative/friend/EPOA consent on behalf of someone else. As an alternative, the language should reflect that the document seeks the friend/relative/EPOA’s view that the non-consenting person would be agreeable in participating.
2. Please provide a form to be completed by the clinician enrolling participants unable to provide informed consent under Right 7(4). This form should detail: why the participant cannot provide informed consent, who enrolled this participant, whether it is in their clinical judgement that participation is in the best interest of the participant, what has been done to obtain the views of the participant where possible, and whether another suitable person was consulted regarding whether they believe the participant would want to be in the study if they could provide consent.
3. Please provide a very simple Participant Information Sheet to explain the study to participants who may have reduced capacity. The Committee suggests that a short form including pictures may be suitable.
4. Please add information about reimbursement for travel expenses to the Participant Information Sheet.

Decision

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

1. Please amend the information sheet and consent form, taking into account the suggestions made by the Committee (*Ethical Guidelines for Intervention Studies* *para 6.22*). Including revising the forms for family members and friends to ensure they are in line with Right 7(4) of the HDC Code of Rights
2. Please provide a form for clinicians to complete when enrolling participants under Right 7(4) of the HDC Code of Rights.

This following information will be reviewed, and a final decision made on the application, by Dr Nora Lynch and Mr John Hancock.

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| **2** | **Ethics ref:** | **16/NTB/113** |
|  | Title: | (duplicate) A rapid non drug treatment for anxiety- the rapid symptom shifting therapy |
|  | Principal Investigator: | Professor Bruce Arroll |
|  | Sponsor: | The University of Auckland |
|  | Clock Start Date: | 09 June 2016 |

Mr Danyon Harris 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 ethical issues (outstanding)

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

1. The Committee noted that this study had previously been declined by the Central HDEC and although the resubmission is much improved there are still a number of issues with the study application.
2. The Committee questioned the suitability of the study design, including the use of a placebo/control (visualising washing a car) that may also relieve anxiety and is not a true control. The Committee suggested that a cross-over design may be more suitable as participants could be told that the study is investigating two forms of visualisation and all participants would receive first one and 8 weeks later they would receive the other visualisation. This would allow the researchers to make stronger claims regarding any differences in outcomes being directly attributed to the different visualisation scenarios. .
3. The Committee noted that the protocol describes a different study design to what is included in the application form. The Researcher explained that this was an error and it appears an older version of the protocol was uploaded. The accurate study design compares two forms of visualisation, whereas the older study design compared the study visualisation to participants receiving pamphlets. The Committee noted that comparing two forms of visualisation directly is better as it allows the Researchers to determine if the specific visualisation being studied is responsible for any benefit observed, rather than any benefit simply being attributed to participants seeing a clinician in person (as opposed to pamphlets).
4. The Committee noted that to have scientifically robust results, that can be attributed to the visualisation being studied, as many other variables as possible must be consistent between study groups, including the length of time they have to speak about their anxiety. This will allow any differences between the study arms to be attributed specifically to the study intervention rather than other factors.
5. The Committee stated that it is essential that the application form and supporting documents provide accurate and consistent information about the study. This application contained a number of inconsistencies and inaccuracies that made it difficult for the Committee to assess. In future, please ensure that the application form is completed more accurately and that the information that is provided in the application is consistent with the Participant Information Sheet and the protocol.
6. The Committee questioned why the Researchers believed the study technique would be beneficial. The Researcher stated that it was from the CI’s clinical experience.
7. The Committee noted that the response to question p.4.1 Please describe whether and how your study may benefit Māori Stated “This study aims to test a technique which could prove cheap, quick and effective. This would significantly benefit the Māori population.” The Committee found this response inappropriate and offensive. Please consider your response to this question more carefully in future. The answer should include incidence and prevalence (statistics) of the disorder under study in Māori.
   * The Secretariat notes that some disorders are particularly important for Māori health, while others are relatively rare in Māori and may have less of an impact. If the impact of treatment or prevalence of disease is low or the same as other populations please state this clearly to the Committee. Generally, any available statistics relating to Māori should be provided where possible. If relevant, please include information on how researchers will ensure that Māori benefit at least equally (and actually how they can disproportionately benefit if they are disproportionately represented) –for example, what extra measures if any are in place to ensure Māori participation (iwi consultation, Māori researchers, active follow up etc.) as well as interpretation of results and presentation of findings back to those consulted.
8. The Committee questioned the evidence of scientific peer review provided and requested information on whether the issues raised in this peer review have been addressed.
9. The Committee noted that it is important that the study design is suitable to answer the study question. Please provide more information on the suitability of the study design, the Committee suggests that a better design could be used to produce more reliable results.
10. Please clarify the exact protocol for the control arm, the Committee suggests this appears to be an active control and requests that if this is the case that this is clarified.
11. The Committee questioned whether a power calculation has been conducted regarding the number of participants needed for this study.
12. The Committee asked the Researcher to clarify how participants would be recruited for this study. The Researcher stated that a bulk email address was available through the University and they would send information out through this, additionally they have advertising. The Committee noted that the advertisement that had been provided was not accurate and seemed to refer to a different study. Please provide the correct advertising material.

