|  |  |
| --- | --- |
| **Committee:** | Northern B Health and Disability Ethics Committee |
| **Meeting date:** | 06 June 2017 |
| **Meeting venue:** | Novotel Ellerslie, 72-112 Greenlane Rd East, Ellerslie, Auckland |

|  |  |
| --- | --- |
| **Time** | **Item of business** |
| 12:00pm | Welcome |
| 12:05pm | Confirmation of minutes of meeting of 02 May 2017 |
| 12:30pm | New applications (see over for details) |
| p | i 17/NTB/85  ii 17/NTB/96  iii 17/NTB/91  iv 17/NTB/87  v 17/NTB/98  vi 17/NTB/92  vii 17/NTB/99  viii 17/NTB/94  ix 17/NTB/86  x 17/NTB/97  xi 17/NTB/90  xii 17/NTB/93 |
|  | Substantial amendments (see over for details) |
| 5:40 | i 12/NTB/42/AM18 |
| 6:05pm | General business:   * Noting section |
| 6:15pm | Meeting ends |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Member Name** | **Member Category** | **Appointed** | **Term Expires** | **Apologies?** |
| Mrs Maliaga Erick | Lay (consumer/community perspectives) | 01/07/2015 | 01/07/2018 | Present |
| Mrs Stephanie Pollard | Non-lay (intervention studies) | 01/07/2015 | 01/07/2018 | Present |
| Miss Tangihaere Macfarlane | Lay (consumer/community perspectives) | 20/05/2017 | 20/05/2020 | Present |
| Mrs Kate O'Connor | Lay (ethical/moral reasoning) | 14/12/2015 | 14/12/2018 | Present |
| Dr Nora Lynch | Non-lay (health/disability service provision) | 24/07/2015 | 24/07/2018 | Present |
| Mrs Leesa Russell | Non-lay (intervention studies), Non-lay (observational studies) | 14/12/2015 | 14/12/2018 | Present |
| Mr John Hancock | Lay (the law) | 14/12/2015 | 14/12/2018 | Present |
| Mrs Jane Wylie | Non-lay (intervention studies) | 20/05/2017 | 20/05/2020 | Present |

## Welcome

The Chair opened the meeting at 12:00pm and welcomed Committee members.

The Chair noted that the meeting was quorate.

The Committee noted and agreed the agenda for the meeting.

## Confirmation of previous minutes

The minutes of the meeting of 02 May 2017 were confirmed.

## New applications

|  |  |  |
| --- | --- | --- |
| **1** | **Ethics ref:** | **17/NTB/85** |
|  | Title: | What works? Individuals' experiences and knowledge of suicide prevention interventions in Aotearoa / New Zealand. |
|  | Principal Investigator: | Miss Behiye (Becky) Ali |
|  | Sponsor: |  |
|  | Clock Start Date: | 25 May 2017 |

Miss Becky Ali and Dr Barbara Staniforth were present in person for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. The Committee stated that they enjoyed reading the application and it is clear that the Researcher has been working on their application based on feedback from the Southern Committee.

Summary of ethical issues (resolved)

