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| **Committee:** | Northern A Health and Disability Ethics Committee |
| **Meeting date:** | 13 October 2015 |
| **Meeting venue:** | Novotel Ellerslie |

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| **Time** | **Item of business** |
| 1:00pm | Welcome |
| 1:05pm | Confirmation of minutes of meeting of 08 September 2015 |
| 1:30pm | New applications (see over for details) |
| 1:30-1:55pm  1:55-2:20pm  2:20-2:45pm  2:45-3:10pm  3:10-3:35pm  3:35-4:00pm  4:00-4:25pm  4:25-4:50pm  4:50-5:15pm  5:15-5:40pm  5:40-6:05pm  6:05-6:30pm | i 15/NTA/156 Mark / Kerry  ii 15/NTA/152 Christine / Susan  iii 15/NTA/153 Shamim / Mali  iv 15/NTA/142 Mark / Susan  v 15/NTA/143 Christine / Mali  vi 15/NTA/144 Shamim / Kerry  vii 15/NTA/146 Mark / Mali  viii 15/NTA/149 Christine / Susan  ix 15/NTA/150 Shamim / Kerry  x 15/NTA/139 Karen / Brian  xi 15/NTA/140 Karen / Brian  xii 15/NTA/141 Karen / Brian |
| 6:30pm | General business:   * Noting section |
| 6:45pm | Meeting ends |

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| **Member Name** | **Member Category** | **Appointed** | **Term Expires** | **Apologies?** |
| Dr Brian Fergus | Lay (consumer/community perspectives) | 01/07/2012 | 01/07/2015 | Present |
| Ms Susan Buckland | Lay (consumer/community perspectives) | 01/07/2012 | 01/07/2015 | Present |
| Mr Kerry Hiini | Lay (consumer/community perspectives) | 01/07/2012 | 01/07/2015 | Present |
| Dr Karen Bartholomew | Non-lay (intervention studies) | 01/07/2013 | 01/07/2016 | Present |
| Dr Christine Crooks | Non-lay (intervention studies) | 01/07/2013 | 01/07/2015 | Present |
| Mrs Maliaga Erick | Lay member in consumer/community perspectives | Co-Opt NTB | Co-Opt NTB | Present |
| Mr Mark Smith | Non-lay (intervention studies) | 01/09/2014 | 01/09/2015 | Apologies |
| Ms Shamim Chagani | Non-lay (health/disability service provision) | 01/07/2014 | 01/07/2015 | Present |

***Welcome***

The Chair opened the meeting at 1:00pm and welcomed Committee members.

The Chair noted Mark Smith had submitted apologies.

The Chair co-opt members of other HDECs in accordance with the SOPs. Mrs Maliaga Erick 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 08 September 2015 were confirmed.

## New applications

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| **1** | **Ethics ref:** | **15/NTA/156** |
|  | Title: | Is Intraoperative tissue oxygenation increased with humidified CO2 |
|  | Principal Investigator: | Dr Prathima Chowdary |
|  | Sponsor: |  |
|  | Clock Start Date: | 01 October 2015 |

Dr Prathima Chowdary 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. The pilot study investigating whether tissue oxygenation is increased with the use of humidified Carbon dioxide (CO2) blown over the surgical cavity.
2. Humidified CO2 is used in different kinds of surgery and has been tested in studies in Australia.
3. It is believed that the use of humidified CO2 in the surgical cavity will improve oxygenation of the surrounding tissue and this will reduce wound infection rates.
4. This study will measure oxygenation of tissue surrounding the wound site.
5. The Researcher explained that they currently have a wound infection rate of 1 per week and hoped that this technique could reduce this rate.

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 the researcher to explain the basis for this study, and to clarify why they believed it may improve tissue oxygenation as they will blow CO2 over the wound rather than Oxygen. The Researcher explained that because the CO2 used is warm they hoped that this would help improve blood flow. Because open abdominal surgery can take between 3 and 7 hours the tissue surrounding the area can get cold and have reduced blood flow, meaning that oxygenation of this tissue is not supported. It is believed that insufflating CO2 into the open abdominal cavity during surgery can improve the amount of oxygen delivered to tissue surrounding the wound.
2. The Committee queried whether this study is sponsored by Fisher & Paykel Healthcare and whether they would have any ownership of study data or any influence over the publication of study results. The Researcher confirmed that Fisher & Paykel are not funding or sponsoring the study, although they are donating the probe that will be used to measure tissue oxygenation, they also confirmed that Fisher & Paykel will not have any control over study results or publication.
3. The Researcher confirmed that no member of the research team is employed by Fisher & Paykel and that Fisher & Paykel would not be helping to set up the equipment, although they had seen Fisher & Paykel set up the equipment in the past.
4. The humidified CO2 is already used at Auckland Hospital and does not need to be provided specifically for the study, Fisher & Paykel are only donating the probe being used to test tissue oxygenation levels.
5. The Committee questioned the expected end point of tissue oxygenation in this study. The Committee noted that another study is already underway considering the impact of humidified CO2 on wound infection rates, and the other study is sponsored by Fisher & Paykel. The Researcher explained that they were aware of this other study and stated that the other trial is not directly looking at oxygenation.
6. The Committee asked if the use of humidified CO2 was standard care. The Researcher explained that it was standard in some kinds of surgery, but not in the kind of surgery being studied in this research project.
7. The Committee asked whether the Humidified CO2 would simply leak out of the wound site without providing any benefit. The Researcher stated that this was one of the aspects being considered in this pilot study.
8. The Committee questioned why patients with a high BMI were being sought. The Researcher explained that although they are not actively looking to recruit participants with a high BMI this would not be an exclusion criteria due to the impact this would have on their ability to recruit because of the low numbers of patients having this kind of surgery.
9. The Committee asked for clarification of the recruitment and consent process. The Researcher explained that when potential participants come to the ward to be scheduled for surgery they would be approached about the study and given the Participant Information Sheet. Participants who are interested in being involved in the study would then be consented when they return to the ward for their surgery, as this would give them time to consider if they would like to be involved in the study. The Researcher explained that the Primary Investigator would not be directly recruiting participants or performing their surgery, although they would be present at the time of surgery to conduct the tissue oxygenation tests.
10. The Committee noted that although humidified CO2 was used for some surgery already this trial involved a different strategy for use that involved turning the machine on and off. The Committee noted that this, combined with recruiting participants with a high BMI, meant that there are a lot of variables to consider in this study. The Committee and the Researcher agreed that this was suitable due to this being a Pilot study.

