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| **Committee:** | Northern A Health and Disability Ethics Committee |
| **Meeting date:** | 14 April 2015 |
| **Meeting venue:** | Novotel Ellerslie, 72-112 Greenlane Road East, Ellerslie, Auckland |

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| **Time** | **Item of business** |
| 1.00pm | Welcome |
| 1.10pm | Confirmation of minutes of meeting of 10 March 2015 |
|  | New applications (see over for details) |
| 1.30pm | i 15/NTA/29  ii 15/NTA/31  iii 15/NTA/33  iv 15/NTA/34  v 15/NTA/36  vi 15/NTA/37  vii 15/NTA/38  viii 15/NTA/40  ix 15/NTA/41  x 15/NTA/42  xi 15/NTA/43  xii 15/NTA/44 |
|  | General business:   * Noting section of agenda |
| 7.00pm | 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 |
| Ms Shamim Chagani | Non-lay (health/disability service provision) | 01/07/2012 | 01/07/2015 | Present |
| Mr Kerry Hiini | Lay (consumer/community perspectives) | 01/07/2012 | 01/07/2015 | Present |
| Ms Michele Stanton | Lay (the law) | 01/07/2012 | 01/07/2015 | Present |
| Dr Karen Bartholomew | Non-lay (intervention studies) | 01/07/2013 | 01/07/2016 | Apologies |
| Dr Christine Crooks | Non-lay (intervention studies) | 01/07/2013 | 01/07/2015 | Present |
| Mr Mark Smith | Non-lay (intervention studies) | 01/09/2014 | 01/09/2015 | Present |

## Welcome

The Chair opened the meeting at 1.06pm and welcomed Committee members, noting that apologies had been received from Dr Karen Bartholomew.

The Chair noted that the meeting was quorate.

The Committee discussed whether the statement “there is no cost to you for taking part in this study” often included in generic advertisements would be considered an inducement. The Committee recommended the HDEC Secretariat develop standard wording for flyers.

The Committee noted and agreed the agenda for the meeting.

## Confirmation of previous minutes

The minutes of the meeting of 10 March 2015 were confirmed.

## New applications

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| **1** | **Ethics ref:** | **15/NTA/29** |
|  | Title: | Evaluation and update of TF-CBT |
|  | Principal Investigator: | Miss Olivia Taylor |
|  | Sponsor: |  |
|  | Clock Start Date: | 03 April 2015 |

No researchers were 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

* The Committee noted that this study was a PhD proposal which is looking at the effects of using Cognitive Behavioural Therapy (CBT) on children who have been diagnosed with PTSD.

Summary of ethical issues (outstanding)

The main ethical issues considered by the Committee and which require addressing by the researcher were as follows.

* The Committee noted that it is not clear in the PIS what the study fully involves. They asked that more information be included in the PIS (listed below)
* Please clarify whether information will be de-identified (B.4.4.1 of the application) or anonymous as stated in the PIS.
* The Committee asked for clarification on why there was no exclusion criteria, for example somebody being in a distressed state.
* The Committee noted that health information needs to be retained for 10 years after a participant turns 16.
* Please clarify who will transcribe the tapes.
* Please clarify when the tapes will be destroyed.
* Please clarify who will take responsibility for the long-term storage of the tapes.
* Please clarify if there are any costs in participating as it is not clear in the PIS. Please also confirm if transport costs will be reimbursed.
* The Committee advised that those who are nearly 16 years may be able to provide consent.
* The Committee advised that P.4.1 was answered incorrectly as this study does not involve kaupapa Maori research.
* The Committee encouraged the researcher to call in for future applications as it helps with HDEC review.
* Please provide the outcome of Maori consultation.
* Please explain what a battery test is.

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

* Please include more information on the purpose of the study, what the study will involve for participants, information on what CBT is and how it is relevant to people who have suffered PTSD.
* Please elaborate on what are the discomforts and risks (page 2 of the PIS).
* Please include contact details, including a telephone number which is available after hours, for the researcher.
* Please include an ACC compensation clause. Sample text can be found on the PIS template on the HDEC website.