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

1. Please reconsider the study design or at least rephrase the Participant Information Sheet to be clear that participants will be randomised to receive one of two interventions, to ensure it is clear that there is an active control and participants may be assigned to this study arm.
2. Please ensure that terms are used accurately in the Participant Information Sheet. For example the term ‘blinding’ is used incorrectly in the Participant Information Sheet.
3. Please ensure it is clear that all health information is stored for a minimum period of 10 years (Health (Retention of Health Information) Regulations 1996).
4. Please clarify in the Participant Information Sheet what happens if participants withdraw from the study, such as whether their data retains identifiers and can be withdrawn from the study or not.
5. Please provide more information on confidentiality in the Participant Information Sheet, such as who will see the date and what identifiable information will be included.
6. Please clarify in the Participant Information Sheet whether it is optional for the participant’s GP to be informed of their participation in the study.
7. Please expand the ‘What are my Rights” section of the Participant Information Sheet to provide more information.
8. Please ensure that all questionnaires are mentioned in the Participant Information Sheet, currently some are mentioned in the Protocol but not in the Participant Information Sheet.
9. The Participant Information Sheet suggests that the study intervention has scientific evidence supporting it, however, this is not accurate as the study intervention has not yet been rigorously tested, and is based on clinical experience only Please update this for accuracy.
10. Please ensure it is clear in the Participant Information Sheet where the study visits will be held.
11. If participants will need to travel to attend the study visits please ensure suitable compensation for travel costs if provided and explained in the Participant Information Sheet, the Committee noted that participants should not incur any costs associated with participation in a study.

Decision

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

1. Please amend the information sheet and consent form, taking into account the suggestions made by the Committee (*Ethical Guidelines for Intervention Studies* para *6.22*).
2. Please provide evidence of favourable independent peer review of the study protocol (*Ethical Guidelines for Intervention Studies* Appendix 1).
3. The Committee noted that scientific soundness is ethically important, projects without scientific merit needlessly expose participants to risk and misuse their time, and waste resources (*Ethical Guidelines for Intervention Studies* para 5.5). The Current proposal does not assure the committee of the scientific rigour of the project.

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| **3** | **Ethics ref:** | **16/NTB/111** |
|  | Title: | HET vs RBL Trial |
|  | Principal Investigator: | Dr Rhys Filgate |
|  | Sponsor: |  |
|  | Clock Start Date: | 15 June 2016 |

Dr Rhys Filgate 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 study investigates a new treatment for the management of Grade I and II Internal Haemorrhoids.
2. The Study device is currently marketed and used in Australia, however, the Researchers believe that insufficient evidence to support the claims of its manufacturers exists.
3. This study will compare standard care to the study device to determine if it is significantly better, as the manufacturers claim, to justify the cost associated with changing to the new device.

Summary of ethical issues (resolved)

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

1. The Committee questioned how participants’ pain scores will be reviewed given the personal differences between individuals’ pain tolerance. The Researcher agreed that using pain as a measure poses some difficulties, however, the claims about the benefits of the study device relate to reduced pain. Because of this, the pain measure for this study is suitable and essential.
2. The Committee questioned whether participants with multiple Haemorrhoids can be treated with both methods. The Researcher explained that they could not do both methods on one participant at the same time as the participant would not be able to differentiate between the Haemorrhoid sites, and it is not suitable to do one method and wait to do the other method as this would expose participants to unnecessary discomfort and risk.
3. The Committee questioned whether data from this study is likely to be used for any other projects in the future. The Researcher stated that this is not their intention, they intend to only use the study data for this project and then destroy the data.
4. The Committee noted that the Researcher had not mentioned whakama (shame) in response to the question in the application form regarding potential cultural issues, especially given the part of the body that is being treated. In future applications please take this in to consideration and provide mitigation strategies to manage whakama.
5. The Committee questioned who the sponsor for the study is. The Researcher explained that although the manufacturer is providing the study device that the study was developed and undertaken by the research team, not for the benefit of the manufacturer. The Committee noted that the DHB may be the study sponsor for HDEC purposes.
6. The Committee requested that ethnicity data is collected as part of the study.
7. The Committee questioned what grade Haemorrhoids are being included in the study as there was a discrepancy between the application form and the protocol. The Researcher confirmed that Grade III Haemorrhoids are an exclusion criteria for this study and only Grade I and II will be included.
8. The Committee questioned how participants will be randomised in this study. The Researcher explained that a research nurse would randomise participants once they were enrolled by the research team.
9. The Committee questioned how blinding would be maintained for the study participants. The Researcher stated that they did not intend to have formal blinding, but were not going to directly tell participants which arm they are randomised to. The Committee stated that it is important to the scientific validity of the study results that participants are effectively blinded to their group allocation. The Researcher agreed to ensure formal blinding is included in the study.