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

1. The Committee requested that the Participant Information Sheet be reconsidered to improve the readability for lay participants.
2. The Committee requested that the language in the Participant Information Sheet be reconsidered, for example to reword ‘Methods and Demands on Participants’ on the first page.
3. Please ensure accurate compensation wording regarding ACC is included in the Participant Information Sheet. The Committee suggested the wording from the HDEC template: *“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”*
4. For completeness please provide a copy of the Consent Form.

Decision

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

1. Please make changes to the Participant Information Sheet detailed in points 16-19 above.
2. Please provide a copy of the Consent Form and the Māori Consultation response for completeness.

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

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| **2** | **Ethics ref:** | **15/NTA/152** |
|  | Title: | PADDOCK |
|  | Principal Investigator: | Dr Humphrey, W, H Pullon |
|  | Sponsor: | CNS - Clinical Network Services Ltd |
|  | Clock Start Date: | 01 October 2015 |

Dr Humphrey Pullon and a representative from the Study Sponsor were present by teleconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. This study investigates a drug APL-2 that is proposed as a treatment for Paroxysmal Nocturnal Hemoglobinuria (PNH).
2. The Researcher explained that similar treatments are available in many countries, however no treatments of this kind are funded by PARMAC in New Zealand.
3. The Researcher explained that they know of one patient that received this kind of treatment under compassionate grounds in New Zealand and saw a significant improvement. However, these drugs are not available in New Zealand as they are very expensive.
4. This study will include a total of 6 participants, 2 cohorts of 3 participants each. The first cohort of 3 participants will receive a first dose level and then depending on efficacy cohort 2 will receive a different dose level, the researchers expect the second dose level to be higher.
5. This is a Phase 1b trial looking at dose levels of the study drug.
6. The Primary Investigator will consult with haematologists throughout New Zealand to ensure they are aware of the study and are able to refer their eligible patients to the study.
7. The Committee noted that the Participant Information Sheet was well written and had good statements about the potential cultural issues surrounding the use of tissue.

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 whether it will be easy to recruit the participants due to the rare nature of the disease. The Researcher explained that they believe there are approximately 8 suitable patients in New Zealand.
2. The Committee questioned the number of trial sites and asked about compensation for travel costs. The Researcher explained that there are two trial sites, one in Hamilton and one in Christchurch, although this may mean that participants may need to travel a long distance the low number of participants means that further sites are not justified. The Researcher also confirmed that all participants travel costs would be covered.
3. The Committee questioned why this study was only being conducted in New Zealand. The Researcher explained that patients with this disease in other countries will already be treated by this form of medication.
4. The Committee asked the Researcher to clarify how potential conflicts of interest would be minimised. The Researcher explained that they do not believe there is any commercial conflict of interest as they have no connection or financial tie to the study sponsor. The Committee discussed the conflict between the researcher being the treating clinician. The Researcher noted this was a potential conflict.
5. The Researcher clarified that there may be some incentive offered to participants, in terms of the availability of a drug if they participate in the study. However, the Researcher explained that it would be made clear to participants that they would only have access to the study drug for a short period of time as it will not be available after the study, although there is a possibility of an extension study at the discretion of the sponsor.
6. The Committee noted that the Participant Information Sheet states that the trial may stop for commercial reasons, the Committee explained that this was not acceptable in New Zealand. The Researcher agreed to remove this from the Participant Information Sheet.
7. The Committee asked about the status of Māori consultation. The Researcher explained that they have submitted and are awaiting the response to their Māori consultation. The Committee requested that this was submitted for completeness when it is available.
8. The Committee asked the researcher if they are comfortable with the data safety monitoring arrangements for the study. The Researcher confirmed that they are comfortable with the arrangements.

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

1. Please remove the statement from the Participant Information Sheet regarding the study being stopped for commercial reasons.

Decision

This application was *approved* by consensus with non-standard conditions.