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

1. The Committee raised concerns over the use of a focus group methodology in this vulnerable group and requested further information on the safety measures in place and the reasons for selecting this methodology. The Researcher explained that the reason they decided on a focus group methodology is that they feel the focus group will be more supportive than one-on-one interviews and participants would feel less pressured to directly respond to questions. The Researcher explained that this was well supported by research. The Researcher also explained that to help protect participant’s safety they will have two psychologists attend the focus groups, one will be in the room and the other will wait outside, to assist any participants who decide to leave. These psychologists will be able to assist any participants that experience distress during the focus group and will also be available for 1 week afterwards. Participants will also be able to bring a support person to the focus group, although they will be required to wait outside to help maintain the confidentiality of other group members.
2. The Committee noted that the proposed protocol for if the psychologists feel that a participant is in crisis is for them to be followed up by one of the study psychologists. The Committee questioned the suitability of this, given that the study psychologists will not know participants well and it may be more suitable to refer them to their service provider. The Researcher explained that the reason for not referring participants to their service provider is to maintain confidentiality, as participants are being asked specifically about their views about the services provided to them. The Committee agreed this was sensible, but if the psychologists feel a participant is a danger to themselves or others they must be referred to an appropriate service provider. Individuals’ privacy and confidentiality of information need to be ensured unless there is an overriding ethical concern (for example, health or safety) justifying the release of such information or if such release is required by law (*Ethical Guidelines for Observational Studies* Paragraph 9.2). The Researcher agreed that this is the current protocol.
3. The Committee questioned how participants will be recruited. The Researcher explained that the service providers will send letters to past and current service users who are not in active crisis. The Committee questioned how the service providers will know if a past service user is currently in active crisis. The Researcher stated that if they had not gone back to the service provider then the provider would not know, in these cases participants would need to self-select and opt-out if they believe the study is not right for them.
4. The Committee questioned whether Māori and Pacifica consultation is being undertaken. The Researcher explained their consultation process.
5. The Committee questioned whether participants needed to be fluent in English. The Researcher explained that due to the nature of the focus groups having a translator would not be reasonable, and, consequently, participants needed sufficient English to participate.
6. The Committee questioned whether the proposed timeframe is reasonable. The Researcher confirmed that they can seek an extension as required.

Summary of ethical issues (outstanding)

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

1. The Committee noted that rules will need to be established at the beginning of each focus group, they requested that the script for this is provided.
2. The Committee requested a copy of the site safety plan for the researchers when attending focus groups and one-on-one interviews.
3. The Committee questioned whether there are any criteria to exclude potential participants who had a recent suicide attempt, even if they feel well enough to participate. The Researcher explained that they believe service users are experts in their own care and must decide for themselves if they are safe to participate in the study. The Committee expressed concerns regarding this and requested a formal exclusion criteria and screening process is added to the study protocol.
4. The Committee requested evidence of the peer review conducted by a psychiatrist, this should include information on their assessment of the new safety arrangements for the study.
5. The Committee questioned why the participant’s support person cannot be in the room during the one-on-one interview, if the participant wants them to be. The Researcher explained that this is because they want to hear from the participant in their own voice. The Committee requested that the study protocol and Participant Information Sheet is altered to allow the support person to remain in the room but not talk during the one-on-one interviews if the participant requests this level of support.

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

1. The Committee raised concerns about the number of different Participant Information Sheets and Consent Forms, they stated that this may lead to some confusion about which one should be used when consenting participants. The Committee noted that some of the Participant Information Sheets provided appear to be for people helping with the project who are not participants, such as the psychologists. The Committee explained that Participant Information Sheets and Consent Forms are only needed for study participants, although it may be appropriate to give those helping with the study written information about the study.
2. Please revise the formatting of the Participant Information Sheets to improve clarity and readability. For example, please increase the spacing between paragraphs, make the headings between sections bolder, reformat the contact details section, increase the size of the title, add a footer with the study title and version numbers.
3. Please clarify in the Participant Information Sheet that participants may be referred to their service provider if the study psychologists feel that they may be a danger to themselves or others.
4. Please clarify in the Participant Information Sheet that participants cannot withdraw their data from the focus group, due to the nature of this research methodology.
5. Please add contact details for a suitable Māori cultural support person to the Participant Information Sheet.

Decision

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

* Please amend the information sheet and consent forms, taking into account the suggestions made by the committee *(Ethical Guidelines for Observational Studies para 6.10)*
* Please respond to the outstanding ethical concerns detailed above.

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

|  |  |  |
| --- | --- | --- |
| **2** | **Ethics ref:** | **17/NTB/96** |
|  | Title: | M16-043 |
|  | Principal Investigator: | Dr Rajeev Rajagopal |
|  | Sponsor: | AbbVie Pty Ltd. |
|  | Clock Start Date: | 25 May 2017 |

Dr Rajeev Rajagopal and Catherine Howie were present by teleconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. This study involves comparing standard care to standard care plus Ventoclax in patients with Acute Myeloid Leukemia who are unsuited to conventional more aggressive therapies.

