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| **Committee:** | Northern B Health and Disability Ethics Committee |
| **Meeting date:** | 04 February 2014 |
| **Meeting venue:** | CEO Meeting Room, Level 3, Hocking Building, Waikato Hospital Campus |

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| **Time** | **Item of business** |
| 12.00pm | Welcome |
| 12.05pm | Confirmation of minutes of meeting of 03 December 2013 |
| 12.30pm | New applications (see over for details) |
| 3.30pm | i 14/NTB/8  ii 14/NTB/2  iii 14/NTB/3  iv 14/NTB/4  v 14/NTB/7  vi 14/NTB/10  vii 14/NTB/11  viii 14/NTB/12  ix 14/NTB/13 |
| 3.35pm | General business:  Noting section of agenda |
| 3.50pm | 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 12.10pm and welcomed Committee members.

The Chair thanked Mary-Anne for coming in for lunch and officially saying goodbye to the Committee. The Committee thanked Mary-Anne for her time and expertise. The chair explained how the NTB Committee, as a whole, works really hard. Mary-Anne has taught the Committee a great deal about communication and accessibility of information, and the Committee is better off for it.

Mary-Anne expressed her thanks and joy from her time sitting on the Committee, noting the quality and passion of the research and researchers that has come through the NTB Committee. The research is often ground breaking and should be recognised as such.

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 3 December 2013 were confirmed.

## New applications

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| **1** | **Ethics ref:** | **14/NTB/8** |
|  | Title: | The INTENT trial |
|  | Principal Investigator: | Dr Michael Collins |
|  | Sponsor: |  |
|  | Clock Start Date: | 23 January 2014 |

Dr Michael Collins and Kirstin Ryan 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.

* Nutrition issues related to kidney transplant are typically obesity and weight gain. Currently the data about best ways to combat post-transplant weight gain is limited. This study aims to generate knowledge with the goal of establish useful information that may guide future research and treatments.
* The Committee commended the readability of the application.
* The Committee queried what the reasons are for weight gain after kidney transplants. Dr Collins explained the reasons for weight gain were to some degree controversial, though factors include dietary restrictions being relaxed post-transplant. Patients often feel better, are no longer having renal failure, and may be on drugs that stimulate appetite.
* Dr Collins confirmed the intervention was fairly basic (motivational interviewing, promoting adherence, food logs and exercise). It was more about being consistent and recording data to see if this approach worked.
* P.2.1.2 (recruitment). Please confirm who is approaching patients and the context of recruitment. Dr Collins explained all recipients post-transplant have a close relationship with the kidney transplant team. Patients spend a week in hospital and are often discharged within a week, with daily visits every week for a month with a staggered reduction in visits over time.
* Dr Collins envisions recruitment to occur by a series of talks over time as participants attend their standard practice appointments following transplant. The participants have a month to be consented from recruitment so they have time to think about it. Dr Collins’s past experience with similar trials found that participants are concerned about weight gain and are quite keen to take part.
* Dr Collins and the Committee both noted there could be a degree of coercion as participants may want to ‘please’ their physician but this is mitigated by the period of time to consider participation and consent.
* Dr Collins confirmed there is no rush to consent before surgery.