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| **3** | **Ethics ref:** | **15/NTA/153** |
|  | Title: | BAY 94-9027 paediatric pharmacokinetics, safety, and efficacy trial. |
|  | Principal Investigator: | Dr Mark Smith |
|  | Sponsor: | Bayer New Zealand Limited |
|  | Clock Start Date: | 01 October 2015 |

Dr Mark Smith 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 application is for an expansion and an extension study assessing the safety and efficacy of the study drug in haemophilic children under 6 years of age.
2. The study drug is proposed as a better alternative to standard treatment as it last longer in the body by attaching itself to proteins.
3. This drug has been tested in children and adults previously in other countries. Previous studies found that when used in under 6 year olds a small but important incidence of hypersensitivity reactions were reported. These reactions were mostly minor and did not require treatment.
4. It is believed that this reaction may be common in children and it is hoped that it will not reoccur with continued use.
5. This study will consider whether the study drug is safe to use in children or if it should only be used in adults.
6. This application includes an extension study that will hopefully offer ongoing access to the study drug for participants who received a benefit from it.
7. 25 children will be recruited worldwide for this study, with 2 participants in New Zealand.

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 if the researcher is happy with the data safety monitoring for this study. The Researcher confirmed that they are happy with the arrangements.
2. The Committee questioned if participants were able to have major surgery during the study. The Researcher explained that during the expansion study they would not be able to have major surgery, but they could during the ongoing extension study. The Committee requested that this was made clearer in the Participant Information Sheets.
3. The Committee questioned if tissue samples would be sent overseas. The Researcher explained that tissue samples would be sent to Singapore. The Committee requested that this be added to the Participant Information Sheet.
4. The Committee noted that small sample size and questioned the Māori consultation process. The Researchers explained that Māori consultation will be done as part of the locality approval.
5. The Committee questioned if interpreters would be available. The Researcher explained that they did not believe an interpreter would be required but could access one if it is was necessary. The Committee requested that the availability of an interpreter was included in the Participant Information Sheet.
6. The Committee noted that parents would be asked to complete a questionnaire regarding the impact of the study and treatment on their work activities, therefore, the parents would also be participants. The Committee requested that a short Information Sheet was included with the questionnaire explaining why is was important and that it was voluntary, completing the survey can be considered consent from the parents.
7. The Committee noted that written withdrawal of consent is not required in New Zealand and that participants could withdraw verbally.

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

1. The Committee noted that data collected as part of this study needed to be kept for 10 years after the youngest child turned 16. They requested that this is clarified in the Participant Information Sheet.
2. Please rewrite the Participant Information Sheet to improve clarity and reduce jargon for lay participants.
3. Please add a lay summary of the study to the top of the Participant Information Sheet.
4. Please explain in the Participant Information Sheet that previous studies found some children under 6 years old had hypersensitivity reactions and that this study is testing whether children continue to react with continued exposure.
5. Please clarify in the Participant Information Sheet that participants can withdraw verbally at any time without giving a reason.
6. Please clarify the restrictions against major surgery in the expansion study.
7. Please specify that tissue samples will be sent overseas.
8. Please include the availability of interpreters in the Participant Information Sheet.
9. Please consider rewording the ACC statements, especially regarding ‘indemnity’ for the child. The Committee suggests the wording from the HDEC template: *“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.”*
10. Please remove or reword the ‘Declaration of Anonymisation’ from the Participant Information Sheets as it is confusing and unclear.
11. Please add a short information sheet to the questionnaire for parents.

Decision

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

1. Please make the changes to the Participant Information Sheet detailed in points 15-24 above.
2. Please add an information sheet for the questionnaire for parents.

This following information will be reviewed, and a final decision made on the application, by Ms Shamim Chagani and Dr Brian Fergus.

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| **4** | **Ethics ref:** | **15/NTA/142** |
|  | Title: | POSNOC - A randomised trial of armpit (axilla) treatment for women with early stage breast cancer |
|  | Principal Investigator: | A/Prof Ian Campbell |
|  | Sponsor: | ANZ Breast Cancer Trials Group Ltd (ANZBCTG) |
|  | Clock Start Date: | 01 October 2015 |

A/Prof Ian Campbell and Ms Jenni Scarlet 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. The study follows a similar study conducted in the US that found no benefit of axillary node treatment, which is currently part of standard care.
2. However, this previous study was controversial as it used a specifically low risk group of participants.
3. This study hopes to build on the results of this earlier study.
4. 3 sites across New Zealand will recruit approximately 50 women a year, the study will continue for possibly 2-3 years with a total of approximately 100-150 participants.

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 the statement in the Participant Information Sheet regarding the availability of counselling if participants became distressed during the study. The Committee asked if the researchers expected participation in the study to distress participants and if the counselling was provided free of charge as an aspect of the study. The Researchers explained that they do not believe that participation in the study will increase the risk of distress to participants, however participants may be distressed due to recently being diagnosed with breast cancer. Further, the Researcher explained that participation in the study may increase the risk of distress to participants as they may develop lymphoedema if they are in the control group and have axillary node treatment, or participants in the investigational group have a higher risk of a recurrence in the axilla which may also be distressing.
2. The Committee requested that it is made clear in the Participant Information Sheet if the counselling available is free of charge, and if it is additional to the counselling that would be offered to patients not participating in the study.
3. The Committee noted that tissue samples would be obtained from both groups, they questioned if unexpected results may be found. The researcher confirmed that they did not expect any unexpected results from tissue samples.
4. The Committee questioned if the future testing on banked tissue from this study could be used for genetic testing. The Researcher explained that genomic testing may be done on samples from the tissue bank to consider the DNA make-up of tumours.
5. The Committee questioned why tissue would be banked in an overseas tissue bank. The Researchers explained that tissue samples would be sent to an established tissue bank in Australia as this is a centralised location for international samples from this study to be stored and available for future testing.

