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| **Committee:** | Northern B Health and Disability Ethics Committee |
| **Meeting date:** | 06 September 2016 |
| **Meeting venue:** | Novotel Ellerslie, 72-112 Greenlane Road East, Ellerslie, Auckland |

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| **Time** | **Item of business** |
| 12.00pm | Welcome |
|  | Confirmation of minutes of meeting of 02 August 2016 |
|  | New applications (see over for details) |
| 12.30pm | i 16/NTB/140  ii 16/NTB/152  iii 16/NTB/141  iv 16/NTB/145  v 16/NTB/143  vi 16/NTB/150  vii 16/NTB/151  viii 16/NTB/153  ix 16/NTB/154  x 16/NTB/155  xi 16/NTB/156  xii 16/NTB/157 |
|  | Substantial amendments (see over for details) |
|  | i NTY/08/06/055/AM07 |
| 5.55pm | General business:   * Noting section of agenda |
| 6.00pm | 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 | Present |
| 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 | Apologies |
| Mrs Kate O'Connor | Lay (ethical/moral reasoning) | 14/12/2015 | 14/12/2018 | Apologies |
| 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 | Present |
| Mr John Hancock | Lay (the law) | 14/12/2015 | 14/12/2018 | Present |
| Dr Kate Parker | Non-lay (observational studies) | Co-opt | Co-opt | Present |

## Welcome

Mrs Kate O’Connor sent her apologies. Mrs Stephanie Pollard was voted to be acting chairperson in Mrs O’Connor’s absence.

The Acting Chair opened the meeting at 12.05pm and welcomed Committee members, noting that apologies had been received from Mrs Kate O’Connor and Ms Phyllis Huitema.

The Acting Chair noted it would be necessary to co-opt members of other HDECs in accordance with the SOPs. Dr Kate Parker confirmed their eligibility, and were co-opted by the Acting 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 02 August 2016 were confirmed.

## New applications

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| **1** | **Ethics ref:** | **16/NTB/140** |
|  | Title: | 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: | 25 August 2016 |

Dr Bruce Arroll (CI) and Danyon Harris in person 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. The Committee noted the additional peer review and Prof Arroll's letter responding to the previous decline.

Summary of ethical issues (resolved)

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

1. The Committee requested clarification about data collection for participants changing interventions at 8 weeks. The Researcher(s) stated in the past trial they did try to continue data collection however they found that once the participants depart from the intervention it proves very hard to follow up, as the participants lose interest. Due to this experience the researchers have decided not to conduct further study follow up.
2. Please also confirm no further follow up, noting that the peer review mentions 12 month follow up but this is not in the protocol uploaded. The Researcher(s) stated they did not plan to do a 12-month follow up.
3. P.1.1- still says control will be reading about stress management, hasn't been adjusted from last application – however HDEC Secretariat this can’t be changed.

Summary of ethical issues (outstanding)

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

1. Please provide a CV for Suzanne Henwood.
2. The Committee queried if there is a statistician analysis plan in place. The Researcher(s) explained the protocol outlines the analysis plan.
3. The Committee noted there was still some lack of clarity around primary and secondary outcomes in the protocol. Specifically, it states anxiety scale described as the primary outcome, though the Committee remained unclear what category of outcome heart rate variability and dichotomised STAI are. They are currently listed between primary and secondary outcomes. Furthermore, in data analysis section, HADS is mentioned as a secondary outcome. It is not mentioned in the "Outcomes" section. The Researcher(s) provided more information about the expected outcomes of the study.
4. The Committee requested the statistician provide advice in a letter form, on how to measure the outcomes for the study.

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

1. Add correct NTB reference (page 1 and 2).
2. Consider use of word 'treatment' throughout and change to intervention.
3. Describe generically what the interventions are, e.g. ‘you will be asked to think about some scenarios’.
4. Currently directs participant to get a 'high enough' score. Use more neutral language, e.g. researchers will review the completed questionnaires for suitability to participate.
5. Confirm how patient may withdraw, i.e. tell researcher and what this means including limitations, i.e. of data analysed will it continue to be used.
6. Add that this study is part of a Masters degree.
7. State you can stop for any reason, not just ‘if you feel you can’t go on’.
8. Clarify the interpretation options.
9. Make it clear what information will go to GP and how that will work for participants.
10. Please confirm if reimbursement for travel is available, including for parking. The Researcher(s) stated they have some funds available for reimbursement. Please add a clear statement about reimbursement.
11. The Committee noted the wording for compensation is confusing, it could state ‘there is no cost to participate in this study, and if you do have a treatment injury, you are eligible to seek compensation from ACC’.
12. The Committee queried whether it was possible to have a Maori contact person listed, and requested the researchers check with ADHB who often have someone who can provide Maori support.

Decision

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

* Provide a review from the statistician with respect to outcomes of the study. (Ethical Guidelines for Intervention Studies para 5.5).
* Provide CV of co-investigator (Ethical Guidelines for Intervention Studies para 5.36)
* 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 Stephanie Pollard and Ms Mali Erik.