Summary of ethical issues (resolved)

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

1. The Committee questioned whether the contact details provided on the Participant Study Card are available 24/7. The Researcher confirmed that they are.
2. The Committee questioned whether as part of standard care participants would be admitted to hospital for 4 days, as is required for the study. The Researcher explained that approximately 30% of patients (patients considered to be high risk) would be admitted to hospital in standard care.
3. The Committee questioned the Māori cultural statement about the use of tissue in the Participant Information Sheet. The Researcher explained that each of their sites has their own required wording, based on Māori consultation. The Committee accepted this.

Summary of ethical issues (outstanding)

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

1. The Committee questioned whether the insurance certificate provided will be sufficient to receive locality approval. The Researcher explained that the level of insurance may not be sufficient for locality approval. The Committee stated that they require suitable insurance is provided by the study sponsor and would like confirmation that this updated level is sufficient for locality approval. The Committee noted that locality approval must be obtained before the study can begin.

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

1. The Committee requested that it is clarified in the Participant Information Sheet that 70% of study participants would not have a 4 day stay in hospital as part of standard care.
2. The Participant Information Sheet is excessively long and repetitive. Please revise this form to remove any information that is not required, this will help emphasize the information participants do need to know.
3. Please remove any information from the Participant Information Sheet that only relates to standard care, the study Participant Information Sheet should only contain study specific information and all information about standard care should be provided separately.
4. Please use New Zealand appropriate terms, such as ‘breast feeding’ instead of ‘nursing’.
5. Please separate the risk information in to sections, such as common and less common.
6. Please remove all information from the main Participant Information Sheet about any optional tests or aspects of the study. This will help ensure it is clear from the Participant Information Sheet what aspects of participation are mandatory to study participation and which are optional extras.
7. The contraception section currently refers to participants calling 111 in case of an emergency. Please move this section to a more suitable location in the Participant Information Sheet.
8. The Participant Information Sheet currently seems to restrict participants access to information collected about them. Please revise this as participants can access this information at any time, although doing so may break the study blinding and cause them to be withdrawn from the study.
9. The Pregnant Partner Participant Information Sheet and Consent Form are currently very Australian and should be revised to have the relevant New Zealand references and terminology.
10. Please clarify in the Participant Information Sheet that participants can contact the study doctor verbally, not just in writing.
11. Please add a short lay title to the Participant Information Sheet.
12. Please ensure that New Zealand spellings are used throughout the Participant Information Sheet.
13. Please include randomisation ratios on page 2 of the Participant Information Sheet.
14. Please re-word the clumsy phrase "ask you about your sterility status" in the Participant Information Sheet.
15. In the risks and disadvantages of study procedures section please clarify how many extra bone marrow aspirations and blood test episodes the study confers and include a clear statement about hospitalisation for all participants. This section does not need to laboriously describe every procedure as this obscures the real burdens of study participation.
16. Please include information in page 10 of the main Participant Information Sheet about Animal Studies or similar and list risks to fertility, hair colour change, and hearing loss.
17. Please remove information regarding optional samples from the procedures table on page 4-5 of the main Participant Information Sheet as this should only be in the optional Participant Information Sheet.
18. Please add a section to page 13 of the main Participant Information Sheet regarding how to take Ventoclax.
19. Please remove the risks associated with high dose cytarabine as this is not relevant to this study.
20. Please remove the statement from the main Participant Information Sheet regarding using samples to develop commercial products as this only belongs in the optional Participant Information Sheet.
21. The Committee queried the Māori tissue statement in the Participant Information Sheet. The Committee recommended the following statement is used: “*You may hold beliefs about a sacred and shared value of all or any tissue samples removed. The cultural issues associated with sending your samples overseas and/or storing your tissue should be discussed with your family/whanau as appropriate. There are a range of views held by Māori around these issues; some iwi disagree with storage of samples citing whakapapa and advise their people to consult prior to participation in research where this occurs. However, it is acknowledged that individuals have the right to choose.”*

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 provide an updated insurance certificate and assurance from the study locality that the level of insurance is sufficient.