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 raised concerns regarding the tissue banking aspect of the study. Specifically they questioned the mandatory nature of the tissue bank aspect of the study.
2. The Researchers explained that the reasons for wanting to store some tissue in the tissue bank is for future testing, for example to see what markers may be associated with different outcomes.
3. The Committee stated that Part One: Consent (2) of the Ministry of Health Guidelines for the Use of Human Tissue for Future Unspecified Research Purposes 2007 states that “Consent to the future unspecified use of a person’s tissue samples must be distinct from consent to collect the sample and distinct from consent to use the sample in specified research.”
4. Although tissue samples from this study stored in the tissue bank will be used for further Breast Cancer research, the Committee noted that because it is not known the exact tests or studies that the tissue would be used for it may be considered future unspecified use of tissue.
5. Because providing tissue for tissue banking is not an essential aspect of the purpose of this study the Committee noted that it would still be possible to do this study without collecting any tissue for the tissue bank.
6. The Committee also noted the specific cultural issues that may be raised for Māori participants by tissue being sent overseas.
7. Therefore, the Committee requests that providing tissue for the tissue bank be made an optional aspect of the study with its own separate Participant Information Sheet and Consent Form.

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

1. The Committee noted that as tissue samples would be sent overseas more information should be included in the Participant Information Sheet regarding the ethics approval that studies wanting to use tissue from the tissue bank would need to go through. Specifically, the Committee requested that this information clarified that the studies would probably be approved by an Australian ethics committee rather than a New Zealand committee.
2. The Committee noted that more information would also need to be included regarding the kinds of tests that may be conducted on tissue stored in the tissue bank.
3. The Committee requests that it is made very clear that it is not mandatory to withdraw from the study in writing.

Decision

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

1. Please address the Committees concerns regarding the mandatory nature of tissue banking in this study, outlined in points 10-16 above
2. Please address our concerns about making sending tissue to an overseas tissue bank for future unspecified research a mandatory requirement to participate.
3. Please modify the Participant Information Sheet and Consent Form as outlined in points 17-19 above.

This following information will be reviewed, and a final decision made on the application, by Dr Brian Fergus and Ms Susan Buckland.

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| **5** | **Ethics ref:** | **15/NTA/143** |
|  | Title: | CLS001-CO-PR-005: Safety and effectiveness of once-daily CLS001 gel in Papulopustular Rosacea with 4 week follow-up. |
|  | Principal Investigator: | Dr Nicholas Birchall |
|  | Sponsor: | Cutanea Life Sciences, Inc. |
|  | Clock Start Date: | 01 October 2015 |

No member of the research team was 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. The study investigates the safety and efficacy of a once-daily gel for the treatment of Papulopustular Rosacea.
2. 450 participants will be recruited worldwide, with 9 participants in New Zealand.
3. The study will be run through Auckland Dermatology.

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 whether participants who withdraw from the study should be asked to come in for a final visit. The Committee agreed that this was acceptable for safety.

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 appropriateness of a placebo arm in this study as participants will be involved in the study for a long time and involvement in the study prevents participants from using a number of other medications or treatments.
2. The Committee raised concerns regarding the lack of contact details contained on the alert card participants would carry. Contact details to allow participants to be un-blinded if necessary should be included on this card.
3. The Committee noted that the Participant Information Sheet stated that the Principal Investigator may benefit financially from the study, however their institution should be the one benefiting from the study. Could the researcher clarify whether it is the study doctor or their institution would benefit financially from conducting this study.
4. The Committee requested information regarding the Māori Consultation process being undertaken for this study when it became available.
5. The Committee noted that the Participant Information Sheet stated that the study can be stopped for commercial reasons, however, this is unacceptable in New Zealand. Please confirm that the study cannot be stopped for commercial reasons and modify the Participant Information Sheet to reflect this.
6. The Participant Information Sheet states on page 11 that the participant’s GP will be contacted and that their health information from past, present and future medical records would be collected. The Committee requests that this is clarified as they are unsure of the justification of enforced contact with the GP and the justification for or limits on collection of future medical records. There should be a start and end date to data collection for this study to protect patient confidentiality.
7. The Committee noted that a number of studies have already been conducted on this product and they requested clarification of why a further study was necessary.
8. The Committee noted that the Participant Information Sheet states that participants could die if they have a severe allergic reaction. The Committee questioned if the safety of the product has not yet been established even though this is a Phase 3 trial. If this is a serious risk the Committee stated that it must be clearer on the Participant Alert Card. Because this is a blinded study in case there is an emergency the contact details for the PI ( and potentially medical monitor) should be on the alert card. This provides contact details for emergency staff if they need to know what trial medication the patient is on in an emergency. The trial will need to be unblended and only the medical monitor can do this. The fact that severe allergic reactions may occur emphasises the need for contact details on alert card.
9. The Committee questioned how long health information and samples would be kept for.
10. The Committee requested that the researchers confirm that samples would be destroyed after 3 months.
11. The Committee questioned what is meant by Immune Testing on page 5 of the Participant Information Sheet. The Committee requested that this is clarified, including the reasons for doing it.