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| **2** | **Ethics ref:** | **16/NTB/152** |
|  | Title: | MK-8521 Phase IIa Trial in Subjects with Type 2 Diabetes Mellitus (protocol MK-8521-004) |
|  | Principal Investigator: | Dr Simon Carson |
|  | Sponsor: | Merck Sharp & Dohme (New Zealand) Limited |
|  | Clock Start Date: | 11 August 2016 |

Dr Simon Carson was not present 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 a 4 arm blinded randomised controlled trial of a new drug (and also an established drug that is not registered in New Zealand yet) in type 2 diabetics with poor control.
2. Participants receive either MK-8521 at one of 2 doses, lirogluteide or placebo. Interventions are added to metformin but some participants will have a second oral antidiabetic drug washed out before starting the trial interventions/placebo.
3. Duration of treatment 12 weeks, total study time 25 weeks.

Summary of ethical issues (resolved)

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

1. F.1.1 The Committee noted that there is a disproportionate incidence of the disease in Maori, but acknowledged that this particular trial may not reduce inequalities due to its early phase.
2. R.1.6 stopping the study for "administrative reasons" is not legitimate.

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 the extensive exclusion criteria in Participant Information Sheet may be unnecessary, please explain the need for this or reduce to the most important ones.
2. The Committee noted the use of a placebo for 12 weeks in 25% participants, some of whom may have had one of their existing antidiabetic drugs removed at trial beginning. The Committee noted the periods without any medication for medication-controlled diabetes is concerning, particularly because there is no plan for what to do if this medication-free period produces adverse events.
3. The Committee noted the participant information does not cover this sufficiently and even states there is no rescue therapy.
4. Please explain safety and monitoring mechanisms to ensure participants are kept safe and harms are reduced.
5. The Committee would be reassured if positive peer review by a local diabetologist could be provided.
6. The Committee noted the composition of DMC is lacking a statistician and is all internal. The protocol refers to charter for SIDMC but does not give details. Please submit the DMC charter.
7. Confidentiality: Pg. 13 of PIS. The Committee queried why there are both initials and DOB as well as study number need to do on tissue / study data that is sent to Sponsors. Either initials or DOB should be a sufficient cross check, but the Committee does not see the need to send both, noting this increases possibility of identification.
8. The Committee queried whether potential participants are to sign additional consent for HIV testing in New Zealand, and requested information on what will happen if they were to test positive?
9. The Committee queried how participants report adverse events and how will these be managed.
10. The Committee noted that the statement 'your condition will not be treated' under placebo risk section is not true, as Metformin is a treatment and equally cannot infer the experimental arm is a treatment. The risk of condition worsening/staying same is equal across groups.
11. The Committee queried the data storage for 50 years, which is much longer than the study.
12. Pg. 12 of PIS. What will be photographed? Please provide more information to the Committee.

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

1. Make the lay title the first title (to both information sheets).
2. Future Research Consent Form: What happens to my sample? Provide details regarding ‘sponsor’s designate storage facility’ i.e. tissue goes from Singapore to where?
3. Clearly indicate payment to participants. The Committee also queried if there is a cap on claims, please clarify for the Committee.
4. Please ensure Maori health support details are included.
5. Move interpreter to front of consent form not the end.
6. Please explain what rescue medication means for participants.
7. No need to withdraw in writing. Please amend.
8. Pg. 14 - remove ref to US law.
9. Consent form - add pregnancy risks statement and that samples are being sent overseas.
10. The Committee requested the risks of not taking medications are outlined.
11. The Committee noted that a simple brief diagram to explain timeframe would be helpful, i.e. 25 weeks total but made up of various washouts, treatment and follow ups. etc. NZ English. Simplify language, e.g. sympathomimetic, gastroperesis.
12. Liraglutide not available in New Zealand. Clarify for participants - i.e. not registered or not funded.
13. 'PK" samples not explained prior. Please explain for participants.
14. The Committee noted there is a remote risk that identifiable data is sent. There should be a protocol for dealing with this, which should include notification to participant and possibly notice to Privacy Commissioner.

Decision

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

* 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*).
* Provide details of the Data Safety Monitoring Committee’s composition and monitoring plan *(Ethical Guidelines for Intervention Studies para 6.50).*
* Provide further justification of withholding standard of care *(Ethical Guidelines for Intervention Studies para 5.15).*
* *Address outstanding ethical issues in a cover letter.*

This following information will be reviewed, and a final decision made on the application, by Mrs Leesa Russell.

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| **3** | **Ethics ref:** | **16/NTB/141** |
|  | Title: | Genomic mechanisms underlying long‐term response to treatment in serous ovarian cancer. |
|  | Principal Investigator: | Doctor Bryony Simcock |
|  | Sponsor: |  |
|  | Clock Start Date: | 25 August 2016 |

Dr Bryony Simcock 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.

Dr Kate Parker declared a potential conflict of interest, and the Committee decided that the conflict was not substantial and Dr Parker could stay and participate in the discussion.

Summary of Study

1. This is an Australian observational study that aims to include 10 participants from New Zealand. The study looks at long term survivors (chemo responders) with ovarian cancer.
2. Genetic, demographic and lifestyle information collected and linked, with optional future research including immortalised cell lines.

