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| **Committee:** | Northern B Health and Disability Ethics Committee |
| **Meeting date:** | 01 April 2014 |
| **Meeting venue:** | Novotel Ellerslie, 72-112 Greenlane Road East, Auckland |

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| **Time** | **Item of business** |
| 12.00pm | Welcome |
| 12.10pm | Confirmation of minutes of meeting of 04 March 2014 |
| 12.30pm | New applications (see over for details) |
|  | i 14/NTB/33  ii 14/NTB/34  iii 14/NTB/36  iv 14/NTB/35  v 14/NTB/39 |
| 2.35pm | General business:   * Noting section of agenda |
| 2.55pm | Meeting ends |

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| **Member Name** | **Member Category** | **Appointed** | **Term Expires** | **Apologies?** |
| Mrs Raewyn Sporle | Lay (the law) | 01/07/2012 | 01/07/2015 | Present |
| Mrs Maliaga Erick | Lay (consumer/community perspectives) | 01/07/2012 | 01/07/2014 | Present |
| Mrs Kate O'Connor | Non-lay (other) | 01/07/2012 | 01/07/2015 | Present |
| Mrs Stephanie Pollard | Non-lay (intervention studies) | 01/07/2012 | 01/07/2015 | Present |
| Dr Paul Tanser | Non-lay (health/disability service provision) | 01/07/2012 | 01/07/2014 | Present |
| Ms Kerin Thompson | Non-lay (intervention studies) | 01/07/2012 | 01/07/2015 | Present |

## Welcome

The Chair opened the meeting at 12.13pm and welcomed Committee members, noting that no apologies had been received.

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 4 March 2014 were confirmed.

## New applications

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| **1** | **Ethics ref:** | **14/NTB/33** |
|  | Title: | Use of a 5:2 fasting dietary plan in obese patients with type 2 diabetes: A pilot study |
|  | Principal Investigator: | Dr Jeremy Krebs |
|  | Sponsor: | Capital and Coast DHB |
|  | Clock Start Date: | 20 March 2014 |

Dr Richard Carroll and Dr Amber Parry-Strong 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 ethical issues

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

* The Committee noted that this was an interesting study and application.
* Dr Carroll explained that the plan was being investigated as it was becoming very popular and it tied in with the researchers interests on the impact of caloric restriction on diabetes.
* Dr Carroll explained that it is caloric restriction which induces weight loss. However it is difficult to maintain this restriction long term due to hormonal, psychological and environmental factors. He advised that it may be easier for people to restrict their calories dramatically over two days, as opposed to cutting back a little bit every day.
* Dr Carroll explained that after bariatric surgery, changes in diabetes control are seen within the first few days, even before changes in weight loss occur. It may be that it is the caloric restriction that impacts these changes.
* Dr Carroll confirmed that there would not be a person independent of the research group in the internal data safety monitoring group (R.1.4). The Committee noted that while the risks of harm were low, they recommended asking a colleague from another district health board, for example an endocrinologist or diabetologist, to monitor the data at the same time and give an independent view of risk.
* Dr Carroll confirmed that the results of the Māori consultation were pending.
* The Committee asked how standard treatment was being withheld for this study (question O of the application form). Dr Carroll explained that weight loss is generally recommended in the treatment of diabetes. He noted that patients are generally given a series of dietary plans, of which the 5:2 plan is only one. It has also been proposed that diabetes medication will be adjusted in anticipation of the increased risk of hypoglycaemia.
* The Committee asked if all of the participants would be doing the 5:2 plan as B.2.1 states that the study will be randomised 1:1 basis to a standard dietary or a 5:2 dietary plan. Dr Carroll explained that this answer was in error but that there would be randomisation in that some participants would fast for two consecutive days, while others would fast on random days.
* The Committee requested the following changes to the participant information sheet and consent form:
  + Please include a lay title for the PIS.
  + Page 1 of the PIS – Please change “Insulin is a hormone made in the gut” to “Insulin is a hormone made in the pancreas”.
  + Page 4 of the PIS under compensation – Please change “you may be covered by ACC” to “you will need to apply for ACC compensation.”
  + Please review the yes and no options on the consent form and only include those that are truly optional. Please remove the yes/no boxes which will make the options statements that participants must agree to.
  + Please include in the PIS that samples may be stored for future research which may be sent overseas and that ethical review will be sought for future use.
  + Please include a statement in the PIS on what will happen to samples. This should include information on how long they will be held, where they will be stored, whether they will be sent overseas and that participants can ask for them to be destroyed.
  + Please include contact details for a Māori cultural support person.