Summary of ethical issues (outstanding)

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

1. Please provide more information in the Participant Information Sheet about what is involved in the study.
2. The Participant Information Sheet is currently bias towards the study device and makes it sound significantly better than standard care. Please rephrase the Participant Information Sheet to be clear that you do not know which method is better and it is not currently known which method is less painful.
3. Please remove the yes/no tick boxes from the consent forms for any statements that aren’t truly optional, that is that participants could select ‘no’ and still be involved in the study.

Decision

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

1. Please amend the information sheet and consent form, taking into account the suggestions made by the Committee (*Ethical Guidelines for Intervention Studies* *para 6.22*).

This following information will be reviewed, and a final decision made on the application, by Mrs Kate O'Connor and Miss Tangihaere Macfarlane.

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| **4** | **Ethics ref:** | **16/NTB/115** |
|  | Title: | A Novel Nanosensor array for Heart Failure diagnosis |
|  | Principal Investigator: | Dr Patrick Gladding |
|  | Sponsor: |  |
|  | Clock Start Date: | 23 June 2016 |

Dr Patrick Gladding 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 study investigates a potential new method of identifying heart failure.
2. The proposed tool will measure components in people’s exhaled breath and hopefully be able to identify heart failure.
3. This study uses a less advanced version of the proposed device that measures the headspace in urine samples for the same markers.
4. This study involves recruiting a group of participants with heart failure and a group without heart failure to compare the results for both groups to validate the proposed sensor.

Summary of ethical issues (resolved)

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

1. The Committee questioned whether samples would be kept for future unspecified research. The Researchers confirmed that this was an optional aspect of the study and is currently included as a tick box on the consent form. The Committee explained that optional storage of tissue for future unspecified use should be contained in a separate Participant Information Sheet and Consent Form.
2. The Committee questioned whether samples stored beyond the end of this study would be stored in a HDEC registered tissue bank. The Researcher confirmed that all samples stored for future unspecified research would be stored in a HDEC registered tissue bank.

Summary of ethical issues (outstanding)

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

1. The Committee questioned the recruitment protocol for the study. The Researcher explained that potential heart failure participants will be identified through their medical records and sent an invitation to the study by the hospital’s booking clerk. The Committee noted that it was unclear from the application whether healthy control participants would be recruited from advertising or whether they had already provided samples that could be used for research. The Researcher clarified that they had some blood samples from another study that the participants had agreed could be used for other projects, but that if they were to use these samples they would need to invite these participants back to provide a urine sample and they felt that because of this they may need to advertise to recruit healthy volunteers. The Committee noted that any advertising must be provided to the HDEC for their consideration and approval.
2. The Committee questioned whether any breath is being tested or used in this study. The Researcher explained that although they hope to be able to measure breath in the future that the technology doesn’t currently allow this. The Committee requested this is removed from the study protocol and participant facing documents as these need to detail the study that is currently being applied for, if you would like to add the testing of breath in the future an amendment can be submitted.

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

1. Please develop a separate Participant Information Sheet and Consent Form for future unspecified use of tissue. The Committee suggested the use of the HDEC template when developing this form.
2. The Participant Information Sheet currently includes reference to some optional tests, please clearly separate the compulsory aspects of the study from the optional aspects by having each optional aspect of the study contained in a separate information sheet and consent form and only the compulsory aspects included in the main Participant Information Sheet.
3. Please remove all mentions of testing breath from the Participant Information Sheet and Consent Form.
4. Please revise the Participant Information Sheet to remove typographical errors.
5. Please ensure all of the necessary information is included in the Participant Information Sheet. For example, the application form states that participants will be reimbursed for travel expenses, but this is not included in the Participant Information Sheet.
6. The Committee requested the compensation wording is updated for accuracy, they suggested the following statement: *“If you were injured in this study, which is unlikely, you would be eligible to apply for compensation from ACC just as you would be if you were injured in an accident at work or at home. This does not mean that your claim will automatically be accepted. You will have to lodge a claim with ACC, which may take some time to assess. If your claim is accepted, you will receive funding to assist in your recovery. If you have private health or life insurance, you may wish to check with your insurer that taking part in this study won’t affect your cover.”*

Decision

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

1. Please provide the advertising material for recruiting control participants.
2. Please remove references to collecting or testing breath from the study documents.
3. Please amend the information sheet and consent forms, taking into account the suggestions made by the committee (Ethical Guidelines for Observational Studies para 6.10).