* P.3.1 – Please clarify who will screen for eligibility. Dr Collins explained it would be the study team and Co-ordinating Investigator. The inclusion criteria are very broad so most people who undergo a kidney transplant who live in the Auckland region will be eligible.
* F.2.1 – One exclusion criteria is ‘significant risk of non-adherence’. Please explain potential grounds – how is this identified? Dr Collins explained that if the person is ‘totally breaking down’ or unable to continue with the study, perhaps due to the high intensity involvement aspect of the trial. The exclusion criteria was added to ensure they could justify excluding participants who found the intensive attendance was too much. Dr Collins added in past studies there have not been any instances of adherence issues.
* The Committee queried if the standardised body composition measures are validated. Dr Collins explained they had been validated. The standard body composition is considered the gold standard, compared to surrogate measures, including cadaveric body composition comparisons.
* The Committee queried whether the Masters student would be involved in the study long enough to have sufficient data for the Masters project. The Researchers acknowledged the risk for the student, noting there should definitely be enough for the methodology of the study, even if the total amount of anonymous data for analysis is not sufficient.
* The Committee noted the high number of Maori affected by obesity. Is there a particular number considered appropriate for the study Dr Collins explained the transplant numbers are 20-30%. This number fluctuates. This number is lower than the number of Maori who actually have kidney diseases. We will try and recruit as many as we can to the trial, and involvement will be offered to all eligible.
* Dr Collins explained the study has gone through the Maori research committee (Helen Wihongi). Since submission the study has received approval on the condition that the main laboratory can confirm via letter than the samples will be (appropriately managed.
* A.5.1 The Committee noted the study is considered to have no sponsor, noting the DHB is going to be the main locality and would be responsible. Dr Collins responded that he was unsure what to put, noting that it could be the DHB. The researcher added that management would be internal, though has research governance by the research committee at the DHB and would have legal responsibility for the study.
* Committee queried whether all the scientific review had been received, noting peer review for ethics was sufficient (HRC grant) but Australasian Kidney Trials Network review was outstanding. Dr Collins explained that further details have not been received yet, though the reviews are not contingent for study commencement.
* The Committee queried whether any changes from further review came back would be changed and implemented. Dr Collins confirmed that it was unlikely but that any suggested changes would be taken on board.
* The Committee requested the following changes to the Participant Information Sheet and Consent Form:
* Please review the physical activity schedule noting the lack of backslashes.
* The Committee noted on the CF some of the options are not truly optional and should be mandatory for study participation. Dr Collins noted he were aware of this and was happy to take this suggestion on board, as it is a reasonable condition and it makes requirements clear to participants. Dr Collins confirmed they would remove all options from ones where it is a condition of study participation.
* Pg.4: ‘You have the right to access information about you collected for the study’. Please explain how the participant can access this information, such as who they should speak to and the process involved.
* Pg.2: ‘Random selection’. Please explain what this is in lay language for participants.