Decision

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

* Please amend the participant information and consent form, taking into account the suggestions by the Committee *(Ethical Guidelines for Intervention Studies, para 6.22).*
* Please provide the outcome of Maori consultation.

This following information will be reviewed, and a final decision made on the application, by Dr Mark Smith and Mr Kerry Hiini.

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| **2** | **Ethics ref:** | **15/NTA/31 (CLOSED)** |
|  | Title: | Implementation of a national guideline in babies on postnatal wards |
|  | Principal Investigator: | Dr Jane M Alsweiler |
|  | Sponsor: | University of Auckland |
|  | Clock Start Date: | 02 April 2015 |

Dr Jane Alsweiler 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.

Dr Christine Crooks declared a potential conflict of interest, and the Committee decided that she could take part in the discussions.

Decision

This application was *provisionally approved* by consensus.

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| **3** | **Ethics ref:** | **15/NTA/33** |
|  | Title: | Haemorrhage alleviation with tranexamic acid- Intestinal system (Halt-It) |
|  | Principal Investigator: | Mrs Racheal Bergman |
|  | Sponsor: | London School of Hygiene & Tropical Medicine |
|  | Clock Start Date: | 02 April 2015 |

Mrs Racheal Bergman 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

* The Committee noted that this was a study that was developed in the UK with funding from the UK government and an A+ research grant.

Summary of ethical issues (resolved)

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

* The Committee asked why it was justified to use non-consenting patients. Mrs Bergman explained that they think that those who are incapable of giving consent have a different type of bleeding. She also said that elderly people with GI bleeding often become incompetent and it is important to capture this group.
* The Committee asked what percentage of patients would be unable to give consent. Mrs Bergman advised that it is only around 5% but excluding this group would skew the data. She said that she had asked the researchers in London if this group could be excluded but they were not keen.
* The Committee asked for the definition of adult for this study. Mrs Bergman explained that GI bleeding is unusual in those under the age of 20 and that she was not expecting anyone younger than that in this study.
* The Committee advised that in New Zealand representatives of patients cannot give consent to participate in a trial.

Summary of ethical issues (outstanding)

The main ethical issues considered by the Committee and which require addressing by the researcher were as follows.

* The Committee advised that as per Right 7(4) of the Code of Health and Disability Services Consumers’ Rights, research in non-consenting participants must be in the patients’ best interests. They said that Colin McArthur and Shay McGuinness at Auckland DHB have developed guidelines around research on non-consenting participants and recommended that the researchers discuss this study with them.
* The Committee noted that the PIS needs more information for a New Zealand audience. They recommended the researcher refers to the PIS and consent form template available on the HDEC website.
* The Committee advised that Maori consultation is required.
* The Committee advised that most studies in New Zealand collect ethnicity data.
* The Committee suggested reviewing the application as there is a lot of useful information in there that is not included in the PIS.
* The Committee advised that there needs to be a separate PIS and consent form for participants who were enrolled in the trial when they were not able to give consent. This needs be given to them when they are able to give consent and should explain that they were enrolled in a trial when they were non-competent and that the researchers are now seeking their permission to carry on with the trial. The Committee advised that the researchers will not be able to use any data if participants do not give consent at this stage.

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

* Please include the ACC compensation clause.
* Please include HDC advocacy contact details.
* Please include contact information for the study team.
* Please include more information on the study drug and the risks.
* Please include the evaluation of daily activities in the PIS.

Decision

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

* Please amend the participant information and consent form, taking into account the suggestions by the Committee *(Ethical Guidelines for Intervention Studies, para 6.22).*
* Please provide evidence of Maori consultation *(Ethical Guidelines for Intervention Studies, para 4.9).*
* Please provide justification for including non-consenting patients *(Ethical Guidelines for Intervention Studies, para 5.28).*

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

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| **4** | **Ethics ref:** | **15/NTA/34** |
|  | Title: | DISRUPT PAD |
|  | Principal Investigator: | Dr Andrew Holden |
|  | Sponsor: | Shockwave Medical Inc |
|  | Clock Start Date: | 02 April 2015 |

Dr Andrew Holden was not present in person for discussion of this application but Ms Donna Katae available on teleconference.