This following information will be reviewed, and a final decision made on the application, by Dr Nora Lynch and Mrs Maliaga Erick.

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| **5** | **Ethics ref:** | **16/NTB/116** |
|  | Title: | LSFACT |
|  | Principal Investigator: | A/Prof Jonathan Koea |
|  | Sponsor: |  |
|  | Clock Start Date: | 23 June 2016 |

A/Prof Jonathan Koea 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 study seeks to validate a way to measure the fat content in a patient’s liver without taking a biopsy.
2. Participants will receive an MRI and have surgery to remove part or all of their liver as part of standard care. This study involves using a computer algorithm to interpret the MRI prior to their surgery. A tissue sample from the participant’s liver will also be taken to confirm the fat content that was determined by the MRI algorithm.

Summary of ethical issues (resolved)

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

1. In future applications please do not state ‘refer to protocol’ when asked for a summary in the application form.
2. In future, please use include more specific information in response to question p.4.1 regarding the potential benefits for Māori.
3. The Committee noted that the use of tissue had not been listed as a potential cultural issue from this study. Please take more care to identify these issues in future application.
4. The Committee questioned whether ethnicity data will be collected as part of this study. The Researcher confirmed that it will be collected, it was an error in the application form to state that it would not be.
5. The Committee questioned whether surgeons will be informed of the algorithm’s results before they perform the surgery. The Researcher explained that some surgeons will be informed of the results to see if this changes how they plan the surgery.
6. The Committee questioned whether it was possible that a scan results would reveal a very fatty liver, which would stop the surgery from going ahead. The Researcher stated that although a fatty liver slightly increases the risks from surgery they would not expect this to stop the surgery.
7. The Committee questioned why some participants will have a second scan. The Researcher explained that this is to determine if the results are repeatable.
8. The Committee asked how the number of participants had been determined. The Researcher explained that the total study numbers needed had been determined when the study was designed in Australia, and New Zealand is contributing the number of patients they reasonably expect to have in 1 year.
9. The Committee questioned whether study samples will be stored beyond the end of the study for any future purposes. The Researcher confirmed that the samples will be disposed of after the study.
10. The Committee questioned who is sponsoring the study. The Researcher explained that the study is sponsored by the University of Western Australia and they will be providing the software to analyse the MRI scans.
11. The Committee noted that the application form indicated that they did not intend to publish the study results in peer reviewed journals. They questioned whether this is accurate. The Researcher stated that this was a mistake in the application form.

Summary of ethical issues (outstanding)

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

1. Please adjust the Participant Information Sheet to make sure it is New Zealand appropriate, such as referring to the New Zealand Ethics Committee and where tissue samples will be sent in New Zealand.
2. Please remove the statement about jumping to conclusions from the Participant Information Sheet as this suggests that decisions are normally made ad hoc
3. Please clarify in the Participant Information Sheet what it means for participants to withdraw at various stages of the project. For example, after their sample has been collected and scan analysed they can choose to withdraw their data from the study, but if they withdraw earlier in the project they will still receive surgery and an MRI as part of standard care.
4. Please be clear in the Participant Information Sheet that tissue samples will stay in New Zealand and be analysed here, and only the results will be sent to Australia.
5. The Committee requested the compensation wording is updated for accuracy, they suggested the following statement: *“If you were injured as a result of treatment given as part of this study, which is unlikely, you* ***won’t*** *be eligible for compensation from ACC. However, compensation would be available from the study’s sponsor, [x], in line with industry guidelines. We can give you a copy of these guidelines if you wish. You would be able to take action through the courts if you disagreed with the amount of compensation provided. If you have private health or life insurance, you may wish to check with your insurer that taking part in this study won’t affect your cover.”*
6. Please remove the information on the risks of standard surgery from the Participant Information Sheet as this surgery is occurring regardless of the study and the Participant Information Sheet only needs to explain study specific risks and information.
7. Please remove the tick boxes from the Consent Form for everything that is not truly optional, that is, participants could tick ‘no’ and still participate in the study.
8. The Committee queried the lack of a Māori tissue statement in the Participant Information Sheet. The committee recommended the following statement: “*You may hold beliefs about a sacred and shared value of all or any tissue samples removed. The cultural issues associated with sending your samples overseas and/or storing your tissue should be discussed with your family/whanau as appropriate. There are a range of views held by Māori around these issues; some iwi disagree with storage of samples citing whakapapa and advise their people to consult prior to participation in research where this occurs. However, it is acknowledged that individuals have the right to choose.”*
9. Please remove the statement in the Participant Information Sheet about tissue samples being a gift or koha as the Committee feel that this is inappropriate.