Decision

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

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| **2** | **Ethics ref:** | **14/NTB/2** |
|  | Title: | Kahungunu Infant Safe Sleep (KISS) Pepi Pod Study |
|  | Principal Investigator: | Prof Barry Taylor |
|  | Sponsor: |  |
|  | Clock Start Date: | 23 January 2014 |

Prof Barry Taylor 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 the study area was very important and it was a clear application.
* Please explain the prior studies involving wahakura. The same intrusive recording was involved in that study? Prof Taylor confirmed that it did involve the same method of observing and this new study is an extension of that study. The reason we did not follow up earlier was because we ran out of funding. Now that we can fund it we can continue with the follow up.
* Has the earlier study started recruitment? Prof Taylor confirmed the study had finished and papers were being written and or published.
* Prof Taylor explained that all the investigators were all Maori and in this community everyone knows everyone. The relationships are strong and family like. Prof Taylor noted that 92% of recruited participants to wahakura study were retained over 6 months which is something we are proud of and shows our relationship in the community.
* The Committee asked if there were any instances in wahakura study of participants being uncomfortable with the recording. Prof Taylor explained they can turn it off at any time. No audio is recorded, just video. Prof Taylor explained that majority of refusals to participate in recordings was from the male partners but these refusals only resulted in 30% of those approached declining.
* The Committee queried the exclusion criteria relating to excluding infants born at less than 36 weeks when this is a known risk factor for SUDI. Prof Taylor explained that the criteria are the same as the prior study in order to compare the data between the studies.
* The Committee queried if only mothers who are breastfeeding are recruited. Prof Taylor explained that many aspects of breastfeeding were important and other feeding patterns were included in the study. The recording covers all other feeding and mothers can be recruited regardless of feeding preference. The committee suggested that the observance of all feeding was made explicit in PISCF as this currently refers only to breastfeeding. .
* The Committee queried the timing of recruitment. Please clarify the difference between being given the information and consenting to participate. Prof Taylor explained they were using DHB processes to conduct recruitment. We are hoping that the consenting visit is when they consent. The Committee asked whether there is any coercion to get a Pepipod as they cost 100+ dollars. Prof Taylor acknowledged the possibility and said they would avoid this.
* The Committee queried if Otago University was the sponsor. Prof Taylor responded they are happy to have Otago University as the sponsor though was unsure at the time of filling out the application.
* The Committee requested the following changes to the Participant Information Sheet and Consent Form:
* The Committee requested that other forms of feeding were added into the PIS/CF.
* Please refer to NTB Health and Disability Ethics Committee.
* Please add more contacts for Health and Disability Advocacy
* The Committee queried whether it was possible to have an independent person to talk to about cultural issues with the study, noting it was difficult due to the close-knit relationship in the community. The Committee felt the health and disability advocate was independent and would suffice.
* Please include information about how vital signs are monitored during the night, in lay language. Prof Taylor clarified that they were recorded, not monitored. Please amend PISCF to state these are recorded rather than monitored.
* The Committee noted on the CF some of the options are not options and should be mandatory, without yes/no options. Prof Taylor explained that some are options. The Committee responded it is just the conditions that are mandatory for study involvement where optional boxes should be removed. The optional ones can stay optional. Please review and remove options and make mandatory statements where applicable..
* Add information on intention of video being used for educational purposes.
* The Committee noted the information will be potentially identifiable, rather than de-identified (b.4.4.1). This is due to the tracking purposes information. Prof Taylor explained that during the study it is potentially identifiable though after the study is over it will be de-identified. The Committee noted for this is just for reference for future applications.
* Please review version dates, ensuring the version date referred to on consent form is provided on information sheet.
* Please clarify why contact information is on the PIS/CF. Prof Taylor said it was for tracking due to the participants frequently moving around. This was accepted by committee.
* Please add the name of the person who is consenting the participant on the CF.
* Please include information about where samples will be stored and analysed

Decision

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

* Please amend the information sheet and consent form, taking into account the suggestions made by the Committee (*Ethical Guidelines for Observation Studies* *para 6.11*).

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

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| **3** | **Ethics ref:** | **14/NTB/3** |
|  | Title: | A study on the Long-term Treatment with BELVIQ (lorcaserin HCl) in obeseand overweight patients with Cardiovascular Disease and/or multipleCardiovascular risk factors |
|  | Principal Investigator: | Prof. Harvey White |
|  | Sponsor: | Eisai Limited |
|  | Clock Start Date: | 23 January 2014 |

Dr Jocelyn Benatar, a Co-investigator, 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.