Decision

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

* Please amend the PIS 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 Paul Tanser and Mrs Raewyn Sporle.

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| **2** | **Ethics ref:** | **14/NTB/34** |
|  | Title: | Mirena® ± Metformin ± Weight Loss for the treatment of Early Endometrial Cancer (feMMe) |
|  | Principal Investigator: | Associate Professor Peter H Sykes |
|  | Sponsor: |  |
|  | Clock Start Date: | 20 March 2014 |

Associate Professor Peter Sykes and Ms Dianne Harker 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 ethical issues

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

* Ms Harker noted that they had just come back from Australian conference where the study is up and running and progressing well.
* The Committee thanked the researchers for a very interesting and useful application.
* The Committee noted that it took a while for them to understand the key information for the study in the PIS, for example that Mirena releases a drug. Please put this information earlier in PIS for people unfamiliar with the device.
* The Committee asked if the matching of participant’s health information against other government health registers was optional. Associate Professor Sykes said he hoped it would be mandatory but it would be possible to make this optional. He explained that this was seeking permission to look at clinically relevant information, primarily cancer registries, to access information on cancer related outcomes. The Committee were concerned that this explanation was too broad. They explained that it needs to be clear for participants what they are consenting to for this study and what future study they will be consenting to. Information needs to be included in the PIS on whether obtaining further information will be the subject of another ethics application.
* The Committee commended the use of the New Zealand census ethnicity data question.
* The Committee asked if anyone outside the research team had peer reviewed the protocol. Associate Professor Sykes confirmed that this study had been reviewed by the research advisory committee of ANZGOG and in a second review process as it received a grant from ANZGOG.
* The Committee asked whether it was appropriate to withhold standard treatment and what the risks would be in terms of disease progression or overall survival rates (R.1.3.1). Associate Professor Sykes explained that participants considered for conservative treatment have low grade tumours and are low risk patients. He explained that there are no studies that he is aware of that compare conservative management of low risk patients vs standard care. Conservative management has been used when patients have co-morbidities or want to have children. He advised that Mirena is generally the preferred method of conservative management as it does not have the risks associated with other treatments such as high dose progesterone. He does not know much about Metformin in combination with Mirena but does not believe there will be a short term increased risk for participants. There will need to be a long term follow up to ensure that they don’t relapse but he does not perceive there to be any risk for the duration of the study.
* The Committee asked whether the Data Safety Monitoring Committee was independent. Associate Professor Sykes confirmed that they are based at Queensland Health and in previous studies they were independent. The Committee asked for the Charter of the Data Safety Monitoring Committee to demonstrate their independence.
* The Committee noted that if a participant withdraws from the study, they should not have to notify their withdrawal in writing (R.3.12). Associate Professor Sykes agreed the researchers would do the written withdrawal on behalf of the participant.
* The Committee asked if there were issues around compliance with the weight loss intervention part of the study. Associate Professor Sykes explained that Queensland has had reasonable success with this part of the study. While he was not particularly optimistic, he believes that this should be investigated.
* The Committee asked if there are any New Zealand representatives on the Monitoring Committee. Associate Professor Sykes confirmed that there were not but that he could talk to study group if the Committee thinks this is important. The Committee agreed that this was not necessary.
* The Committee recommended that the researchers look at governance issues around the establishment of a tissue bank.
* The Committee requested the following changes to the participant information sheet and consent form:
  + Please consider making the language in the PIS more neutral, for example page 1 of the PIS “sparing women from major surgery.”
  + Please remove the heading “How is the research project being conducted?” at the bottom of page 8.
  + Please simplify the PIS, for example page 1 please define morbid obesity, page 2 please use simplified wording for somatic vs germline mutations.
  + Please include information that the participant will be on Metformin for approximately six months, earlier in the PIS.
  + Please remove the reference to “Genetic Testing and the feMMe Study” (page 5 of the PIS) as it will not apply in this study as researchers will need father’s genetic material.
  + Please ensure that conditions of main study and future study are kept separate, for example page 9 of the PIS refers to retaining information for a minimum of 15 years and indefinitely.
  + Please look at the yes/no boxes in the CF and remove any where they are not truly optional, i.e. where ticking no would exclude participants from the study. Please remove the yes/no options and keep the information as a statement rather than an option.
  + Please make it clear in the PIS what samples will be stored and for how long.