This following information will be reviewed, and a final decision made on the application, by Dr Nora Lynch and Mrs Kate O'Connor.

|  |  |  |
| --- | --- | --- |
| **3** | **Ethics ref:** | **17/NTB/91** |
|  | Title: | Evaluation of Community Interventions for Unhealthy Weight Pre-schoolers in the South Island |
|  | Principal Investigator: | Professor Barry Taylor |
|  | Sponsor: |  |
|  | Clock Start Date: | 11 May 2017 |

Professor Barry Taylor, Assoc Prof David Reith, and Dr Gloria Dainty were present by teleconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. This study involves following children who were identified as obese at their Before School Check to see if the recommended community based intervention was offered, and whether this intervention made any difference.

Summary of ethical issues (resolved)

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

1. The Committee questioned whether the researcher believes participants are likely to expect data from the Before School Checks to be used for this kind of research. The Researcher explained that they believe parents know that this is a national programme and that their child’s information may be used to evaluate this service.
2. The Committee questioned the consent arrangements for this study. The Researcher explained that the parents would be asked to provide consent on their children’s behalf to their participation in the study.
3. The Committee questioned whether study data would be linked or shared with data from other organisations. The Researcher confirmed that it would not be.
4. The Researcher stated that one of the DHBs had requested that the one year follow up data is added to the participant’s primary care information, they questioned whether this is acceptable. The Committee explained that it is acceptable if participants explicitly consent to this use of data.
5. The Committee questioned whether study results would be analysed by ethnicity. The Researcher confirmed that they would be.
6. The Committee questioned the funding arrangements for the study. The Researcher explained that some funding is likely to be provided by Canterbury DHB and the University. The Committee suggested that the University is set as the sponsor for HDEC purposes if they have responsibility for the study conduct.

Summary of ethical issues (outstanding)

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

1. The Committee stated that it appears parents are also participants in this study as information about them, such as their height and weight, is also being collected. A Participant Information Sheet and Consent Form for the parents as participants must be provided, as well as the one for their child.
2. The Committee questioned how participants would be approached about the study as the application contained conflicting information. The Researcher explained that an invitation letter would be sent. The Committee stated that they require a copy of this letter to review.
3. The Committee questioned whether children would be asked to give their assent to participate in the study. The Researcher stated that as the children are 4-5 years old they felt an assent form was unnecessary. The Committee stated that it is their preference that a very simple pictorial information sheet is developed to help explain to the children what is involved in study participation. The Committee noted that if it is intended to follow these children for longer this form becomes more important as the children become older and are routinely followed up.
4. The Committee requested more information on the peer review process for this study, including what was considered and whether any suggested changes were made.
5. The Committee questioned whether participants would incur any costs from participation, including travel costs. The Researcher explained that they intend for a research nurse to visit participants in their homes to avoid any travel costs. The Committee stated that they require a safety protocol to ensure the research nurse is safe when doing these visits.
6. The Committee questioned whether the height, weight, and smoking status is being collected about the child’s caregiver or their biological parents. The Researcher confirmed that it will be their biological parents. The Committee stated that this must be clarified in the study protocol, it must also be detailed how this will be screened for and whether biological parents will be approached if they are not the child’s caregiver.
7. The Researcher expressed that they would like to know the mother’s smoking status during pregnancy but were concerned about asking for this as it is a sensitive topic and may cause the mother to feel guilt. The Committee stated that they feel it would be acceptable to ask the mothers about this.

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

1. Please clarify in the Participant Information Sheet that study participation may involve long term follow up.
2. Please add contact details to the Participant Information Sheet for the HDECs and a suitable Māori cultural support person.
3. Please use New Zealand appropriate language in the participant facing documents, such as the quality of life questionnaire which uses the word ‘blue’ when ‘sad’ would be more appropriate for New Zealand participants.
4. Please provide a suitable Participant Information Sheet and Consent Form for parents.

Decision

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

* Please amend the information sheet and consent forms, taking into account the suggestions made by the committee *(Ethical Guidelines for Observational Studies para 6.10)*
* Please respond to the outstanding ethical concerns detailed above.