* Dr Benatar noted that some obesity treatments cause bowel problems but we have conducted a number of earlier tests and have not identified any potential bowel problems with the study drug.
* The Committee noted the study was interesting, adding there was a good potential use for the study drug and people with obesity and type 2 diabetes.
* The Committee confirmed this study is also for EMA regulatory approval.
* New Zealand has not been approached for any other research relating to the study drug.
* The Committee queried whether SCOTT approval was given for the study drug. Dr Benatar confirmed SCOTT approval was pending and the study would not commence until the drug had been approved.
* The Committee queried the lack of re-consenting for genomic research. Dr Benatar clarified that the participants sign a sub-study consent form to participate. The genetic study is explained to patients, noting that the sample may be tested multiple times as new information is discovered. The Committee explained this needs to be explicit in the sub study PIS.
* The Committee queried the composition of the DSMB. Is there an Australasian person on that board? Dr Benatar confirmed there was not. The Committee queried how many people are on the DSMB. The researcher said 5-6 people, hoping by 5 February 2014 they will have the final number at 6-7 with at least one statistician.
* R.1.6: states sponsor can terminate study for any reason. The Committee noted the sponsor can’t terminate for commercial reasons or public relations.
* R.2.3: Committee noted that data would be de-identified rather than anonymous. (NEAC guidelines)
* R.2.5: please keep data for minimum of 10 years.
* P.2.8: please confirm study results will be offered to participants in lay language.
* P.4.6: please clarify the mode of collecting ethnicity data. The Committee suggests using the New Zealand Census model.
* The Committee queried some potential side effects from the drug. Dr Benatar explained that over 3 studies there were about 7 thousand patients who took study drug.In relation to psych disorders there were a number of patients who experienced euphoria. A small number had suicidal ideations. A number had reduced white blood cells on the drug, with 1.9% experiencing cognitive impairment which improved after they stopped the study drug. Dr Benatar explained if patients have side effects we always stop the study drug. Currently there are no identified long term side effects. Dr Benatar noted that 7 thousand is not enough to find the 1 of 10,000 instances of adverse events but the studies would continue in order to get this data.Will do echo sub-studies.
* The Committee requested the following changes to the Participant Information Sheet and Consent Form:
* Please check HDEC PIS/CF template (<http://ethics.health.govt.nz/home>) for further information on ACC and insurance information for participants.
* The Committee queried why participants were asked about illicit drug use. Dr Benatar explained it was due to serotonin levels and potential relations to psychiatric side effects.
* The Committee queried the statement that they study team is not responsible for injury or study related problems. Dr Benatar explained that the study team and CI are responsible for research related problems. Dr Benatar added the PIS was a template and required changing. The Committee confirmed this must be changed.
* Pg.8: please include name and number of doctor.
* Pg.3: please insert authority names.
* Pg. 4: please include where samples will be stored. Please explain what health authority is referred to – FDA or EMA for instance.
* Pg.9: please remove the option to take the study drug after the participant is stopped. Please clarify for participants that study drug is not likely to be available after study completion.
* Pg.14: Dr Benatar explained that follow up is an issue with long studies. A third party can be used to find patients who are lost to follow up, at least to find out whether the patient is alive or dead.
* Pg.8: unfinished sentence on ‘who pays for the study’.
* Pg.9: remove reference to US law.
* Please remove need to withdraw consent in writing (on both PIS/CF).
* Please remove mention of patient finder service, Committee queried if this applicable to New Zealand. Please make it explicit to participants with regards to what this is for.
* Please justify and explain the charging of text message reminders. Is this for New Zealand participants?
* Please remove any yes/no options on the consent form where the answer would affect eligibility. Mandatory aspects of the study should not be optional.
* Please clarify whether hospital ‘switchboard’ should be on this.
* Please clarify whether the clinical doctor contacted through the switchboard would understand the study and be the appropriate person to contact.
* Please include the contact number of the Maori contact (extension number is missing).
* Pg.7: please remove the instructions about the interpreter statement.
* Pg.7: yes/no statements regarding blood samples being stored indefinitely. The application states destroyed after 20 years. Please explain.
* Please explain the option to keep the blood as identifiable, why is this an option?
* Pg.11: please justify need for confidentiality clause about study communications on social media. Explain the purpose of this, adding that the trial will be publically registered.
* Pg.9: please remove “the” before New Zealand.
* Pg.9 and p.2.7 of application ‘what if new relevant information becomes available’ – if you continue to participate after you have withdrawn – please clarify what this means?

Decision

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

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

This following information will be reviewed, and a final decision made on the application, by Dr Paul Tanser and Mrs Mali Erik.

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| **4** | **Ethics ref:** | **14/NTB/4** |
|  | Title: | Investigating Sofosbuvir and Ledipasvir in Patients with Hepatitis C Virus and Human Immunodeficiency Virus (HIV)-1 Co-infection |
|  | Principal Investigator: | Prof Edward Gane |
|  | Sponsor: | PPD Global Limited (New Zealand Branch) |
|  | Clock Start Date: | 23 January 2014 |

Prof Edward Gane 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.