Decision

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

1. Please amend the information sheet and consent form, taking into account the suggestions made by the Committee (*Ethical Guidelines for Intervention Studies* *para 6.22*).

This following information will be reviewed, and a final decision made on the application, by Dr Nora Lynch and Mrs Phyllis Huitema.

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| **6** | **Ethics ref:** | **16/NTB/119** |
|  | Title: | Efficacy of neutral electrolytically activated water use in patients with chronic rhino sinusitis |
|  | Principal Investigator: | Dr James Johnston |
|  | Sponsor: | University of Auckland |
|  | Clock Start Date: | 23 June 2016 |

Dr James Johnston 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. This study investigates an agent that is currently FDA approved but the Researchers believe is not supported by sufficient evidence from clinical trials.
2. The study agent is intended to be used to treat sinusitis by reducing the bacteria in the nose, it is hope that this will also improve post-surgery outcomes.
3. Sometimes patients’ outcomes following surgery can be worse due to infection and the prescribing of antibiotics does not seem to make a difference. This agent reportedly kills what may be living in patient’s noses and improves outcomes by increasing the flushing of the nasal cavity.
4. The study agent is carried in a hydrogel and there is evidence to suggest that the use of any hydrogel has a benefit so the control participants will also use a hydrogel, which does not contain the study agent.
5. Participants will receive standard of care plus a hydrogel, either with the study agent or without (the control arm). Participants in the surgery arm of the study would also usually receive antibiotics if they were not in the study, however, if they consent to being in the study they will not receive antibiotics, but will be monitored closely. The Researcher stated that although patients at their clinic get antibiotics after surgery, approximately 50% of patients across New Zealand will not receive antibiotics after this surgery and it does not seem to make a difference to their outcomes.

Summary of ethical issues (resolved)

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

1. The Committee noted that the peer review provided was quite critical of the study and questioned whether the peer reviewer’s comments had been addressed. The Researcher explained that they have modified the study in response to the peer review, such as by including a control group that get a hydrogel without the study agent.
2. The Committee questioned why the surgery participants will not be split in to 3 arms, adding one that receives antibiotics, as suggested by the peer reviewer. The Researcher stated that it is their view that antibiotics do not improve patient outcomes.
3. The Committee noted that the peer review suggested that the study would benefit from a more specific hypothesis. The Researcher defended their study design against the peer review comments and stated that their previous, similar, studies have provided suitable results.
4. The Committee questioned the data safety monitoring arrangements for the study, specifically will the researchers be able to identify poor results between the fortnightly swabs. The Researcher explained that the swabs will be analysed and compared to that patient’s previous swabs and they will be able to identify if that patient is doing poorly. The Researcher stated they will also be doing symptom scores to help monitor progress and if participants are doing poorly they will have their treatment changed. The Committee suggested that it may be better to have independent data safety monitoring, but that this is probably suitable for this study.
5. The Committee questioned whether this study involves future unspecified use of tissue. The Researcher confirmed that no tissue samples will be stored beyond the end of this study.
6. The Committee suggested that this sounds more like a pilot, or exploratory study. The Researcher agreed that it is really a pilot study. The Committee suggested rewording the study protocol to make this clear.
7. The Committee questioned how long participants have between being told of the study and having to provide informed consent. The Researcher explained that they will be able to go home and think about the study before needing to provide consent.
8. The Committee questioned whether Māori consultation will be obtained. The Researcher stated that they would do this as part of locality approval after HDEC approval.

Summary of ethical issues (outstanding)

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

1. Please revise the Participant Information Sheet to make it less bias towards the study agent.
2. The Committee requested the compensation wording is updated for accuracy, they suggested the following statement: *“If you were injured in this study, which is unlikely, you would be eligible* ***to apply*** *for compensation from ACC just as you would be if you were injured in an accident at work or at home. This does not mean that your claim will automatically be accepted. You will have to lodge a claim with ACC, which may take some time to assess. If your claim is accepted, you will receive funding to assist in your recovery. If you have private health or life insurance, you may wish to check with your insurer that taking part in this study won’t affect your cover.”*
3. Please add more information to the Participant Information Sheet about the rights of participants, such as who could see their data.
4. Please remove tick boxes from the consent form for all statements that are not truly optional, that is that participants could select ‘no’ and still participate in the study.
5. Please include the study inclusion and exclusion criteria in the Participant Information Sheet.
6. Please ensure it is clear in the Participant Information Sheet that study participants must still use the sinus rinses.