Potential conflicts of interest

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

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

Summary of ethical issues (outstanding)

The main ethical issues considered by the Committee and which require addressing by the researcher were as follows.

* The Committee noted that no ethical issues had been identified for A.1.6 but advised that as one of the primary aims is safety, this study is more risky than standard care. Please outline the ethical issues that may arise from this.
* Please clarify why the sub-study is only occurring in New Zealand.

Decision

This application was *approved*, subject to the following non-standard conditions.

* Please clarify ethical issues.
* Please clarify why the sub-study is only occurring in New Zealand.

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| **5** | **Ethics ref:** | **15/NTA/36** |
|  | Title: | Ocriplasmin for Vitreomacular Traction/Symptomatic Vitreomacular Adhesion |
|  | Principal Investigator: | Dr. Stephen Guest |
|  | Sponsor: | Alcon Laboratoris (Australia) Pty Ltd |
|  | Clock Start Date: | 26 March 2015 |

Dr Stephen Guest, Ms Eileen Bisley, Mrs Anneke Marais and Mrs Claire Perrott 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 (resolved)

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

* The Committee noted that this was a phase 4 trial and asked if this study was still looking at safety and efficacy issues. The researchers advised that the phase 3 study was quite broad in the patient selection and this study would narrow the selection criteria. They said that the aim of the study is to get real world experience of the drug and to get six month follow up data as they do not have much of this.
* The Committee asked for clarification on how the study met the equipoise standard. The researchers explained that surgery is the most effective option but has more side effects. They said that doing nothing sometimes provides spontaneous resolution but the results are usually better with JETREA or surgery. The Committee asked if a patient could be at a disadvantage if they agreed to be on the trial and JETREA is not the best treatment for them. The researchers advised that if JETREA does not work within a month, surgery will be offered and there is very little loss if surgery is deferred.
* The Committee advised that the head is tapu for Maori so doing anything to the eye would be culturally significant. Ms Bisley confirmed that Maori consultation had been applied for.
* The Committee noted that when people are taking part in a sponsored trial they are giving up their right to ACC. They advised that they expect the sponsor to take responsibility for following up if there are issues, rather than passing on to the insurers.
* The Committee advised that there needs to be study IDs on the questionnaires rather than names to protect patient confidentiality. Ms Bisley explained that the questionnaires were not yet site specific but that this would be done.

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

* Please make it clear in the PIS that the treatment will be administered by an injection to the eye.
* Please include additional information on risks and possible side effects. Information in the lay summary could also be included in the PIS along with more information on the study procedures. Please note that JETREA may obviate the need for surgery but if it does not work that surgery will be offered to participants.
* Please update the PIS based on information provided from Maori consultation.

Decision

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

* Please amend the participant information and consent form, taking into account the suggestions 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 Christine Crooks and Dr Brian Fergus.

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| **6** | **Ethics ref:** | **15/NTA/37** |
|  | Title: | FAME 3 |
|  | Principal Investigator: | Dr Gerard Devlin |
|  | Sponsor: |  |
|  | Clock Start Date: | 26 March 2015 |

Dr Gerard Devlin and Mrs Liz Low 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

* The Committee commended the researcher for a clear PIS.

Summary of ethical issues (resolved)

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

* The Committee asked if there would be 100 participants at Waikato. Dr Devlin advised that they are hoping to randomise up to 100 patients but this will depend on recruitment in other places. Mrs Low subsequently advised that they were expecting around 30 participants in Waikato.
* The Committee asked if the risk of this study was no greater than the normal procedure. Dr Devlin advised that pressure wire is considered standard care.
* Dr Devlin advised that the study will involve seven intervention cardiologists and five cardiac surgeons at Waikato Hospital and they are all familiar with the technology.
* Dr Devlin advised that the study has been peer reviewed at Waikato Hospital and everybody supports it.
* The Committee noted that in B.2.2 a study sponsor had been selected but there was no evidence of a sponsor later in the application. Mrs Low explained that the sponsors are the main investigators in the US and that there is no financial sponsor. The Committee agreed that the ACC compensation provisions apply.
* The Committee asked if the researchers were worried about there being large dropout rates due to the five year follow up period. Mrs Low explained that the primary endpoint is after one year and they hope to follow up patients for two years. She said that they had allowed for a certain number of patients being lost tofollow up.
* The Committee noted the letter from the Department of Health and Human Services which stated that quarterly safety reports will be submitted to the FDA and asked what the content would be. Mrs Low explained that these are regular reports from data safety and these will also be sent to the HDEC.
* The Committee asked if the suggestions in the FDA letter were implemented. Mrs Low said that she was not sure but that she thought they would have been.