Summary of ethical issues (outstanding)

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

1. Please explain who will pay for the genetic counselling.
2. Please clarify how long samples are kept if they are not stored for future unspecified research.
3. The Committee noted the application stated that there are no ethical issues – this is incorrect. Just some examples of ethical issues are future unspecified research and genetic research.
4. Please confirm independence of peer reviewer.
5. The Committee noted Comprehensive Maori consultation response from Eru Waiti, Komiti Whakahaere. The Committee requested the researchers respond to the reviews suggestions and address any points raised, in full, to the HDEC.
6. Related to the note above, the Committee noted there is a need for much clearer information for Maori regarding sending tissue overseas for future research. Suggested to include the Maori review comments in the Participant Information Sheet.
7. The Committee noted that statistics regarding this disease in Maori women would be useful at p.4.1 on pg. 22 of the application.
8. The Committee noted the potential for stress on women who want to forget about their cancer. Stress of a possible heritable genetic mutation being discovered. This may be balanced for some by the knowledge that their good fortune in having a good outcome can be shared with others.
9. What is the protocol in New Zealand for dealing with genetic info that may confer future risk and needs to get back to the participant?
10. Please explain how this study will interact with established tissue banks.
11. Please explain how identification of participants occurs. Clarify what time (in relation to women’s treatment) is approach occurring and how stress or harm due to anxiety is being managed.
12. Please explain how consent for use of tissue that may be taken in future surgery actually work in New Zealand.
13. Remove ethnicity collection from Participant Information Sheet, as this is for informed consent not data collection, but do collect that data using New Zealand census categories elsewhere.
14. The Committee queried whether consent is multifactorial, i.e. can an individual choose certain components only, eg biomarkers, genetics.

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

1. Add other institutions that are involved (their location).
2. Remove mention of NHMRC as this is not relevant for a New Zealand audience.
3. Please make it clear that this study involves tissue, not just data.
4. The Committee noted that cell lines are not talked about later, though the PIS/CF states cell lines will be explained. Please review.
5. Last two points of consent form – page 12 – are confusing as the answers can’t both be yes. Please revise.
6. Please add HDEC information, for example that HDEC reviewed the study (see HDEC template participant information sheet for information to include).
7. The clause in consent regarding return of significant genetic information regarding a disease risk needs to be divided into two parts - one to indicate participants wish to be informed and a second giving permission for family to be informed if patient "not around".
8. Can you participate at all in the main study if you don't want to give blood? PIS suggests you can but I think this is not the intention.
9. Future unspecified research consent form: the Committee noted participants can’t withdraw information that is already analysed. Please describe limitations of withdrawal for participants.

Decision

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

* Please amend the information sheet and consent form, and assent forms, taking into account the suggestions made by the Committee (*Ethical Guidelines for Observation Studies* *para 6.11*).
* Provide more information on return of study results (*Ethical Guidelines for Observation Studies* *para 9.1*).
* Respond to Maori review and incorporate suggestions into the study (*Ethical Guidelines for Observation Studies* *para 4.4).*
* *Respond to outstanding ethical issues in a cover letter.*

This following information will be reviewed, and a final decision made on the application, by Dr Kate Parker.

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| **4** | **Ethics ref:** | **16/NTB/145** |
|  | Title: | Antibiotic Timing and Culture Yields in Paediatric Musculoskeletal Infection |
|  | Principal Investigator: | Mr Matthew Boyle |
|  | Sponsor: |  |
|  | Clock Start Date: | 25 August 2016 |

Mr Matthew Boyle was not present 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 a retrospective cohort study of data from children who have had blood-culture positive bone or joint infection between 1997-2007.
2. The study question explores whether those with positive and negative cultures on biopsied deep tissue or synovial fluid differ with regards to whether antibiotics were given before or after biopsy collection.
3. The project aims to inform future practice at Starship.

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 it is unclear whether data has been consented for this use, noting the claim that data comes from a database to which consent has already been given (p.1.4). Please clarify what participant’s guardians consented to. The Committee noted that regardless of this consent, the study would seem to satisfy 6.43 a) + b) of Observational Guidelines, and stated they did not have an ethical problem with the use of the data.

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 the lack of detail on data analysis. The Committee queried if the has researcher spoken to the statistician yet. Please provide more information.
2. The Committee noted that the researchers have not considered confounders. This is important if guidelines are to be developed from this research. This study must address confounders due to it being a retrospective study e.g. possibility that severity of illness might influence timing of antibiotic and also bacterial burden as reflected in deep tissue/joint fluid culture - positive rate.
3. The Committee noted that the retrospective Canadian study, given as an example, showed presurgical antibiotics associated with higher culture rate on biopsied tissue. This is counter intuitive and may be due to such confounding.
4. The Committee noted that while the peer review is very positive it has not considered design limitations. The Committee requested further peer review from research expert (including a statistician) who may be able to improve study design. Please use the HDEC peer review template.
5. The Committee expressed concerns with observational data being used to justify changing practice, opposed to the data informing an RCT which would then inform practice change. Please explain this decision-making.
6. A.5.1 The Committee noted that the sponsor is the DHB for this study.
7. Clarify where it will be stored and whether study number will be allocated.
8. P.4.3 the research issue is of relevance for Maori health, so Maori consultation will be required.

Decision

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

* Please provide evidence of favourable independent peer review of the study protocol (*Ethical Guidelines for Intervention Studies* Appendix 1)
* 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 Observational Studies* para 5.7). The Current proposal does not assure the committee of the scientific rigour of the project.