* B.2.2 – Please confirm Medsafe approval is received. Prof Gane confirmed Medsafe has approved.
* R.1.5 – Confirm DSMC. Researcher confirmed there was a DSMC. The combination is considered in phase III. The same DSMC will be looking after all the phase III programmes.
* The Committee noted the investigator’s medical certification has very recently expired. Please submit current.
* The Committee noted that the questionnaires have the space for names on it in hardcopy. Prof Gane noted they would confirm with sponsor but was fairly sure there would be no area to record their name on database/CRF.
* R.2.4.1 – the data is potentially identifiable due to the linking list. Prof Gane explained that while there was a linking mechanism there were so many difficulties in doing so that the data could be considered de-identifiedit was more. The Committee noted this still means it is potentially identifiable – see NEAC guidelines for intervention studies <http://ethics.health.govt.nz/ethical-standards-health-and-disability-research>
* The Committee confirmed the patients won’t be offered the re-treatment PIS until they are at least 24 weeks after starting treatment. (12 weeks treatment, 12 weeks follow up).
* P.2.9 – Committee confirmed the participants have the option of receiving summary in lay language.
* P.4.6 - Please confirm method of collecting ethnicity statement is similar to that of New Zealand Census questions.
* Committee queried if there would be a lot of Asian New Zealand participants. Prof Gane noted that the patient population is quite different in people with HIV co infection. The Committee queried whether the interpreter box is appropriate for the target population. Prof Gane confirmed that they would tailor it to accommodate for the patient population being recruited.
* The Committee requested the following changes to the Participant Information Sheet and Consent Form:
* Please remove need to withdraw in writing (pg.4). Participants can stop participation verbally.
* Pg.2: include relevant contraception information
* Pg.2: include central lab information (left blank currently).
* Remove references to US law.
* Pg.19: please amend HDEC study number.
* Please remove yes/no answers on CF unless they are truly optional.
* For pharmacogenomic-sub study: participant should not need to withdraw from the study in writing. Remove reference to US law and include main lab name.
* Pg.11: please add a summary of serious adverse events rather than covering them in such individual personal detail.
* Pg.14: please add you will be asked to consent for follow up if becoming pregnant, rather than assuming consent.
* Pg.17: third paragraph – ‘you do not give you any legal rights’. Please amend.

Decision

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

* Please amend the information sheet and consent form, taking into account the suggestions made by the Committee (*Ethical Guidelines for Intervention Studies* *para 6.22*).
* Please submit evidence of CI indemnity. (*Ethical Guidelines for Intervention Studies* *para 4.20)*

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

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| **5** | **Ethics ref:** | **14/NTB/7** |
|  | Title: | Stress ulcer prophylaxis in the intensive care unit (SUP-ICU) |
|  | Principal Investigator: | Dr Colin McArthur |
|  | Sponsor: |  |
|  | Clock Start Date: | 23 January 2014 |

Dr Colin McArthur 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 the application was very interesting.
* The study involves the use of prevention treatments for stress ulcers. The study is an international study and is observational, involving linking to patient data.
* Committee confirmed the patient population is not able to be consented.
* The Committee queried if there is an opt-out consent to be offered once participants are well. Dr McArthur confirmed this was considered and was used in another intervention study but this study was so close to being an audit, as it is observing current practice that opt-out was considered unnecessary.
* The Committee queried the 90 day follow up. The researcher confirmed this was just for DoA mortality.
* Please explain when data may be re-identified. Dr McArthur explained that it is always possible to re-identify, there is no increase in exposure as the people who would do this are already aware of the participant’s identity.
* R.5.1 – the study sponsor. The study will have lead investigators. This study is investigator initiated.

Decision

This application was *approved* by consensus.