Decision

This application was *approved* by consensus.

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| **7** | **Ethics ref:** | **15/NTA/38** |
|  | Title: | ACH422-004: A study of ACH-0143422 and ACH-0143102 in patients with chronic Hepatitis C |
|  | Principal Investigator: | Prof Edward Gane |
|  | Sponsor: | Clinical Network Services Ltd |
|  | Clock Start Date: | 26 March 2015 |

Professor Ed Gane, Ms Angelica Edwards and Mrs Carolyn Harris 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

* The Committee asked why this trial was being conducted. Mrs Harris explained that this trial was looking to find a cheaper alternative to sofosbuvir.

Summary of ethical issues (resolved)

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

* The Committee asked for clarification on what standard of care is in New Zealand. Professor Gane explained that this is considered the best available treatment in the country so in New Zealand, this is sofosbuvir in combination with simeprevir. This is approved by Medsafe but is currently not yet funded by PHARMAC and is available if patients want to purchase it. He said that if the treatment is not working for participants, they will go onto 12 weeks of standard care which will be purchased by the sponsor.
* The Committee asked if Phase 3 trials were planned after this trial. Professor Gane confirmed that they were.
* Mrs Harris confirmed that this study did not have a future research component and that tissue would be disposed of at the end of the study.
* Ms Edwards confirmed that the results of Maori review had just been received.
* The Committee asked for clarification on the pregnancy PIS and asked what information would be collected. Mrs Harris said it would be the outcomes of the pregnancy. Professor Gane confirmed that neither of the study drugs should have any effect on a foetus, but he would not include anyone who was pregnant or breastfeeding.
* The Committee asked if dosages would be adjusted. Ms Edwards confirmed that if the internal data safety monitoring committee determined that a patient had reached the dose threshold, the researchers would look at reducing the dose.

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

* Please include the names of the laboratories that tissue samples will be sent to in Australia and the United States.

Decision

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

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

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| **8** | **Ethics ref:** | **15/NTA/40** |
|  | Title: | BIOFLOW-V |
|  | Principal Investigator: | Dr Mark Webster |
|  | Sponsor: | BIOTRONIK Australia Pty, Ltd |
|  | Clock Start Date: | 26 March 2015 |

Miss Nicole Somerville 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

* The Committee noted that this was a well written PIS.
* The Committee noted that this was a study comparing two common drug eluting stents, Osiro and Xience.

Summary of ethical issues (resolved)

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

* Miss Somerville confirmed that they are still awaiting the results of the Maori review committee.
* Miss Somerville explained that there will be 100 participants recruited in New Zealand, split across four centres.
* Miss Somerville explained that Xience is standard treatment and will be funded by the DHB. Biotronik is funding Osiro.
* The Committee noted that this study will be run in 14 other countries and asked if ethical approval had been received in other countries. Miss Somerville advised that it had been applied for in Australia but had not been received anywhere else.
* The Committee asked why the study was being done if the two stents were well known. Miss Somerville explained that Osiro is not currently approved in the US and FDA approval is required. While there have been previous trials, there were not enough participants to generate the data that the FDA needs.
* Miss Somerville advised that the safety concerns for this study were the usual safety concerns with putting in a stent.
* Miss Somerville advised that information provided to the FDA will be failure at 12 months, with a follow up phone call at two, three, four and five years.

Decision

This application was *approved* by consensus.