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| **5** | **Ethics ref:** | **16/NTB/143** |
|  | Title: | Evaluation of MORSim (Multidisciplinary Operating Room Simulation). |
|  | Principal Investigator: | Dr Peter Beaver |
|  | Sponsor: | The University of Auckland |
|  | Clock Start Date: | 25 August 2016 |

Associate Professor Jennifer Weller (Co-investigator), Dr Peter Beaver (Coordinating investigator) 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 is an evaluation of a training programme for theatre staff aimed at reducing intraoperative error. The Committee noted it was a complicated study that uses a stepped wedge cluster design. The intervention is progressively rolled out across DHBs all of whom contribute data from the outset giving 'before and after' data. Many outcomes measures that seem like they are going to be treated as separate studies. Both surgical patients and surgical staff are participants.
2. 12 outcome measures including 7 directly involving staff or surgical patients.

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 the Maori consultation that had occurred. The Researcher(s) noted that they think they can show they can improve health outcomes for all surgical patients, however the concerns in relation to analysis of differences between Maori and other ethnicities is an additional resource.
2. The Committee queried if ethnicity collection will be incorporated into the study. The Researcher(s) stated we would from national minimum dataset, and ACC claims. Probably in orthopaedic registries too. We can’t support it in patient outcomes measure as a funding application for this was declined.
3. The Researcher(s) explained someone in future could conduct the research, provided we collect it where possible.
4. Make it clear that participant data may be used in future research, and give examples.
5. The Committee queried the access of staff employment data without consent. The Researcher(s) explained this did not involve any individual data – just aggregate data. The Committee accepted this.
6. The Committee asked under what circumstances researchers would be asked to leave if clinicians perceive that a patient is being disadvantaged by the research. The Researcher(s) stated for some kinds of surgery having more people in the room it could cause problems, or if a patient has an anxiety that is known to the participants. The Committee noted it could also occur if something went wrong with a surgery, the surgeon should have the right to need space and focus in the room.
7. R.2.6 The Committee noted there is a stated risk of identifying participants in publication. The Committee asked whether this referred to staff, and queried how this be minimized or mitigated. The Researcher(s) stated they will not attribute quotes to particular job titles, but this is a risk due to the size of the sample size, and those reading it know the mannerisms of individuals, through the content provided. The Researcher(s) added the participants can redact transcripts and also understand the audience of the work.
8. The Researcher(s) noted graduations of protection, i.e. paraphrasing to avoid direct quotation. Individuals will get a right of review of the publication.

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 queried what kind of information is given to participants, noting the large amount of ‘informal consent’. The Researchers explained the engagement they were conducting to inform people of the study.
2. The Committee queried what informal consent / verbal consent actually means, is this recorded in writing? The Researcher(s) stated there is agreement sought from staff, but were unclear whether this was recorded.
3. The Committee noted the potential for indirect pressure to be applied if for example some theatre staff have consented but another doesn't want to participate, particularly in group settings. The Committee queried whether there is a conflict of interest, due to power imbalances between junior staff being asked to be observed by their superiors. The Committee queried whether the staff actually have a choice. The Researcher(s) noted it could be possible to approach consent individually, before the observation occurs.
4. The Researcher(s) explained in past work we have meetings and posters so that individuals are aware of the project.
5. The Committee discussed consent and mitigation of pressure to participate. The Committee suggested consenting everyone prior. The Researcher(s) explained other practices during audit about consent (verbal) – however the Committee noted difference between audit and research.
6. The Committee discussed opt out, with written documentation on the day. The Researcher(s) noted that the researchers could write this consent down. The Committee agreed.
7. The Researcher(s) confirmed there is a website with lots of information on this project.
8. The Researcher(s) noted they will add the research information on the website too.
9. The Committee queried who determines vulnerability for patient outcome measures? The Researcher(s) stated informed consent for the surgical procedure would demonstrate whether someone can or can’t consent for research.
10. The Committee queried whether it was possible someone could consent for surgery but would be inappropriate for the research. The Researcher(s) stated yes in theory. The Committee requested a process around those who are consenting would have some method of indication of appropriateness of participation.

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

1. The Committee noted that the participant information does not include details of what MORSIM is about or what each participant will be expected to do. For example, who will be performing interviews and administering surveys given number of these over various locations. Please add more information.
2. Please review the HDEC template participant information sheet to identify what information is currently missing.

Decision

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

* Please amend the information sheet and consent form, and assent forms, taking into account the suggestions made by the Committee (Ethical Guidelines for Observation Studies para 6.11).
* Provide an overview of the new consent plan that provides more opportunity to say no, and reduce coercion.
* Formalise the privacy mitigation plan by outlining process to ensure confidentiality when publishing.

This following information will be reviewed, and a final decision made on the application, by Mrs Stephanie Pollard.

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| **6** | **Ethics ref:** | **16/NTB/150** |
|  | Title: | DESIGNING The SCORECARD Project |
|  | Principal Investigator: | Mr Steve Waqanivavalagi |
|  | Sponsor: | University of Auckland |
|  | Clock Start Date: | 25 August 2016 |

Mr Steve Waqanivavalagi 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 is a feasibility study to test intrathoracic cardiac ultrasound during coronary vein grafting to check graft patency. This is a forerunner to a definitive study that will use this measurement tool to evaluate the effect of sildenafil (blood vessel dilator, anti sludging effect, cardiac "pre-conditioner").
2. The investigators are simulating the effects of sildenafil in this study in half the participants; by BP cuff inflation to produce forearm ischaemia that is hoped will have a dilating effect on grafts.