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| **6** | **Ethics ref:** | **14/NTB/10** |
|  | Title: | Gastrointestinal effects of 0.9% Saline vs. Plasma-Lyte® 148 |
|  | Principal Investigator: | Dr Sumeet Reddy |
|  | Sponsor: | Medical Research Institute of New Zealand |
|  | Clock Start Date: | 23 January 2014 |

Dr Sumeet Reddy 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 studies are sub studies from previously approved applications. This study looks at different outcomes.
* Please confirm if there has been separate peer review for these stub studies. Dr Reddy confirmed that the studies have been through anaesthetics departments and are considered warranted.
* The Committee confirmed that when there is a cross over for fluids at site level, processes are in place to ensure patients will remain on the fluids they are initially given.
* The Committee requested the following changes to the Participant Information Sheet and Consent Form:
* Opening header runs to a blank – please check this and amend.

Decision

This application was *approved* by consensus.

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| **7** | **Ethics ref:** | **14/NTB/11** |
|  | Title: | Herbal supplement Arthrem in osteoarthritis |
|  | Principal Investigator: | Dr Simon Stebbings |
|  | Sponsor: | Promisia Ltd |
|  | Clock Start Date: | 23 January 2014 |

Dr Sheena Hunt was present in person for discussion of this application.

Potential conflicts of interest

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

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

Summary of ethical issues

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

* The Committee commended the team for conducting a trial for an agent that is available yet has not been subject to scientific scrutiny.
* The Committee queried if the study was a phase I study, noting the sample size. Dr Hunt responded that it was a phase II due to the patient population having osteoarthritis, and they were looking for a therapeutic effect.
* The Committee queried the sample size. Dr Hunt explained a bio-statistician had worked with the study sample size. The Committee asked whether the results would be meaningful. The researcher explained if there is are trend identified of clinical significance there will be follow up trials with large sample sizes.
* The Committee queried what was known about the chemical content of the study drug. Dr Hunt explained there are a large number of compounds in the herb, with further in-vitro testing being conducted to identify and isolate other compounds. The extract has been analysed. The exact extract is not known.
* Please review questionnaires and remove area to include name, and ensure there are fields for initials and identifier.
* R.2.1.4 – please check the NEAC guidelines for intervention studies for the difference between anonymous, potentially identifiable and de-identified (<http://ethics.health.govt.nz/ethical-standards-health-and-disability-research>)
* R.4.1 – please note that as you are taking blood tests there is a possibility that it may produce findings that are not related to the study. Please ensure an appropriate follow up pathway exists.
* P.2.1 – please note the end of the sentence has dropped out. Dr Hunt confirmed.
* Please check with SCOTT to see whether approval is required before commencing study.
* The Committee confirmed the safety tests involved for participants.
* The Committee noted there was a large potential for participation, as osteoarthritis is common.
* P.2.1 – please explain how you plan to approach participants. Dr Hunt explained that a co-investigator has a database with patients who are interested in alternative medicines. Dr Hunt also added that people with osteoarthritis were often interested in trying new things.
* R.1.5 – please note that SAE are not required to be reported to HDEC.
* The Committee queried if there was any form of DSMB that oversaw the data, from an unblinded perspective. Dr Hunt explained that the CI would be able to unblind individual patients if there were any adverse events of concern. There would be no unblinding or safety analysis until end of study. The Committee discussed this approach and decided given the sample size and nature of trial this would be appropriate.
* F.2.1 – the Committee queried the criteria relating to potential participants who were staying on their current treatments (anti-inflammatory), but are not able to take vitamins or minerals. Dr Hunt explained that this was because an improvement observed on top of anti-inflammatory would still show an improvement. The Committee queried any stratification for those on anti-inflammatory. The researcher explained that at this stage, with this study sample size, it was not planned.
* Committee confirmed ethnicity data would be collected using the New Zealand Census method.
* The Committee queried if 3 weeks was a long enough wash out period for existing treatments. The researcher confirmed the CI felt it was.
* The Committee queried who would be involved in creating the safety summary profile once the trial has provided data. Dr Hunt explained that this was one of the prime goals of the study and it would be an internally produced profile to accompany the study drug and for future phase trials of the study.
* The Committee queried policing the halting of treatments readily available over the counter, for study involvement. Dr Hunt explained they will have a study diary to fill in but acknowledged that clinical trials require some extent of trust.
* The Committee queried the follow up study planned. Dr Hunt confirmed that the study would be offered after 12 weeks, and noted this information was included in the PIS/CF.
* The Committee requested the following changes to the Participant Information Sheet and Consent Form:
* Pg.2: please include the process to follow if participants become pregnant.
* Please add that it will be the lower dose of study drug (in the long term study).
* Please consider being specific about what treatments should be stopped in order to be eligible for study involvement.
* Please review the yes/no options and remove the options unless they are truly optional.