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

|  |  |  |
| --- | --- | --- |
| **4** | **Ethics ref:** | **17/NTB/87** |
|  | Title: | SAFRON II |
|  | Principal Investigator: | Dr Giuseppe Sasso |
|  | Sponsor: | Trans Tasman Radiation Oncology Group (TROG Cancer |
|  | Clock Start Date: | 25 May 2017 |

Dr Giuseppe Sasso and Beth Caudwell were present by teleconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. This is a Randomised Controlled Trial of two different radiotherapy schedules.
2. The Committee commended the quality of the application, including the Participant Information Sheet and peer review.

Summary of ethical issues (resolved)

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

1. The Committee questioned whether there are risks associated with the study treatment over standard care. The Researcher explained that this is one of the things being investigated in this study. The Researcher explained that this is a rapidly developing area with a lot of uncertainty.
2. The Committee noted that the Participant Information Sheet indicates that there is a 4 week break between the planning visit and beginning treatment, they questioned if this is standard. The Researcher confirmed that it is a standard timeframe.
3. The Committee questioned how study documents are de-identified before being sent to the overseas research office. The Researcher explained their process that involves de-identifying and checking these documents before emailing them overseas.
4. The Committee questioned whether participants would be reimbursed for any study related expenses, such as attending extra appointments. The Researcher clarified that they did not have funding for this but study participation does not require much above standard care.
5. The Committee questioned the process for handling any possible incidental findings. The Researcher confirmed that it would be handled as per their standard process.
6. The Committee suggested that information on potential cultural issues for Māori are added to future study protocols.

Summary of ethical issues (outstanding)

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

1. Please clarify in the Participant Information Sheet that the break between the planning visit and beginning treatment is similar to standard care.
2. Please clarify in the quality of life questionnaire that any reported symptoms won’t be reviewed by someone involved in their care and if they are having any symptoms they should tell their doctor about this also.
3. Please add some information on the potential risk of delayed toxicity to the Participant Information Sheet.
4. Please add HDEC contact details to the Participant Information Sheet.
5. The Participant Information Sheet indicates that participants may need to pay for medication to help side effects from treatment, please clarify that this refers to paying prescription fees.
6. Please clarify in the Participant Information Sheet that all information sent to Australia is a de-identified duplicate of information held at the New Zealand site, it should be clear so that participants know that they can access any information held about them through the New Zealand site.

Decision

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

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

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

|  |  |  |
| --- | --- | --- |
| **5** | **Ethics ref:** | **17/NTB/98** |
|  | Title: | Steroids To Reduce the Impact on Delirium Study (STRIDE) |
|  | Principal Investigator: | Dr Michal Kluger |
|  | Sponsor: |  |
|  | Clock Start Date: | 25 May 2017 |

Dr Michal Kluger 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 (resolved)

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

1. The Committee noted that the application proposes enrolling participants unable to provide informed consent, the Committee questioned whether this is necessary for this study and noted their preference that only consenting participants are recruited. The Committee specifically noted that they believe they would be unable to approve this study with participants unable to provide informed consent as insufficient evidence exists about the potential benefits of steroids. The Researcher agreed to exclude all participants unable to provide their own informed consent.
2. The Committee considered this application in relation to only participants able to provide their own informed consent.
3. The Committee questioned the recruitment process. The Researcher explained that the ED doctor will make a provisional diagnosis and provide some information for the potential participant to read and consider, then a researcher will approach them and if they are interested will conduct the informed consent process. The Researcher confirmed that participants would be able to think about it for a few hours and would not need to decide until they are more stable and comfortable.
4. The Committee discussed the level of dosing of steroids in this study, noting that it is a very high level. The Researcher provided justification for the dosing level, indicating that they believe it is a realistic dose within the current publication range.
5. The Committee questioned the expected rate of delirium, noting that the literature reports a hugely varied rate, and the up to 60% rate indicated in study documents is at the very upper limit of these reported rates. The Researcher agreed and explained that they do not have evidence of the rates of delirium at their institution.
6. The Committee questioned whether there is a time limit following the fracture where steroids would not be given, as it would no longer be considered ‘early’. The Researcher stated that they will give the steroids as soon as possible after the fracture, but as this is a pilot study they do not have enough information to determine when to begin excluding participants as too much time had passed following the break.
7. The Committee questioned how it will be determined which participants are eligible for the sub-study. The Researcher explained that they will consecutively approach participants until a sufficient number have been recruited.