Summary of ethical issues (resolved)

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

1. The Committee asked how long the probing intervention takes. The Researcher(s) stated maximum of 2 minutes.
2. The Researcher(s) explained that Christchurch conducts this routinely in most cases, but not in Auckland. With in service training we have worked with nursing team and got it down to 2 minutes. A SCORECARD project investigator checks this.
3. The Committee noted the researchers provide potential participants with the HDC consumer rights booklet.
4. The Researcher(s) confirmed this study population would be comparative with sildenafil population.
5. The Committee queried when exclusion criteria for blood pressure (BP) are assessed. The Researcher(s) stated it would be at the time of wheeling patient pre-operatively.
6. The Researcher(s) confirmed if BP dropped we would exclude. The Researcher(s) noted sildenafil reduces BP, but some evidence suggests the drop of ischemic BP is not important, but we think it could be important. Exclusion will therefore be a decision between surgeon and anaesthetist.

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 request explanation of what ischemic pre-conditioning is. The Researcher(s) explained that pre-conditioning gives the heart some idea of the conditions where there is low oxygen to reduce risks. For example if you suddenly take oxygen away from a heart it can result in a heart attack. In situation where you have patient with severe coronary heart disease (narrow) you get reduction of blood flow. The sudden introduction of blood can lead to problems. Therefore you train the heart to be used to those conditions – one way of doing this is to use blood pressure inflation after patient is put to sleep. This technique is well validated in literature though the benefits are not established enough to made it widely used. In terms of risk, the researchers stated they felt the risks were minimal. The Committee suggested explaining this in the Participant Information Sheet in lay language, as you have explained today.
2. The Committee queried DSMC arrangements. See if anyone is available to give oversight to the study. Ideally someone who is removed from the study.

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

1. Add lay language explanation of how the BP cuff inflation regimen links to the ultrasound, as that is the crux of the research and it is currently not clear.
2. Please add that participation adds 2 minutes to surgery length.
3. Ethics committee NTB not NTA
4. Add that it is going to form part of educational degree.
5. Please amend sentence that explains that nothing in terms of patient care changes, to accurately state additional monitoring that is purely for the study.

Decision

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

* Please provide a peer review from anaesthetists. (*Ethical Guidelines for Intervention Studies* Appendix 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*).
* Every intervention study should have appropriate oversight of the conduct of the study to ensure the safety of the participants and the integrity and validity of the study data. Please clarify whether a qualified person could provide oversight of the study, ideally someone who is independent. (*Ethical Guidelines for Intervention Studies* *para 6.38)*

This following information will be reviewed, and a final decision made on the application, by Secretariat.

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| **7** | **Ethics ref:** | **16/NTB/151** |
|  | Title: | THRIVER-F |
|  | Principal Investigator: | Professor Alan F Merry |
|  | Sponsor: | Fisher & Paykel Healthcare Limited |
|  | Clock Start Date: | 25 August 2016 |

Jacqueline Hannam or Alan Merry 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 is a randomised controlled trial of a new nasally delivered system of pre anaesthetic oxygenation compared to conventional face mask. This is a feasibility study, with primary outcomes being anaesthetist and patient satisfaction.
2. The study involves children 10-16years.
3. The Committee noted the appropriate range of consents/assent provided.

Summary of ethical issues (resolved)

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

1. The Committee queried why a feasibility study design was chosen when using a device that has been tested in thousands of patients already. The Researcher explained that there had not been any formal research into these study questions.
2. The Committee queried if they should be looking at oxygen saturation in participants. Is this being measured in this study or the larger trial? The Researcher(s) stated they are collecting FEo2 levels immediately after intubation. This method will confirm our assumptions about what this data looks like. The Researcher(s) explained it is just how the data is looked at, not that it is new data collection.
3. The Researcher(s) noted having 200 participants’ means we can publish on ease of use in its own right, through this study. The Researchers also want to know about recruitment rates to help plan the larger study.
4. The Researcher(s) explained why anaesthetists are participants too.
5. The Researcher(s) confirmed fees go to uni-services for an account used for research.
6. The Committee queried whether pre-oxygenation is a standard of care. What percentage of New Zealand anaesthetists use it? The Researcher(s) stated 2/3 get some attempt at pre-oxygenation but only small amount get an appropriate level. The Committee asked whether it is actually a standard of care. The Researcher(s) stated it is debatable – the new guidelines state it is a standard of care. The Committee accepted that attempts to pre-oxygenate are standard of care.

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

1. Go through all PISs and standardise the font so it doesn't look like a 'cut and paste' job.
2. PIS is a bit light on what sort of "information" is collected i.e. personal health information as well as demographics should be spelled out.
3. Remove 18 years on the assent form.
4. Reword phrase about " you will be helping other kids'. Could be seen as coercive.
5. Please put pictures of the 2 different oxygenation systems on the PIS.

Decision

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

* 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 Kate Parker.

|  |  |  |
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| **8** | **Ethics ref:** | **16/NTB/153** |
|  | Title: | The FAB study |
|  | Principal Investigator: | Dr Rachael Parke |
|  | Sponsor: |  |
|  | Clock Start Date: | 25 August 2016 |

Dr Rachael Parke and Dr Shay McGuiness 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 is an Investigator led New Zealand study. The study will assess 2 approaches regarding how much IV fluid to give to post cardiac surgery patients in ICU.
2. The two arms of the study are either amount per protocol or amount per decision of clinician (usual care).
3. Primary outcome is the length of stay in ICU. Participation also involves two follow up phone calls for information from participants.
4. The Committee commended the Data Safety Monitoring Committee.