Decision

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

* Please amend the information sheet and consent form, taking into account the suggestions made by the Committee (*Ethical Guidelines for Intervention Studies* *para 6.22*).
* Please check and confirm SCOTT review is not required. If SCOTT review is required this will be a provisional approval condition.

This following information will be reviewed, and a final decision made on the application, by Dr Paul Tanser and Mrs Mali Erik.

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| **8** | **Ethics ref:** | **14/NTB/12** |
|  | Title: | 0.9% Saline vs. Plasma-Lyte® 148 for post-operative fluid therapy in adults undergoing cardiac surgery |
|  | Principal Investigator: | Dr Sumeet Reddy |
|  | Sponsor: | Medical Research Institute of New Zealand |
|  | Clock Start Date: | 23 January 2014 |

Dr Sumeet Reddy 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 the applications are very clear.
* The Committee requested the following changes to the Participant Information Sheet and Consent Form:
* Opening header runs to a blank – please check this and amend.

Decision

This application was *approved* by consensus.

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| **9** | **Ethics ref:** | **14/NTB/13** |
|  | Title: | Treatment of Ankle Syndesmosis Injuries |
|  | Principal Investigator: | Dr Logan Walker |
|  | Sponsor: | CCDHB Surgical Services |
|  | Clock Start Date: | 23 January 2014 |

Dr Logan Walker 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 the application was very easy to read and well put together.
* Please confirm the two techniques are familiar by the surgeons. Dr Walker confirmed that co – investigator and surgeon Mr Willis has received training and is more than comfortable doing the newer tightrope procedure.
* The Committee is impressed with the Maori consultation form uploaded.
* Please clarify that the patient name and D.O.B will be de-identified on the Questionnaires. Dr Walker confirmed they would be.
* The Committee requested the following changes to the Participant Information Sheet and Consent Form:
* Please revisit the some of the diagrams as they are quite complicated. Please rename the bones and descriptions. The diagrams can be useful in showing how each technique differ, but they need to be simplified in their labelling.
* Pg.2 please insert it is the Northern B Health and Disability Ethics Committee.
* Please add a Maori cultural support contact.
* Please remove the references.
* Please review the yes/no options and remove the options unless they are truly optional.
* Please explain what randomisation is in lay language such as ‘a flip of a coin’. This makes it clear that there is no choice in treatment.
* Pg.6 Please confirm whether you will be seeking a witness for informed consent. Committee suggested either removing or putting optional above the area to sign as based on response from researcher it appears witnesses will not be used routinely
* Committee added if the interpreter is used then they should also sign the PIS/CF.

Decision

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

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

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

## General business

1. The Committee noted the content of the “noting section” of the agenda.
2. The Committee members discussed avenues for recruiting lay members to Committees.

* July meeting – confirm at Novotel with Secretariat.
* The Committee requested clarification on what a sponsor is, noting a trend of studies answering question A.5.1 as ‘no’ when there were cases where there was a body that could reasonably be considered a sponsor. This has implications for ethics and governance and requires clarification.

1. The Chair reminded the Committee of the date and time of its next scheduled meeting, namely:

|  |  |
| --- | --- |
| **Meeting date:** | 04 March 2014, 12:00 PM |
| **Meeting venue:** | CEO Meeting Room, Level 3, Hocking Building, Waikato Hospital Campus |

The following members tendered apologies for this meeting.

1. Dr Paul Tanser.
2. **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 3.25pm