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| **9** | **Ethics ref:** | **15/NTA/41** |
|  | Title: | Insights into AFOs |
|  | Principal Investigator: | Miss Elizabeth Binns |
|  | Sponsor: | AUT University |
|  | Clock Start Date: | 02 April 2015 |

Miss Elizabeth Binns and Ms Denise Taylor 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

* Miss Binns explained that they hear from wearers that current AFOs are ugly, uncomfortable and that people do not want to wear them. This study will ask for users’ perspectives (children) to see if there are different design options and ideas that could be adopted.
* The Committee noted a well written and easy to understand application.

Summary of ethical issues (resolved)

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

* The Committee asked if there was any mental health expertise available if children became disturbed. Miss Binns explained that the research nurse has done interviews with children before in a research capacity and is experienced with a paediatric population. She said that there is no mental health expertise on hand as they are a university but she is putting together an information sheet of contacts where people can go and talk to someone after the interview. Miss Binns explained that she was not expecting any issues as the focus is on the design of the AFOs rather than if children like wearing them.
* The Committee asked what the next steps would be after this study. Ms Taylor explained that a design group will look at rehab devices, including the AFOs, to see if they can incorporate what people want from their devices into something different.
* The Committee asked how the video will be used for children to tell their stories. Miss Bins said the video is to capture the conversation that is taking place while the children are making their version of an AFO.
* The Committee asked what would happen with the video after the study. Miss Binns advised that it will be kept for 10 years, stored then destroyed. She said that the researchers would not use any images of the children and that they would ask for permission to use the stills of children. Miss Binns said that they would also be happy for parents to be filmed.
* Miss Binns advised that they are awaiting the results of Maori consultation.
* The Committee asked what age participants would be. Miss Binns explained that participants would be aged five to eighteen but the PIS was aimed at parents. She said that a large number of participants may have cerebral palsy so they would be able to assent by putting stickers on the assent form.
* The Committee noted that health information needs to be kept for 10 years after participants turn 16.

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

* Please include the ACC compensation clause in the PIS. Sample wording is available on the PIS template on the HDEC website.

Decision

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

* Please amend the participant information and consent form, taking into account the suggestions by the Committee *(Ethical Guidelines for Observational Studies, para 6.10).*

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| **10** | **Ethics ref:** | **15/NTA/42** |
|  | Title: | CHiPS study |
|  | Principal Investigator: | Miss Joanne Clements |
|  | Sponsor: | Counties Manukau Health |
|  | Clock Start Date: | 26 March 2015 |

Miss Joanne Clements and Dr Michael 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

* Miss Clements explained that babies born at less than 30 weeks go onto CPAP if they do not need to be intubated or mechanically ventilated. She said that babies are kept on high pressures of CPAP until they are stable with saturations and rate of breathing and are slowing weaned from 8cm to 5cm.

Summary of ethical issues (resolved)

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

* The Committee asked if there are any extra risks associated with this study. The researchers said there were not and if babies are distressed they will go back onto CPAP. They said that consent is not sought from parents for CPAP as this is standard treatment. When babies are put onto the high flow, the researchers will seek parents’ consent before enrolling babies onto the trial. Miss Clements explained that babies will need at least a week of CPAP and at the end of this week, the researchers will look at seeking consent from the parents.
* The Committee asked how long babies would stay on CPAP. Miss Clements advised that it if they were born early (24 weeks) this could be up to three weeks. For babies born at 29 weeks, this would normally be one week.
* The Committee asked how safety would be monitored. Miss Clements explained that this patient population has 24 hour monitoring and that there is always a bedside nurse.
* The researchers explained that the high flow method was standard care for many units.
* The Committee asked if the aim of this study was to eventually remove the CPAP method. Miss Clements explained that CPAP is the gold standard but the aim of this study is to see if the high flow method is just as good as it will allow babies to feed earlier. She said that very preterm babies do not manage without CPAP and that it would probably be better after the acute initial stage is over. Miss Clements said that they are hoping to reduce the time for respiratory support which means that babies will be able to feed earlier.
* The Committee advised that records should be kept 10 years after the participant turns 16.