Decision

This application was *approved* by consensus, subject to the following non-standard condition.

1. Please amend the information sheet and consent form, taking into account the suggestions made by the Committee.

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| **7** | **Ethics ref:** | **16/NTB/114** |
|  | Title: | Effect of not fasting prior to coronary angiography and/or percutaneous coronary intervention on the incidence of vomiting and aspiration during the procedure. |
|  | Principal Investigator: | Prof Mark Webster |
|  | Sponsor: |  |
|  | Clock Start Date: | 23 June 2016 |

Prof Mark Webster and Ms Nicole Somerville 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 investigates a clinically important question, whether patients should fast before surgery or not.
2. Some clinics have stopped recommending patients fast before surgery and have not found an increased rate of vomiting with a risk of aspiration.
3. There are risks associated with fasting, such as hypoglycaemia, dehydration and kidney issues.
4. The research team believe that it would be beneficial to stop fasting before these interventions if it is unnecessary and potentially harmful.
5. Both study arms are standard care in different parts of New Zealand, most clinics recommend some level of fasting, while Dunedin does not recommend fasting.
6. The proposed study design involves randomising whole clinics to either fasting or non-fasting arms with the intention of not informing patients, or obtaining their informed consent, as the practice for the whole clinic is being randomised to one standard care arm or the other.

Summary of ethical issues (outstanding)

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

1. The Committee questioned why this study could not be done as a prospective observational study, using only routinely collected health information and comparing the outcomes from clinics that recommend fasting to those that do not. The Researcher explained that due to the very low incidence rates and need to control study variables they feel that a randomised controlled trial is the best study design. The Researchers noted that currently only one site in New Zealand does not recommend fasting and it would take a very long time to get sufficient numbers.
2. The Committee questioned how the number of 30,000 participants was determined. The Researcher stated that they need such high numbers due to the very low incidence rate, and that this is how many total patients they expect to see after 2 years across all study sites.
3. The Committee questioned whether there is any data about the incidence of hypoglycaemia and dehydration due to fasting. . The Researcher was unable to provide these during the meeting.
4. The Committee questioned why participants could not provide informed consent to their participation in the study as they would be asked to provide informed consent to their surgery. The Researcher stated that they felt it would not be possible to obtain informed consent from 30,000 people on practical grounds, and noted that by the time participants present to be consented for their surgery they have already fasted or not. The Committee stated that they did not feel that this is the case as patients are informed about their surgery in advance and at this point could be asked to fast or not prior to their surgery, the Committee felt that at this stage participants could be informed of the study and then consented when they present for their surgery.
5. The Committee stated that it is their view that informed consent could be obtained from participants as an information pack could be sent out with the information about their surgery and then the patient could discuss the study and provide consent when they are being consented to their standard surgery. The Researcher maintained that it was their view that obtaining consent is not practical and the risks associated with the study are so low that they should be able to continue with the study as presented. The Committee stated that regardless of whether they feel it is impractical to obtain consent that it is their understanding that they cannot approve the application in its current form due to it being contrary to New Zealand law.
6. The Committee asked if a patient could decline fasting or insist on fasting regardless of the arm the hospital was assigned to. The researcher said yes they could and they would still be able to undergo the intervention. The Committee noted that if patients do not know they are part of a research project, they could not decline to participate.
7. The Committee stated that it is a patient’s right to be informed and provide consent to their participation in any research project. The right not to be subjected to medical or scientific experimentation without that person's consent is covered by section 10 of the New Zealand Bill of Rights Act 1990. Research involving participants who are not competent to consent is inconsistent with the Bill of Rights unless it is undertaken in accordance with Right 7 (4) of the of the Code of Health and Disability Services Consumers’ Rights. The Committee noted that although Right 7(4) can be applied to research projects where participants are unable to provide informed consent this does not apply in this case as participants are able to provide informed consent. The Committee noted that Right 6 of the HDC Code of Rights secures patient’s right to be informed of their participation in a research project, and Right 7 secures a patient’s right to consent to their participation in research.
8. The Committee stated that, in line with the HDC Code of Rights and the New Zealand Bill of Rights Act 1990, participants who are able to provide informed consent must be informed and provide consent to their participation in a research project. The Committee stated that they cannot approve a study that is contrary to New Zealand law meaning that they cannot approve this project if informed consent is not obtained from study participants.
9. The Committee suggested that the Researchers could obtain their own legal advice and resubmit their study for HDEC approval if they felt this was appropriate.