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

1. Please clarify on the Advertisement that participants will only be compensated for their travel costs, as currently it states that they will be compensated for their time.
2. Please rephrase ‘vehicle’ in the Participant Information Sheet as it is unclear what this means to participants.
3. Please make it clear in the Participant Information Sheet if data from this study will be made available for future research.
4. Please ensure accuracy in the ACC compensation wording in the Participant Information Sheet as at least ACC-equivalent compensation must be available if participants are injured as a result of their participation in the study. The Committee suggests the wording from the HDEC template: “*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.”*

Decision

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

1. Please address the Committee’s outstanding ethical concerns outlined in points 5-15 above.
2. Please modify the Participant Information Sheet, Consent Form, and Advertisement in line with the suggestions in points 16-19 above.

This following information will be reviewed, and a final decision made on the application, by Dr Christine Crooks and Brian Fergus.

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| **6** | **Ethics ref:** | **15/NTA/144** |
|  | Title: | High dose nicotine substitution study for other-drug addicted smokers |
|  | Principal Investigator: | Dr Natalie Walker |
|  | Sponsor: | The University of Auckland |
|  | Clock Start Date: | 01 October 2015 |

Dr Natalie Walker and a co-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 a feasibility study investigating an alternative smoking cessation method.
2. Standard care for smoking cessation does not follow the same treatment pattern as treating addiction to other drugs.
3. This study will attempt to reduce the harm from smoking by helping reduce the number of cigarettes smoked by participants.
4. The Control group in the study will follow the Ministry of Health guidelines with the use of patches and a referral to Quitline.
5. The Active study group will receive increasingly more patches (to a maximum of 5) in an attempt to reduce the number of cigarettes they smoke by replacing the nicotine from cigarettes with nicotine from patches. This aims to reduce harm by satisfying participants’ nicotine cravings with a safer form of nicotine (patches).
6. 60 participants from CADS addiction treatment services would be recruited.
7. The Committee noted that the researchers had developed a good participant Information Sheet.

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 if there was any risk of participants receiving too much nicotine. The Researcher explained that the toxic dose of nicotine is very high and that if participants start to exceed their personal limit they will feel nauseous and can reduce this by removing a patch or smoking less cigarettes or taking off surplus patches. The Committee requested that it is made clearer in the Participant Information Sheet that if participants start to feel sick they should remove a patch or smoke less cigarettes to reduce their nicotine levels.
2. The Committee asked if simply reducing the number of cigarettes smoked, but not removing them completely, reduced the harm from smoking. The Researcher explained that there is evidence to suggest that if people are able to reduce the amount they smoke they are more likely to quit. The Researcher also explained that if participants smoke less they will have less exposure to the toxic chemicals in cigarettes.
3. The Committee questioned the data safety monitoring arrangements for this study. The Researcher explained that they are satisfied with the arrangements as they are not testing a new drug and that clinicians will be available to help if anything goes wrong. The Researcher explained that any adverse events would be monitored.
4. The Researcher clarified that a trained smoking cessation person would be in contact with participants regularly.
5. The Committee questioned how this study would attempt to reduce health inequalities. The Researcher explained that the study would be conducted by the CADS service and that information generated from the study would be shared throughout the country to other CADS services. The Researchers also explained that they will be actively recruiting from areas with a high Māori population.
6. The Researchers explained that they intend to share and publish the results of their study in a number of ways, including by sharing their results with various smoking cessation groups throughout the country.
7. The Committee questioned the inclusion/exclusion criteria. The Researchers explained that one purpose of this feasibility study is to determine if they can recruit participants for this trial, especially whether they can recruit Māori and Pacifica participants.
8. The Committee asked if interpreters would be available if necessary. The Researcher clarified that they would be available. The Committee requested that this is included in the Participant Information Sheet.
9. The Committee questioned the health information that would be collected. The Researcher explained that this would be self-reported health information and participants would be asked general, open-ended, questions about their views on their health.
10. The Researcher explained that participants’ self-reported smoking levels would be confirmed through breath testing to measure the carbon monoxide in their breath as they may report a greater reduction in their smoking levels than actually occurred.

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

1. Please ensure it is clear in the Participant Information Sheet that if participants start to feel sick they should remove a patch or smoke less cigarettes to reduce their nicotine levels.
2. Please include the availability of interpreters in the Participant Information Sheet.

Decision

This application was *approved* by consensus with non-standard conditions.