Summary of ethical issues (resolved)

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

1. The Committee would like to know what changes have been made to the study in response to peer review feedback. In particular, differentiation between the volume and type of fluid. The Researcher(s) noted two studies the researchers have participated in that focused on type of fluid (CHEST and SPLIT study). As a result of CHEST, the researchers do not use starch-based fluids. SPLIT showed only equivalency between different saline fluids, which observational research indicates are used differently around New Zealand, but noted that a study in 2018 would address this study question.
2. The Committee noted that consent is 24 hours prior to surgery ‘where possible’, please explain how often it would be for potential participants to have less than 24 hours to consent. The Researcher(s) explained that in ideal world would the researchers would know that potential participants are having surgery in advance and be able to give them information in advance. In some cases this would be possible, and when it is possible, the Researcher(s) stated they contact patients at home before surgery and send Participant Information Sheets so they can have more time to consider participation. However the way the surgery lists work mean that the patients are sometimes told about their surgery a day before their surgery. The Researcher(s) provided some details, for example 60-65% are inpatients, transferred on afternoon before surgery, some come in from home; some are transferred from other DHBs a day before. The Researcher(s) acknowledged the importance of increasing time to consider as much as possible.

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

1. Add Maori health contact details. The Researcher noted these will be updated at each site.
2. Remove collection of ethnicity off consent form, and collect elsewhere. Please ensure the most recent census categories are used to collect ethnicity.
3. The Committee noted the current layout is hard to read. In future please use the HDEC template. Remove tossing a coin reference and the Northern A HDEC reference and replace with Northern B.
4. In Para 2, cardiac surgery "..places the body under a great deal of stress...". This does not add to the understanding of this particular project and is a bit scary to read even though true. Please consider removing this.
5. Note that participants are only recruited if the study is deemed appropriate for the individual.
6. Under "Risks" it states: 'If you feel there is a problem you should alert the staff caring for you'. Participants shouldn't have to feel that they are playing a part in monitoring whether their fluid regimen is harming them or not. Please consider removing this.
7. Some important information has been omitted:

-What is option for treatment if you don't consent – please add.

-Right to withdraw consent and how to do this.

-Use correct ACC statement - can apply but not guaranteed. See HDEC template.

Decision

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

* 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 Leesa Russell.

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| --- | --- | --- |
| **9** | **Ethics ref:** | **16/NTB/154** |
|  | Title: | A study to evaluate safety and tolerability of GS -5801 in healthy subjects |
|  | Principal Investigator: | Prof Edward Gane |
|  | Sponsor: | Gilead Sciences, Australia & New Zealand |
|  | Clock Start Date: | 25 August 2016 |

Prof Edward Gane and Oliva 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 tests a new antiviral with some prospect of seroconversion i.e. cure.

1. The study is phase 1 first in human. The study has 2 cohorts that each taking progressively bigger doses.
2. Each cohort contains 8 active and 2 placebo participants. All participants get a single dose day 1, then after data analysis indicates safe to proceed, each in Cohort 1 and 2 are further treated for 8 days, Cohort 3 for 2 days.

Summary of ethical issues (resolved)

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

1. The Researcher(s) explained the study design that aims to safely escalate the dose.
2. Participants need to remain in the trials unit throughout the whole process: 21 days for Cohorts 1 and 2, 7 days for Cohort 3. The Committee noted this is a very long stay. The Researcher(s) stated the site had run a 28 day stay before, but acknowledged it is a very long stay.
3. The Committee queried ACS management for long stay studies. The Researcher(s) explained the procedures in place to mitigate any discomfort in such long restricted stays.
4. The Researcher confirmed GPs are notified prior to dosing to ensure participant safety.
5. R.1.6 – commercial reasons to terminate a study are not acceptable.

Summary of ethical issues (outstanding)

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

1. Adverts: clearly indicate that the 22 nights stay consists of 21 x consecutive stays.
2. R.1.4 – The Researcher(s) explained there is a medical monitor, and PI who is part of the monitoring team. The Researcher(s) explained that if it were a later phase study it would be external, but all early phase have internal committees. The Researcher(s) noted they are happy with the internal monitoring. The Committee asked to check with Sponsor about whether independent would be appropriate, but noted the rationale for having internal monitors, which was in line with NEAC guidelines.

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

1. Add details about what information goes to GP and why it is important. Include what other checks occur with the GP, in relation to the participant.
2. The Committee request confirmation of collection ethnicity as per New Zealand census questions. The Researcher(s) confirmed even if the sponsor sends through FDA based race questions the researcher(s) would collect local level ethnicity data too.
3. Please remove optional samples information from the main PIS, or note they will be discussed at optional consent.
4. Add where samples go and are stored, page 5. The Researcher(s) stated samples are sent to lab in US.
5. Please explain on what grounds sponsor would terminate study (page 16). The Researcher(s) stated safety is the primary reason. The Researcher(s) stated they would elaborate on this in the Participant Information Sheet and explain how participants will be followed up in the event of termination.
6. Please explain where Gilead sciences are based (on the first instance they are mentioned).
7. Remove need to withdraw in writing from study. Note verbal withdrawal acceptable – make this clear for participants.