Decision

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

1. Ethical Guidelines for Intervention Studies paragraph 6.8, people are entitled to make free and informed decisions about their participation in a study.
2. Right 6 and 7 of the HDC Code of Rights, the Right to be Fully Informed and the Right to Make an Informed Choice and Give Informed Consent.
3. Section 10 of the New Zealand Bill of Rights Act 1990, the right not to be subjected to medical or scientific experimentation without that person's consent

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| **8** | **Ethics ref:** | **16/NTB/120** |
|  | Title: | MAKO RAPTOR study (Robot Assisted Partial vs. Total knee Replacement) |
|  | Principal Investigator: | Mr Simon Young |
|  | Sponsor: |  |
|  | Clock Start Date: | 23 June 2016 |

Mr Luke Brunton 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. This study compares robot assisted partial and full knee replacement surgery.
2. Surgeons are more experienced at performing total knee replacements, however, partial replacements can produce better results. Partial replacements are also more difficult as there is less margin for error.
3. Robot assisted surgery is proposed to be used to do partial knee replacement more accurately.

Summary of ethical issues (resolved)

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

1. The Committee questioned whether the surgery can be revised if it does not produce the desired result. The Researcher explained that it is difficult to revise full knee replacement so they do not do this often, but partial knee replacement is easier to revise and is done more frequently.
2. The Committee noted that the researchers propose to keep participants blinded for 2 years following surgery but does not mention that this will prevent them from looking at their x-rays. The Researcher noted that maintaining blinding is important, but that of course if participants insist on viewing their x-rays they cannot be prevented from doing so.
3. The Committee suggested asking participants at the end of 2 years to guess which study arm they were assigned to. The Researcher stated that they felt that this would be a good idea to show effective blinding.

Summary of ethical issues (outstanding)

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

1. The Committee questioned whether the peer reviewer is independent from the study. The Researcher explained that the study had been reviewed by the entire department as well as being endorsed by the peer reviewer. The Committee questioned what was considered by the peer reviewer. The Researcher stated that they considered whether the costs of conducting the study were worthwhile given the cost of the device needed for the surgery. The Committee requested further evidence of what was considered by the peer reviewer, they recommend the peer reviewer completes the HDEC peer review template.
2. The Committee questioned the data safety monitoring arrangements for the study. The Researcher stated that they do not currently have any formal arrangements. The Committee stated that they feel it is important to have formal, suitably independent, data safety monitoring for this study, please arrange this.

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

1. Please ensure participants are informed in the Participant Information Sheet that surgeons are more experienced with full knee replacement surgery.
2. Please clarify that participants will be asked to not look at their x-ray to maintain blinding throughout the study.
3. Please revise the Participant Information Sheet to reduce the bias, currently it appears that the robot assisted surgery is far superior but this is not yet known.
4. Please ensure the Participant Information Sheet references the correct ethics committee.
5. Please be clear in the Participant Information Sheet when stating ‘doctor’ whether this is the study doctor, surgeon, or the participant’s GP.
6. The Committee requested the compensation wording is updated for accuracy, they suggested the following statement: *“If you were injured in this study, which is unlikely, you would be eligible* ***to apply*** *for compensation from ACC just as you would be if you were injured in an accident at work or at home. This does not mean that your claim will automatically be accepted. You will have to lodge a claim with ACC, which may take some time to assess. If your claim is accepted, you will receive funding to assist in your recovery. If you have private health or life insurance, you may wish to check with your insurer that taking part in this study won’t affect your cover.”*
7. Please add a lay study title to the top of the Participant Information Sheet.

Decision

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

1. Please provide evidence of favourable independent peer review of the study protocol (*Ethical Guidelines for Intervention Studies* Appendix 1).
2. Provide details of the Data Safety Monitoring plans *(Ethical Guidelines for Intervention Studies para 6.50).*
3. Please amend the information sheet and consent form, taking into account the suggestions made by the Committee (*Ethical Guidelines for Intervention Studies* *para 6.22*).

This following information will be reviewed, and a final decision made on the application, by Dr Nora Lynch and Mrs Maliaga Erick.