1. Please make the minor changes to the Participant Information Sheet detailed in points 18 and 19 above.

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| **7** | **Ethics ref:** | **15/NTA/146** |
|  | Title: | The ABC Study: 'Assisted breathing before cord clamping' |
|  | Principal Investigator: | Mrs Elizabeth Nevill |
|  | Sponsor: | Counties Manukau Health |
|  | Clock Start Date: | 01 October 2015 |

Mrs Elizabeth Nevill and Mike Meyer 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 study investigates whether delayed cord clamping (DCC) and breathing assistance can improve the short and long term outcomes for preterm infants.
2. An observational audit of records showed that preterm (<31 week gestation) infants who did not establish regular respirations during DCC had worse outcomes than those that did breathe.
3. Theoretically, provision of breathing support during DCC may facilitate optimal PTF, reduce the need for RBC transfusion and result in a more stable neonatal transitional circulation.
4. Preterm infants born<31 week gestation will be recruited over an estimated 3 year period. Infants will be randomized to receive standard treatment (position, thermal wrap) or breathing support in addition to standard treatment during 50 sec delayed cord clamping. Infants will remain in the study until discharge from hospital.
5. Infants who are apnoeic or do not have sustained breathing effort will be randomised to

either receive the planned intervention or standard practice. (Infants that have sustained

spontaneous breathing effort at birth and during DCC will not be randomised to receive the

intervention and, will not enter the study).

1. Eligible infants that receive DCC will be randomised at 15 sec of age once the breathing has been assessed. The intervention (study group) consists of positive pressure ventilation (PPV) or continuous positive airway pressure (CPAP) commencing at 20sec of age and continuing for a further 30sec (infants will therefore receive 50sec of DCC).
2. Delayed cord clamping is standard care in some hospitals.
3. The outcomes recorded in this study include whether the infants need a transfusion or develop chronic lung disease, defined as needing help to breathe at 36 weeks or being discharged with oxygen for home use.
4. A data safety monitoring committee will be elected to review serious outcomes every 6 months.

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 three peer reviews reports were submitted, one from the CMDHB advisory group, a funding grant from CMDHB and an independent review from Auckland University.
2. The Committee queried how the concerns raised in the Peer Review have been addressed. The Researcher explained that they felt that changing their outcome to fit the peer reviewer’s suggestion would be too difficult so they are continuing with their original primary outcome. Regarding the suggestions from the peer reviewer about the length of time for cord clamping, changing to match overseas studies that delay for 2-3 minutes would overly complicate their process so the researchers intend to continue with their original timeframe.
3. On balance, the Committee accepts the scientific basis for this study and does not question the design.
4. The principal ethical issue is that of delayed consent from the parent (s). The Protocol states that parents will be given a written information sheet about the study by a study researcher before labour where possible. In cases where active labour is in progress; and consent before birth is not possible, deferred consent for study entry is proposed.
5. The application letter stated that at Middlemore Hospital, deferred consent was granted for two randomized controlled trials for preterm infants. The researchers requested that they be allowed to follow the same process (as their experience has shown ) due to the nature of the admissions obtaining consent before delivery recruiting only antenatally consented patients can result in a skewed patient population, most of the eligible patients are missed, those that do preconsent may deliver within the time frame and be eligible, and study numbers would be compromised
6. The Committee questioned why only one parent would be asked to consent to the study. The Researcher explained that this was standard as it was not certain that two parents would be available to give consent in all cases. Further, obtaining consent from in labour is stressful for parents and family.
7. The Committee questioned the status of Māori consultation. The Researcher explained that it has been submitted and they are still awaiting the response. The Committee requested that the response is provided for completeness when it is available.
8. The Committee questioned the inclusion of infants born by Caesarean. The Researcher explained that although inclusion in the study may be slightly more difficult in these cases, excluding these infants would be undesirable as this would remove a large number of potential participants.

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 stated that their primary concern with this study was the consent process. The Committee explained that from their perspective delayed consent to participation in an intervention trial is ethically equivalent to non-consent and should only be allowed in special circumstances.
2. The Researcher explained that they felt unable to obtain consent prior to inclusion in the study (reasons given above) as it would be undesirable to consent women in preterm labour as they often arrive distressed and in active labour.
3. The Researcher also explained that to consent pregnant women prior to them going into labour would be impractical. In order to obtain enough participants to make the study viable, all pregnant women in the area would need to be approached and at least 1000 consented and only a small number of women would have a birth eligible for participation and this could not be known prior to the woman going into labour. The Researchers also raised concerns regarding advanced consenting as it may bias the study population, especially to exclude a number of Pacifica participants who may not be seen by the clinicians prior to going into labour.
4. The Committee requested clarification regarding how the study intervention differed from standard care. The Researchers explained that all of the treatments done for the study are currently done, and involvement of the study would only alter the timing of these treatments, for example by bringing resuscitation forward.
5. The Researchers explained that they do not believe this is a high risk intervention and it is commonly done overseas.
6. The Committee explained that the only way to approve a study with non-consenting participants was under Right 7.4 of the HDC Code of Rights and this would require the Researchers to satisfy the Ethics Committee that participation in the study is in the best interest of the participants (both the delivering mothers and their infants), as well as consulting with suitable persons interested in the individual’s welfare.
7. Right 7.4 of the HDC Code of Rights states that “Where a consumer is not competent to make an informed choice and give informed consent, and no person entitled to consent on behalf of the consumer is available, the provider may provide services where –
   * a) It is in the best interests of the consumer; and
   * b) Reasonable steps have been taken to ascertain the views of the consumer; and
   * c) Either, -
     + i. If the consumer's views have been ascertained, and having regard to those views, the provider believes, on reasonable grounds, that the provision of the services is consistent with the informed choice the consumer would make if he or she were competent; or
     + ii. If the consumer's views have not been ascertained, the provider takes into account the views of other suitable persons who are interested in the welfare of the consumer and available to advise the provider.”
8. The committee would also need to be convinced that enrolment was in the best interest of the infants. The researcher stated Yes to this question.
9. The Committee explained that to approve a non-consensual study they would also need to be satisfied that it is impractical to obtain consent from participants, not just that it would be difficult.
10. In summary, the Committee is satisfied that this is a soundly based study and that it is well worth carrying out, and of low risk. It notes the difficulty related to delayed consent, but notes the hospital has carried out two prior trials on preterm infants where permission was granted for delayed consent.