Decision

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

* Please amend the PIS and consent form, taking into account the suggestions made by the Committee *(Ethical Guidelines for Intervention Studies, para 6.22).*
* Please send the Charter for the Data Safety Monitoring Committee *(Ethical Guidelines for Intervention Studies, para 6.52).*

This following information will be reviewed, and a final decision made on the application, by Ms Kerin Thompson and Mrs Raewyn Sporle.

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| **3** | **Ethics ref:** | **14/NTB/36 (CLOSED)** |
|  | Title: | Assessment of three e-cigarette nicotine blends, when used by current smokers. |
|  | Principal Investigator: | Dr Chris Wynne |
|  | Sponsor: |  |
|  | Clock Start Date: | 20 March 2014 |

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| **4** | **Ethics ref:** | **14/NTB/35** |
|  | Title: | A pilot study to assess 2 research tools for the study of post bariatric surgery patients. |
|  | Principal Investigator: | Dr Jeremy Krebs |
|  | Sponsor: | Capital and Coast DHB |
|  | Clock Start Date: | 20 March 2014 |

Dr Richard Carroll 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 ethical issues

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

* The Committee noted that this was a very interesting application.
* Dr Carroll explained that evidence suggests that there are very early changes in glucose after bariatric surgery that come before any weight loss is achieved. While the exact mechanism of this is not clear, the researchers believe that this is due to caloric restriction. They are keen to study the first few days after surgery in detail to determine what these factors are.
* Dr Carroll explained that hormones are altered after bariatric surgery and this study is aiming to find what is the best way to study a control group. There has been criticism in previous studies when trying to compare those undergoing bariatric surgery and those with caloric restriction as the energy intake is still markedly higher in the caloric restriction group. After bariatric surgery, patients are on a 340 calorie diet for the few days following surgery. This study will aim to assess the tolerability of this diet which is a significant calorie restriction.
* The Committee noted that pregnant women will be excluded from the study and asked if a pregnancy test will be done. Dr Carroll confirmed that there will be tests where appropriate.
* The Committee recommends asking a colleague from another district health board to monitor the data at the same time and give an independent view of risk.
* The Committee noted that the peer review suggested a 24 hour food diary and asked if the researchers were planning to implement this. Dr Carroll advised that this was being considered as the response to the meal test was dependent on meal intake .
* The Committee asked if participants food intake will be monitored at each visit. Dr Carroll explained that the main objective of the study was to assess the tolerability of the diet and that if patients are not able to adhere to the diet without taking on extra calories, this will need to be taken into account and is a limitation of the study. This will need to be considered when planning later studies.
* The Committee asked whether the researchers were planning to collect information on the effects of a low calorie diet, for example dizziness and irritability. Dr Carroll advised that researchers will be meeting with participants regularly and this will be discussed. The Committee asked how the researchers would ensure that the information is standardised. Dr Carroll explained that objective measures such as blood pressure and renal function would be measured daily but he was happy to consider adding measures like a satiety score
* The Committee asked what criteria would be considered intolerable in order to terminate the study (R.1.6). Dr Carroll advised that this referred to participants finding the diet intolerable.
* The Committee asked if it was safe for participants to be driving after having little to eat for four days. Dr Carroll advised that they recommend that participants are transported and they are happy to provide this support. This will be included in the PIS/CF.
* The Committee requested the following changes to the participant information sheet and consent form:
  + Please include inclusion and exclusion criteria in the PIS.
  + Please number the pages on the PIS.
  + Please include information in the PIS on what will happen to blood samples including the number of samples, where they will be analysed, if they will be sent overseas, whether they will be returned or disposed and whether the plan to store them for future research is optional. If the plan to store blood for future research is optional, please provide a separate PIS/CF which makes it clear that this is optional. This will affect the last statement in the CF.
  + Page 4 of the PIS under compensation – Please change “you may be covered by ACC” to “you will need to apply for ACC compensation.”
  + Please review the yes and no options on the consent form and only include those that are truly optional. Please remove the yes/no boxes which will make the options statements.
  + Please include contact details for a Māori cultural support person.
  + Please change Multi-region Ethics Committee (page 4 of the PIS) to Northern B Ethics Committee.
  + Please include contact details for researchers in the PIS.
  + Please include that participants can withdraw from the study at any time.
  + Page 2 of the CF, third to last box – Please change “us” to researchers or study staff.
  + Please include a visual timeline on the PIS and include information that this study is planned for a Monday to Friday as this may impact on participant’s ability to participate.
  + Please be clear what version numbers will be used as these are different for the PIS and CF. Please consider combining the PIS and CF.
  + The times referred to in the PIS use the 24 hour clock. Please consider using AM and PM and participants are likely to be more familiar with this.
  + Page 2 of the PIS – Please explain what the liquid meal consists of.
  + Please include the statement “if you need an interpreter please tell us” in the CF.
  + Page 3 of the PIS – Please clarify what can be consumed during the period from “we will ask you not to eat or drink anything containing calories.”