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| **9** | **Ethics ref:** | **16/NTB/117** |
|  | Title: | A study to determine the relative bioavailability of ACH-0144471 after administration of a tablet or softgel capsule vs. a liquid filled capsule in healthy volunteers. |
|  | Principal Investigator: | Dr Paul Hamilton |
|  | Sponsor: | Clinical Network Services Ltd |
|  | Clock Start Date: | 23 June 2016 |

Dr Paul Hamilton and Ms Mary Elis-Pegler 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 is an open label crossover bioavailability study comparing different versions of administration of the study drug.
2. Participants will receive a number of tablet formulations over the study period, with a 4 day washout period between dosing.

Summary of ethical issues (resolved)

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

1. The Committee questioned whether there is more than one study site, risking participants being in the study twice. The Researcher confirmed that there is only one study site.
2. The Committee noted that this is not a first in human trial but that only limited research in humans has been conducted so far.
3. The Committee questioned the risk of patients getting meningitis. The Researcher stated that this is a very low risk as the half-life is short and they have a suitably washout period to help prevent this.
4. The Committee questioned whether all participants can be expected to know if they meet some of the exclusion criteria. The Researcher stated that they agree that some participants will not know if they meet some of the exclusion criteria and they will have a liver function test as part of screening to confirm.
5. The Committee questioned how much of a risk the exclusion criteria of excessive drinking is as they are concerned that participants may be incentivised to lie to meet the inclusion criteria. The Researchers stated that it is essential that participants are sufficiently healthy and they do their best to ensure this during screening.
6. The Committee noted that the plan English summary in the application form was not sufficiently written in lay language, in future please ensure that this summary could be understood by a lay person.

Summary of ethical issues (outstanding)

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

1. The Committee questioned whether the researchers have formal independent data safety monitoring for this study. The Researcher stated that they do not currently have any formal data safety monitoring arrangements. The Committee stated that they feel that formal data safety monitoring is necessary for this study and requested this is arranged.
2. The Committee questioned whether tissue samples will be stored beyond the end of the study, currently the Participant Information Sheet and Consent Form contradict each other. The Committee stated that this must be confirmed and if the tissue will be stored in New Zealand for future research beyond the end of the study it must be stored in a HDEC registered Tissue Bank.
3. The Committee questioned how the body detoxifies the study drug. The Researcher was unable to clarify during the meeting. Please clarify this for the Committee.

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

1. If tissue is being stored for future unspecified research beyond the end of this study please provide a separate Participant Information Sheet and Consent Form for this, following the HDEC template.
2. Please clarify in the Participant Information Sheet whether a lure will be put in for blood tests.
3. Please ensure the contraception section is written in lay language so participants will know if these apply to them.

Decision

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

1. Please respond to the Committee’s outstanding ethical concerns detailed above.
2. Provide details of the Data Safety Monitoring plans (Ethical Guidelines for Intervention Studies para 6.50).
3. Please amend the information sheets and consent forms, taking into account the suggestions made by the Committee (Ethical Guidelines for Intervention Studies para 6.22).

This following information will be reviewed, and a final decision made on the application, by Dr Nora Lynch and Mrs Phyllis Huitema.

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| **10** | **Ethics ref:** | **16/NTB/122** |
|  | Title: | A multi-site, open-label extension trial of RPC1063 in relapsing MS |
|  | Principal Investigator: | Dr Deborah F Mason |
|  | Sponsor: | PPD Global Limited (New Zealand Branch) |
|  | Clock Start Date: | 23 June 2016 |

Ms Jane Eagle 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. Currently a number of treatments are available for patients with MS.
2. This study investigates a new generation of one of the treatments that is in a tablet form rather than injectable.
3. This is an open label extension study that will investigate the long term safety and efficacy of the study treatment.

Summary of ethical issues (resolved)

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

1. The Committee questioned the need for the suicide questionnaire. The Researcher stated that this is a requirement for any study drugs that pass the blood brain barrier. The Committee questioned what happens if participants have suicidal thoughts. The Researcher stated that they will be referred to the appropriate services.
2. The Committee questioned whether this study has independent data safety monitoring. The Researcher confirmed that this is the case.
3. The Researcher stated that they accidentally stated in their application form that they are not obtaining Māori consultation, however, this is incorrect and they are pursuing this.
4. The Committee questioned whether any tissue samples will be stored for research beyond the end of this study. The Researcher confirmed that blood samples are only taken for safety and will not be stored beyond the study.

Decision

This application was *approved* by consensus.

## General business

1. The Committee noted the content of the “noting section” of the agenda.
2. The Chair reminded the Committee of the date and time of its next scheduled meeting, namely:

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| **Meeting date:** | 02 August 2016, 12:00 PM |
| **Meeting venue:** | Novotel Ellerslie, 72-112 Greenlane Road East, Ellerslie, Auckland |

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.

The meeting closed at 5:20pm