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

1. If the application is granted for delayed then the PIS will need to be rewritten to reflect . The way it is worded is slanted to preconsent. The researcher could prepare a second PIS for those where delayed consent is being sought. In this case we suggest a simple opening para explaining in lay English that they have been enrolled in a trial and how they are using standard procedures with no risk to the mother etc
2. Please ensure that the Participant Information Sheet carefully explains what has, or will, happened to participants and how this differs from standard care.
3. Please include Māori support contact information in the Participant Information Sheet.
4. Please clarify the Participant Information Sheet as it currently appears that the participant’s family is responsible to help them understand the study.

Decision

This application was *provisionally approved*, with one member voting to decline, subject to the following information being received.

1. Please respond to the Committee’s outstanding ethical concerns regarding the non-consensual nature of the study, outlined in points 17 to 26 above, particularly addressing the issue of why it would in a preterm infant’s best interest to be enrolled in this trial.
2. The Committee notes that it may be possible to enrol some mothers pre-delivery but the majority may well involve delayed consent. The Committee requests a legal opinion from the CMDHB legal team re this trial and section 7.4 of the Act
3. whether it is possible to undertake some form of consultation with different groups and who they might be
4. how information trial might be displayed prominently within the birthing unit.
5. Please adjust the Participant Information Sheet in response to points 27-30 above.

This following information will be reviewed, and a final decision made on the application, by the full Northern A Health and Disability Ethics Committee, via an electronic meeting.

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| **8** | **Ethics ref:** | **15/NTA/149** |
|  | Title: | DIBH for Breast Cancer DIBH in Breast Cancer |
|  | Principal Investigator: | Dr Melissa James |
|  | Sponsor: |  |
|  | Clock Start Date: | 01 October 2015 |

Dr Melissa James 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 pilot study in breast cancer patients to see if a machine can be used to help reduce the amount of radiation their heart is exposed to during treatment.
2. Deep Breathing is an established technique in other clinics, with the goal being for the patient to take a deep breath to move the heart away from the radiation.
3. The goal of this study is to determine if this technique can effectively be implemented in Christchurch.
4. Although it is possible to implement this technique in a basic way without the use of a specialised machine it is hoped that the use of the machine in this study will further decrease the amount of radiation patients hearts are exposed to as this machine only activates the radiation when the participant is holding their deep breath and the heart is moved out of the way.
5. It was intended that the use of this machine in Christchurch could be compared to its use in Tauranga, however Tauranga is implementing it in a different way to Christchurch and this may no longer be possible.
6. The use of this machine may be valuable, but this pilot study will also be considering if its use is reproducible as it is a more time consuming method.

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 how heart damage would be measured as it would take 10-15 years to develop after radiation. The Researcher explained that instead of measuring heart damage directly they will be measuring whether use of this machine reduces the radiation participants’ hearts are exposed to.
2. Other studies have found that reduced radiation exposure correlates with reduced heart damage, therefore, the researchers expect that if they can demonstrate that the machine reduces the radiation the heart is exposed to they can safely assume that it also reduces the amount of damage sustained by the heart.
3. The Committee raised concerns regarding the lack of primary end point data being collected as the study seems more focused on the practicality of implementing the machine in the clinic and patient safety. The Researcher explains that they intend to study how much radiation hearts are exposed to and whether the use of the machine in this study reduces this amount.

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

1. The Committee states that it is not clear in the Participant Information Sheet that they are performing a study, rather than simply trialling the machine. Please reword this to make it clearer to participants what is being done and why.
2. Please remove the statement on page 5 of the Participant Information Sheet referring to participants’ health information being reviewed by an ethics committee or the Food and Drug Administration.
3. Please remove the risks of radiation from the Participant Information Sheet as this is not part of the study.
4. Please ensure the ACC statement is accurate, the Committee suggests the use of the wording from the HDEC template: *“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.”*
5. Please ensure it is clear in the Participant Information Sheet that participating in the study will require them to have more CT scans.

Decision

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

1. Please adjust the Participant Information Sheet in response to points 10-14 detailed above.

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

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| **9** | **Ethics ref:** | **15/NTA/150** |
|  | Title: | Modelling LQTS using iPSCMs |
|  | Principal Investigator: | Dr Jon Skinner |
|  | Sponsor: |  |
|  | Clock Start Date: | 01 October 2015 |

Dr Mary-Anne Woodnorth and Dr Annika Winbo 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. The study uses cells from 5 participants in Sweden with Inherited Arrhythmias to develop more heart cells in order to test the effect of a number of interventions on these heart cells.
2. Participants in Sweden provided their consent for their cells to be used in this way and for them to be used in New Zealand.