Decision

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

* Please amend the PIS 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 Mali Erick and Ms Kerin Thompson.

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| **5** | **Ethics ref:** | **14/NTB/39** |
|  | Title: | Transform a Tooth |
|  | Principal Investigator: | Dr Lyndie Foster Page |
|  | Sponsor: | Faculty of Dentistry |
|  | Clock Start Date: | 20 March 2014 |

Dr Lyndie Foster Page 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 ethical issues

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

* The Committee thanked Dr Foster Page for a very interesting application for a useful and exciting study.
* Dr Foster Page explained that the technique using stainless steel crowns is used routinely in dentistry for children. The Hall Technique is a non-invasive technique whereby caries are not removed and local anaesthetic is not used.
* Dr Foster Page explained that a feasibility study had been conducted in Hawkes Bay in 2011 and ethics approval had been received from the Central Committee.
* The Committee commended the researchers on their peer review.
* The Committee noted that children will be removed from the study if they are starting to exhibit dental fear and asked how this can be identified. Dr Foster Page explained that if a child is not happy to sit in a dentist chair, they will not take part in the study. Dental therapists have been trained to identify this. The Committee asked if this behaviour is starting to manifest in three year olds. Dr Foster confirmed yes.
* The Committee asked why Whanganui had been chosen for this study. Dr Foster Page advised that when working for Southern and Taranaki DHBs, she had provided training in stainless steel crowns for those who could not make training in other regions. She explained that she knows the therapists in Whanganui, already has good support from the DHB and Whanganui has the numbers of children needed.
* The Committee commended the Māori consultation.
* The Committee noted that it appears that the Principal Investigator will be determining whether the study needs to be terminated by looking at events, for example a significant increase in children in the study group acquiring abscesses. The Committee recommended using somebody more removed from the study as it is difficult for the researcher to remain objective. Dr Foster Page agreed to have another academic look at the data.
* The Committee asked if the New Zealand census question would be used to obtain ethnicity data. Dr Foster Page advised that the DHB guidelines will be used and she will check if this is the census data question.
* The Committee noted the differences in answers in recruitment numbers in the application, PIS and protocol. Dr Foster Page explained that they need 766 children between the two arms of the study. She believes that they will need to obtain consent from 1000 children as 75% of children in the region have caries. 25% will not be able to take part in the study due to having no decay or having too much decay.
* Dr Foster Page explained that if participants are allocated to the drilling arm but want to use Transform a Tooth, they will be removed from the study as they have the right not to take part. As the Transform a Tooth technique is currently being used, the participants could go to another dentist who would perform this technique without cost to the patient. While this may impact the study, Dr Foster Page agreed to include this information in the PIS/CF as they cannot withhold information from parents that would affect their decision making.
* The Committee requested the following changes to the participant information sheet and consent form:
  + Please provide an age appropriate PIS for the children, for example using pictures and cartoons. While younger children can give a verbal assent, an assent form should be provided for slightly older children.
  + Please include the statement “if you need an interpreter, please tell us” in the CF.
  + Page 3 of the PIS – Please amend “Central Regional Ethics Committee” to “Northern B Ethics Committee.”
  + Page 1 of the PIS – Please amend typo which refers to “decayed children’s”.
  + Please include a statement in the PIS/CF that the researchers will inform participant’s GPs of their involvement in the study.
  + Please consider the yes/no options on the consent form and decide which ones are truly optional. If a participant cannot take part in the study after ticking no, then they are not optional. Please remove the yes/no boxes.

Decision

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

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

This following information will be reviewed, and a final decision made on the application, by Mrs Kate O’Connor and Mrs Mali Erick.

## 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:** | 06 May 2014, 12:00 PM |
| **Meeting venue:** | Novotel Tainui, 7 Alma Street, Hamilton |

The following members tendered apologies for this meeting.

Mrs Mali Erick

The meeting closed at 2.42pm.