Decision

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

* 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*).
* Seek sponsor comment on possibility of having external DSMC to ensure participant safety. *(Ethical Guidelines for Intervention Studies para 6.50).*

This following information will be reviewed, and a final decision made on the application, by Mrs Stephanie Pollard.

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| **10** | **Ethics ref:** | **16/NTB/155** |
|  | Title: | Comparison of the blood levels of two forms of clobazam suspension in healthy male and female volunteers under fasting conditions |
|  | Principal Investigator: | Dr Noelyn Hung |
|  | Sponsor: | Douglas Pharmaceuticals America Ltd |
|  | Clock Start Date: | 25 August 2016 |

Dr Noelyn Hung, Dr Tak Hung and Lind Folland 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 a pharmacokinetic bioequivalence crossover study of new generic liquid clobazam (from a New Zealand based drug development company) tested against a reference product.
2. Each participant (30 participants) receives a single dose 20mg of each product separated by at least 3 weeks. In house care for 36 hours each time a dose is administered.
3. The study involves blood samples resulting in around 460ml.

Summary of ethical issues (resolved)

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

1. The Researcher confirmed that if a participant needs to be withdrawn due to medical reasons that are related to the drug dose they will be paid the full amount. The Committee requested that this is made clear, as suggests if participants withdraw for medical reasons they will not be paid.
2. The Committee noted the justification of the payment level.
3. The Committee noted consultation had been received. Please email a copy to HDECS for completeness.

Summary of ethical issues (outstanding)

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

1. Please remove full amount of reimbursement from all advertising.

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

1. Change language from ‘ambient’ to ‘room temperature’.
2. Pg 1. Change ethics to NTB from Southern
3. The Committee noted the consent form is being used to collect data on age/gender/address/next of kin/contacts. This should be on a separate administrative form.
4. Note that data withdraw does not include data already analysed.

Decision

This application was *approved* by consensus with nonstandard conditions.

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| --- | --- | --- |
| **11** | **Ethics ref:** | **16/NTB/156** |
|  | Title: | Comparison of the blood levels of two forms of clobazam suspension in healthy male and female volunteers under fed conditions |
|  | Principal Investigator: | Dr Noelyn Hung |
|  | Sponsor: | Douglas Pharmaceuticals America Ltd |
|  | Clock Start Date: | 25 August 2016 |

Dr Noelyn Hung, Dr Tak Hung and Lind Folland 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 a pharmacokinetic bioequivalence crossover study of new generic liquid clobazam (from a New Zealand based drug development company) tested against a reference product.
2. Each participant (30 participants) receives a single dose 20mg of each product separated by at least 3 weeks. In house care for 36 hours each time a dose is administered.
3. The study involves blood samples resulting in around 460ml.

Summary of ethical issues (resolved)

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

1. The Researcher confirmed that if a participant needs to be withdrawn due to medical reasons that are related to the drug dose they will be paid the full amount. The Committee requested that this is made clear, as suggests if participants withdraw for medical reasons they will not be paid.
2. The Committee noted the justification of the payment level.
3. The Committee noted consultation had been received. Please email a copy to HDECS for completeness.

Summary of ethical issues (outstanding)

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

1. Please remove full amount of reimbursement from all advertising.

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

1. Change language from ‘ambient’ to ‘room temperature’.
2. Pg 1. Change ethics to NTB from Southern
3. The Committee noted the consent form is being used to collect data on age/gender/address/next of kin/contacts. This should be on a separate administrative form.
4. Note that data withdraw does not include data already analysed.

Decision

This application was *approved* by consensus with nonstandard conditions.

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| **12** | **Ethics ref:** | **16/NTB/157** |
|  | Title: | The prognostic significance of immune cell infiltrates in meningioma |
|  | Principal Investigator: | Dr Clinton Turner |
|  | Sponsor: |  |
|  | Clock Start Date: | 25 August 2016 |

Clinton Turner 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 Committee noted this study involves non-consented use of existing clinical tissue.
2. The study involves analysis of 600 samples.

Summary of ethical issues (resolved)

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

1. The Researcher explained that the tumours are benign, though there are a variety of grades and are often in and around the brain. They are difficult to treat.
2. The Committee asked about the survival rate. The Researcher(s) stated it depends on age of person though perhaps 20% of tumours recur. Elderly have about 25% mortality at 5 years, but this data is just one paper so is not definitive.
3. The Committee noted that there were considerations relating to practicality, stress or scientific merit that needed to be taken into account when approving use of tissue without consent.
4. The Researcher(s) explained there is practicality element to re-consenting, as the data is from 2002. Participants would be difficult to track down or have passed away. The Researcher explained that the main reason was scientific, and explained the potential for bias if we seek consent, which means the study results would not be generalizable.
5. The Committee and The Researcher(s) discussed what consents were given for the stored tissue samples. There appeared to be a range of statements on the clinical release forms over the years relevant to the samples.
6. The Committee accepted the argument made by the researcher, and felt that the social benefit outweighed the risk to privacy, and noted individuals would not be harmed by their tissue being used in this study.
7. The Committee noted that if there was any evidence available to indicate a sample should not be used for research that should be respected, but noted that it is unlikely for any evidence to exist for such old samples.
8. The Committee queried why keeping tissue identifiable, i.e. linked with records. The Researcher(s) stated need to link to look at outcomes so the samples must be potentially identifiable.
9. The Researcher(s) explained funding arrangements.
10. The Researcher(s) spoken to ADHB Maori review office. Locality review – goes formally though.
11. The Committee noted the value of the study. Public good outweighs privacy.