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

* Please reword ACC wording to a baby’s perspective.
* Please update version number on consent form.
* Please change legislation to Accident Compensation Act.

Decision

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

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

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| **11** | **Ethics ref:** | **15/NTA/43** |
|  | Title: | Impact of Dietary Protein Supplementation Combined with Exercise Training on Diabetic Rehabilitation in Overweight/Obese Adults with Type 2 Diabetes |
|  | Principal Investigator: | Dr Lee Stoner |
|  | Sponsor: | Massey University |
|  | Clock Start Date: | 26 March 2015 |

Dr Lee Stoner and Associate Professor David Rowlands 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

* The Committee noted that researcher had talked to Richard Robson who had advised that SCOTT approval was not required as this pilot study was only looking at physiological effects rather than at therapeutic benefits.

Summary of ethical issues (resolved)

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

* The Committee asked for clarification on how sheep protein was a food if it comes from wool. A/Professor Rowlands explained that the protein is keratin but as humans do not process this well there is a chemical process to break it down.
* The Committee asked if the researchers were manufacturing the drink and food bar. A/ Professor Rowlands explained that the bar is being manufactured by a commercial manufacturer in Tauranga and the drink is being formulated by food technologists in Otago.
* The Committee asked how researchers would manage participant allergies. A/Professor Rowlands explained that they would run health screening questionnaires which would ask about allergies. He said that the manufacturer of the bars also process nuts at their facility so participants would need to be made aware of this.
* The Committee asked why the psychological wellbeing questionnaire was included when the study was based on physiological mechanisms. Dr Stoner advised that there was some evidence to show that whey or wool based protein can help with psychological profiles but that nothing would be done with the questionnaires. The Committee felt that the questionnaires were unnecessarily invasive given that answers would not be followed up on.
* The Committee noted that this study will be done in participants with type 2 diabetes and asked if any adverse events were anticipated and how these would be managed. Dr Stoner explained that a similar study had been done with 30 participants and there had been no major events. He said that there was a registrar on site to do the muscle biopsy and glucose testing. A/Professor Rowlands explained that participants need to be cleared by their GP to participate in the study, clinical exercise physiologists will be monitoring the study and that because the participants are being seen five days a week there are a lot of opportunities to pick up any abnormalities.
* The Committee asked how frequently data would be looked at and noted that more complex trials often have a data safety monitoring board. The Committee also asked if there would be any stopping points. Dr Stoner advised that they can tell if anyone is not doing well as they have regular contact with participants. A/Professor agreed that they could adopt forms used in previous clinical trials around adverse events.

Summary of ethical issues (outstanding)

The main ethical issues considered by the Committee and which require addressing by the researcher were as follows.

* Please use the HDEC PIS and consent form for future unspecified research available on the HDEC website. Please also refer to the Guidelines for the Use of Human Tissue for Future Unspecified Research Purposes for more information on what information needs to be included http://www.health.govt.nz/publication/guidelines-use-human-tissue-future-unspecified-research-purposes-0

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

* Please state that this is a pilot study.
* Please include study inclusion criteria in PIS.
* Please include the study design from the letter to GPs as this is clearer.
* Please include information on whether there are any costs to participate in study or whether there will be any reimbursement of expenses.
* Please specify at whose cost the kaumatua will be.
* Please include that this study has receive approval from Northern A HDEC.
* Please include how many times the wellbeing questionnaires will be administered.
* Please make it clear to participants that any information is potentially identifiable to allow them to withdraw from the study.
* Please make it clear in the main PIS that future unspecified research is optional.
* Please include information on where samples will be tested in the main PIS.
* Please include information in the main PIS on whether urine tests will be done in New Zealand and whether blood, muscle biopsy and urine samples will be destroyed.
* Please include information on intellectual property in the PIS for future unspecified research as this is currently only mentioned in the FUR consent form. IP wording should also be included in the main PIS.
* Please include information in the main PIS on whether samples will be destroyed and returned and that they will have a unique code.

Decision

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

* Please amend the participant information and consent form, taking into account the suggestions 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 Ms Michele Stanton and Dr Christine Crooks.