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 this study was not being conducted in Sweden. The Researcher explained that it is because she is based in New Zealand and the technology is not available in the Swedish University she is connected with.
2. The Committee questioned why New Zealand participants would not be used. The Researcher explained that they may use New Zealand participants in a future study, but for this study they already have the cells available.
3. The Committee asked what happens to the cells after the study and who is responsible for them. The Researcher responded that after the study the cells will be returned to Sweden and that the cells are the responsibility of Dr Annika Winbo.
4. The Committee noted that a future application to use tissue from New Zealand participants may have different requirements regarding the tissue bank and the Participant Information Sheet.

Decision

This application was *approved* by consensus.

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| **10** | **Ethics ref:** | **15/NTA/139** |
|  | Title: | Comparison of the blood levels of two forms of anagrelide 0.5 mg capsules in healthy male and female volunteers |
|  | Principal Investigator: | Dr Noelyn Hung |
|  | Sponsor: | Southern Cross Pharma Pty Ltd |
|  | Clock Start Date: | 01 October 2015 |

Dr Noelyn Hung, Mrs Linda Folland, and Dr Cheung-Tak Hung 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. The Committee noted that the application and Peer Review were of a high standard.

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 whether all participants would be made aware of their Hepatitis test results. The Researcher explained that the test results would be made available on request, but if any abnormal results were recorded the participant would be notified and given information for their GP.
2. The Committee noted the use of headshots by the research centre. The Researcher explained that they found these very useful in past studies.

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

1. Please ensure accuracy in the ACC compensation wording in the Participant Information Sheet as at least ACC-equivalent compensation must be available if participants are injured as a result of their participation in the study.
2. The Committee notes that the Participant Information Sheet states that risks from the study drug may resolve with continued use, however, participants are only taking the study drug once so this statement may not be accurate or useful.

Decision

This application was *approved* by consensus.

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| **11** | **Ethics ref:** | **15/NTA/140** |
|  | Title: | Comparison of the blood levels of four forms of isotretinoin 40 mg capsules in healthy male volunteers |
|  | Principal Investigator: | Dr Noelyn Hung |
|  | Sponsor: |  |
|  | Clock Start Date: | 01 October 2015 |

Dr Noelyn Hung, Mrs Linda Folland, and Dr Cheung-Tak Hung 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. The Committee noted that the application and Peer Review were of a high standard.
2. This study is testing 3 new formulations of a drug that previously needed to be taken with food. A new version in the USA does not need to be taken with food and this study is attempting to develop a new formulation to mimic this labelled drug for Douglas Pharmaceuticals to ensure bioequivalence.

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 whether all participants would be made aware of their Hepatitis test results. The Researcher explained that the test results would be made available on request, but if any abnormal results were recorded the participant would be notified and given information for their GP.
2. The Committee noted the use of headshots by the research centre. The Researcher explained that they found these very useful in past studies.
3. The Committee questioned whether there are any restrictions on the kinds of foods that participants can eat before the study. The Researchers explained that the study meals will be low in Vitamin A but they are not overly concerned with participants consuming Vitamin A before the study as the levels likely to be consumed would not interfere with the study drug or results.
4. The Committee questioned who provides the insurance for the study. The Researcher explained that insurance is provided by the sponsor.

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

1. Please ensure accuracy in the ACC compensation wording in the Participant Information Sheet as at least ACC-equivalent compensation must be available if participants are injured as a result of their participation in the study.

Decision

This application was *approved* by consensus

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| **12** | **Ethics ref:** | **15/NTA/141** |
|  | Title: | Comparison of the blood levels of three forms of insulin |
|  | Principal Investigator: | Dr Noelyn Hung |
|  | Sponsor: | Cipla Limited |
|  | Clock Start Date: | 01 October 2015 |

Dr Noelyn Hung, Mrs Linda Folland, and Dr Cheung-Tak Hung 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. The Committee noted that the application and Peer Review were of a high standard.

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 whether all participants would be made aware of their Hepatitis test results. The Researcher explained that the test results would be made available on request, but if any abnormal results were recorded the participant would be notified and given information for their GP.
2. The Committee noted the use of headshots by the research centre. The Researcher explained that they found these very useful in past studies.
3. The Committee questioned the short time between treatments. The Researcher explained that the half-life of the product is approximately an hour so a short time between treatments was acceptable.
4. The Committee questioned if studies on inhalation v. injection of insulin had been done by the researchers before. The Researcher explained that they had not done a study on inhalation of insulin before, but had conducted studies on inhalable medications for asthma before.
5. The Committee questioned if there are respiratory risks with this product. The Researchers explained that there may be risks with prolonged exposure, but that this would not be a problem given the nature of this study.
6. The Committee requested the researchers confirm they are prepared for resuscitation if necessary. The Researchers explained that they are prepared for a possible anaphylactic reaction with all studies.

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

1. Please ensure accuracy in the ACC compensation wording in the Participant Information Sheet as at least ACC-equivalent compensation must be available if participants are injured as a result of their participation in the study.
2. Please reword the first page of the Participant Information Sheet to accurately reflect the purpose of the study, as this is not a blinded trial.
3. Please ensure that the glucose clamp mentioned on page 5 of the Participant Information Sheet is clearly explained.

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:** | 10 November 2015 |
| **Meeting venue:** | Novotel Ellerslie |

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 5:45pm