Summary of ethical issues (outstanding)

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

1. Provide update (letter) from ADHB Maori research assessment team.
2. The Researcher(s) agreed with the Committee suggestion to get tissue and data, link it then break link so the dataset was anonymised. Please update the protocol to outline this process.

Decision

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

* Please update the HDEC on consultation due to the use of tissue without consent (*Ethical Guidelines for Observation Studies* 4.4)
* The study design must minimise risk of harm. Update the protocol to reflect anonymisation plan (*Ethical Guidelines for Observation Studies* *para 5.5*).

This following information will be reviewed, and a final decision made on the application, by Dr Kate Parker.

## Substantial amendments

|  |  |  |
| --- | --- | --- |
| **1** | **Ethics ref:** | **NTY/08/06/055/AM07** |
|  | Title: | Growing Up in New Zealand |
|  | Principal Investigator: | Dr Susan Morton |
|  | Sponsor: |  |
|  | Clock Start Date: | 25 August 2016 |

Sarah Berry and Peter Tricker, Associate Professor Susan Morton were present in person for discussion of this amendment.

Potential conflicts of interest

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

Dr Leesa Russell declared a potential conflict of interest, and the Committee decided to have Dr Russell leave the room.

Summary of ethical issues

The main ethical issues considered by the Committee were as follows.

1. This amendment is both to seek approval for initiation of the 8-year wave, but also seeks approval to link databases that are educational and social services, to focus on welfare of the participants. This aims to link children and family data to environmental data, including where they live. The amendment requests interviewing the teachers of children, photographs of faces and their dental records.
2. The Committee noted the original consent was from the mother and asked where the new consents come from. The Researcher(s) explained the fathers give consent too. The Committee asked what happens if there is disagreement between parents. The Researcher(s) stated they have sought legal advice on what happens when parents disagree, and the advice was that parents must sort that out herself, however they are often dependent on the mother, as the fathers have not been present at the most recent interview round.
3. The Committee queried if this amendment involved access to the father’s personal information without consent, in order to access benefit information. The Researcher(s) explained that family benefit could be linked through the child’s name only, which means there is no need to identify the father. The Researcher(s) referred to the Dunedin study as a precedent for this linking.
4. The Committee queried that this process is checked with the Office of the Privacy Commissioner to ensure this outlined approach does not breach privacy standards.
5. The Committee queried whether there is a child assent form. The Committee noted the 4.2 and 6.19 and 6.20 of the observational guidelines, noting a child of 8 can meet these considerations. The Committee noted they were happy to send examples and guidance for assent forms in this age group. The Researcher(s) agreed that they would provide assent forms to the HDEC. Please email [HDECS@moh.govt.nz](mailto:HDECS@moh.govt.nz) to follow this up.
6. The Committee noted the statement of no expected harm, but noted potential psychological impact on mothers, who get feedback about other children, as well as their own.
7. The Committee queried what the policy is when regular abuse or smacking is disclosed. In particular, what happens when the mother blocks any action taken about it? The Researcher(s) stated those questions are self-completed. The interviewer won’t know on the answers of the questions. The Researcher(s) explained the nominal data is totally separate from the participant data.
8. The Committee noted the child protection act requires all groups working with children requires a child protection policy. The Researcher(s) noted they are updating their policies to be in line with those requirements. The Committee requested that this is feedback to the HDEC.
9. The Committee noted the Participant Information Sheet could be considered coercive due to the excitement of the language. Please re-word the statement that indicates the videos do not contain any identifiable information.
10. Please add Maori support contact details on the on the Participant Information Sheet.
11. The Committee and The Researcher(s) discussed the ongoing funding of the project. The Researcher(s) reiterated their ethical obligation to follow up with the cohort.
12. The Committee explained the relationship between funding and the new aspects of the study.
13. The Researcher(s) explained their method of determining the scope of each waves focus and questions.
14. The Committee queried the focus on feeling sad opposed to positive questions on the questionnaire. The Researcher(s) explained that that particular scale is an internationally validated scale. Experts and policy prefer this scale, so we are not at liberty to change that scale, but we can add a question to balance it out. The Committee noted the response was acceptable.
15. The Committee requested the pre-interview call script. The Researcher(s) stated they would provide this to HDEC. The Researcher(s) explained that participants can select which parts they are involved in and which they are not, and we have seen participants exercise this right of control.

Decision

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

* The study design must minimise risk of harm. Please provide information requested and address ethical issues in a cover letter. (Ethical Guidelines for Observation Studies para 5.5).
* Please provide age appropriate assent form for non-consenting (children) participants to sign (*Ethical Guidelines for Observation Studies 6.21)*

This following information will be reviewed, and a final decision made on the amendment, by Dr Nora Lynch.

## 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:

|  |  |
| --- | --- |
| **Meeting date:** | 04 October 2016, 12:00 PM |
| **Meeting venue:** | Novotel Ellerslie, 72-112 Greenlane Road East, Ellerslie, Auckland |

The following members tendered apologies for this meeting.

* Mr John Hancock.

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 5.35pm