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| **12** | **Ethics ref:** | **15/NTA/44** |
|  | Title: | A non-inferiority trial of smartphone-based health applications IBDsmart and IBDoc for IBD patients in NZ. |
|  | Principal Investigator: | Assoc. Prof Michael Schultz |
|  | Sponsor: |  |
|  | Clock Start Date: | 02 April 2015 |

Clinical Professor Murray Barclay and Dr Andrew McCombie 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

* Clinical Professor Barclay explained that the aim of this study was to help improve patient care by improving interactions and communication between doctors and patients while people with IBD are waiting between outpatient visits.

Summary of ethical issues (resolved)

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

* The Committee asked for clarification on how the IBD smartphone app would work. Professor Barclay explained that the aim of this study was improve communication of IBD symptoms between patients and doctors. Patients would send details of their symptoms to the team who is looking after them to see what is happening with their IBD over time, rather than having to wait for a six month or yearly appointment. If the team sees that patients are having problems from their symptom scores, they can get in contact and help manage any flares and ask if they need extra medication.
* The Committee asked if information would be downloaded to a central database. The researchers explained that the information would go to a patient’s IBD nurse and doctor and this would be stored in secure database like any other hospital database.
* The Committee asked if the IBD kit had been trialled in Dunedin. Dr McCombie advised that the kit had been tested in usability and validity studies in Europe. These studies found that the kit was highly accurate.
* The Committee asked if there were any chance of false positives or issues around calibration. Clinical Professor Barclay thought it was highly unlikely that there would be false positives or that the kit would fail as all the testing had been positive thus far.
* The Committee asked if there was any need for additional safety monitoring due to patients handling faecal samples. Clinical Professor Barclay did not think so as participants would use gloves and the samples would be disposed of in the toilet.
* The Committee asked if the study would be terminated if there was evidence of patients doing worse. Clinical Professor Barclay advised that they will be monitoring disease activity every three months in the control group and every week in the other group. Results will be compared after three to six months.
* The Committee asked how patients would be recruited and how the risk of coercion from being the treating clinician of patients would be managed. Dr McCombie advised that patients would be recruited from Waitemata, Southern and Canterbury DHBs. He said that he would be coordinating the study and recruiting the first 10 to 20 participants at each centre. He has a PhD and is not a gastroenterologist so will not be the treating clinician of any participants. Dr McCombie advised that he is the Chair of the Canterbury Crohn’s Support Group but this has not been an issue in the past.
* The Committee asked for clarification on confidentiality after the study was over. Clinical Professor Barclay advised that if the research team has supplied the phone, they will take it back at the end. The researchers will recommend that patients delete the application unless it is used at a later stage clinically. The application is structured in such a way that people cannot use it without entering a password even if the phone is on.

Summary of ethical issues (outstanding)

The main ethical issues considered by the Committee and which require addressing by the researcher were as follows.

* The Committee asked if the information would be on a central server for all three DHBs. Clinical Professor Barclay said that he understood it to be on a database but that these were not connected between DHBs. He agreed to provide more information on the security of information to ensure that patients’ confidentiality was protected. If the hospital servers can be accessed, then please provide confirmation on how researchers will ensure that all hospital information will remain confidential.
* Please confirm how confidentiality of this database will be managed regarding links to other databases. If it will be linked with other hospital databases, how will the researchers ensure that patient information in the hospital database is protected?

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

* Please include more information on what is involved with the testing of stool samples. The Committee liked the information given at B.1.2.
* Please include the aim of the study listed at A.1.5 in the PIS.

Decision

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

* Please amend the participant information and consent form, taking into account the suggestions by the Committee *(Ethical Guidelines for Intervention Studies, para 6.22).*
* Please provide more information on how confidentiality and security will be managed *(Ethical Guidelines for Intervention Studies, para 7.3).*

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

## 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:** | 09 June 2015, 01:00 PM |
| **Meeting venue:** | Novotel Ellerslie, 72-112 Greenlane Rd East, Ellerslie, Auckland |

The following members tendered apologies for this meeting.

Dr Christine Crooks

The meeting closed at 6.11pm.