Summary of ethical issues (outstanding)

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

1. Please provide a revised study protocol that specifically excludes participants unable to provide informed consent, and details the process for determining whether a potential participant has sufficient capacity to provide informed consent.
2. The Committee requested further evidence of peer review from a geriatrician independent from the study, this review should refer to the acceptability of this study with vulnerable elderly participants.

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

1. Please revise the statements in the Participant Information Sheet regarding the rates of delirium as the currently reported rate makes delirium sound much more common than the literature suggests.
2. Please revise the benefits and risk section of the Participant Information Sheet to clearly state that participants may receive no benefit.
3. Please add the risks of cardiac arrhythmia and psychosis to the Participant Information Sheet.
4. The Committee requested the compensation wording is updated for accuracy, they suggested the following statement: *“If you were injured in this study, which is unlikely, you would be eligible* ***to apply*** *for compensation from ACC just as you would be if you were injured in an accident at work or at home. This does not mean that your claim will automatically be accepted. You will have to lodge a claim with ACC, which may take some time to assess. If your claim is accepted, you will receive funding to assist in your recovery. If you have private health or life insurance, you may wish to check with your insurer that taking part in this study won’t affect your cover.”*
5. Please remove the yes/no tick boxes from the Consent Form for all statements that are not truly optional, meaning that a participant could respond ‘no’ and still participate in the study.
6. Please revise the Participant Information Sheet to make the optional sub-study more distinct and to make it clearer that it is truly optional.
7. Please remove the reference to participants’ family members being asked to remember what the participant was like from 10 years ago.
8. Please clarify in the Participant Information Sheet that the optional blood tests are done in New Zealand.
9. Please clarify in the Participant Information Sheet how many millilitres of blood will be taken.

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 provide evidence of favourable independent peer review of the study protocol from a geriatrician independent from the study, this review should refer to the acceptability of this study with vulnerable elderly participants (*Ethical Guidelines for Intervention Studies* Appendix 1).
* Please provide an updated study protocol.

This following information will be reviewed, and a final decision made on the application, by Dr Nora Lynch and Mrs Kate O'Connor.

|  |  |  |
| --- | --- | --- |
| **6** | **Ethics ref:** | **17/NTB/92** |
|  | Title: | Vitamin D in SUFE |
|  | Principal Investigator: | Dr Marinus Stowers |
|  | Sponsor: |  |
|  | Clock Start Date: | 25 May 2017 |

Dr Marinus Stowers was present by teleconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. This study investigates whether there is an association between vitamin D levels and children with Slipped upper femoral epiphysis.
2. A current cohort of children with this condition will be matched with a historical control of children without the condition, and their vitamin D levels compared.

Summary of ethical issues (resolved)

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

1. The Committee questioned how vitamin D deficiencies in participants will be handled. The Researcher explained that they have a standard process for this, and this will be followed as per standard care.

Summary of ethical issues (outstanding)

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

1. The Committee questioned how the matched historical control group would be identified and selected. The Researcher explained that they would search their database for children who have had a vitamin D level taken and try to match these children to the participating children as closely as possible.
2. The Committee noted that vitamin D levels can be expected to be lower in winter than in summer and questioned if this factor would also be considered when matching the historical controls. The Researcher stated that they has not considered this factor.
3. The Committee questioned whether the researchers had considered prospectively recruiting the control participants. The Researcher stated that they had not considered doing this.
4. The Committee stated that factor children with bad hips may spend more time inside, leading to lower vitamin D levels. The Committee questioned how this would be addressed as it may have a significant impact on the study results.
5. The Committee requested further detailed information is included in the protocol regarding how the matching to historical controls will be done and how confounding variables will be controlled for.
6. The Committee questioned the justification for the use of health information without consent for the historical control group. The Researcher explained that they believe it is justifiable to use this information without consent as their participation will not affect their ongoing care. The Committee referred the researcher to paragraph 6.43 of the *Ethical Guidelines for Observational Studies* and requested that a response is provided justifying this use of health information in line with these guidelines:
   * Access to identified or potentially identifiable data for research without the consent of the people the data identifies or makes potentially identifiable may be justifiable when:

a) the procedures required to obtain consent are likely to cause unnecessary anxiety for those whose consent would be sought; or the requirement for consent would prejudice the scientific value of the study; or it is impossible in practice to obtain consent due to the quantity or age of the records; and

b) there would be no disadvantage to the participants or their relatives or to any collectivities involved; and

c) the public interest in the study outweighs the public interest in privacy.

1. The Committee questioned the peer review process, including whether the reviewer is independent and who was involved in the review process. The Researcher explained that the reviewer would have raised the study at the business meeting as they overlook and are responsible for all research in the department. The Committee requested more details regarding who was involved in reviewing this study and whether they raised any issues that needed to be addressed.
2. The Committee questioned how data would be de-identified. The Researcher explained that they would include the participant’s age, ethnicity, and NHI number. The Committee requested that the data is stored with fewer identifiers included, possibly initials and date of birth. Please revise the study protocol to reflect this.
3. Please use Statistics New Zealand's ethnicity classifications when collecting ethnicity data to ensure the options available are suitable for New Zealand participants. These classifications are: New Zealand European, Maori, Samoan, Cook Islands Maori, Tongan, Niuean, Chinese, Indian, Other (such as Dutch, Japanese, Tokelauan) please state.
4. The Committee requested more information on the proposed Māori and Pacifica consultation process for this study, given that Māori and Pacifica children are over represented in this condition.
5. The Committee requested information on whether participants who are discovered to have a low vitamin D level will be provided with supplements, or only suggested lifestyle changes. The Committee also questioned whether their GP would be informed.
6. The Committee requested further details are included in the study protocol regarding the definition of the primary outcome, including how low vitamin D would be defined.

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

1. The Committee requested that the HDEC Participant Information Sheet template is considered and the study Participant Information Sheet revised to more closely align with this, including adding a number of relevant sections of information.
2. Please remove the collection of data from the consent form, this is not a data collection form or part of the screening process.
3. Please revise the Participant Information Sheet and Consent Form to remove typographical errors.
4. Please provide suitable information sheets and assent forms. This includes an information sheet and consent form for parents of participants unable to provide informed consent, an information sheet and consent form for participants able to provide their own informed consent (this includes all participants aged 16 years or older and may include some younger participants if they are deemed competent), an information sheet and assent form for children, and a very simple information sheet and assent form for young children that should very simply explain their participation in the study. Guidance on assent can be found at <http://ethics.health.govt.nz/guidance-materials/assent-guidance>.
5. Please clearly state in the Participant Information Sheet whether de-identified study data will be available for future researchers.
6. Please clarify in the parents Participant Information Sheet that only the child’s parents or legal guardian can provide informed consent for their participation.

Decision

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

* Access to identified or potentially identifiable data for research without the consent of the people the data identifies or makes potentially identifiable may be justifiable when:
  + the procedures required to obtain consent are likely to cause unnecessary anxiety for those whose consent would be sought; or the requirement for consent would prejudice the scientific value of the study; or it is impossible in practice to obtain consent due to the quantity or age of the records; and
  + there would be no disadvantage to the participants or their relatives or to any collectivities involved; and
  + the public interest in the study outweighs the public interest in privacy.
  + *(Ethical Guidelines for Observational Studies* paragraph 6.43)
* Please amend the information sheet and consent forms, taking into account the suggestions made by the committee *(Ethical Guidelines for Observational Studies para 6.10)*
* Please provide evidence of favourable independent peer review of the study protocol (*Ethical Guidelines for Observational Studies* Appendix 1).

|  |  |  |
| --- | --- | --- |
| **7** | **Ethics ref:** | **17/NTB/99** |
|  | Title: | HIP ATTACK |
|  | Principal Investigator: | Dr Julian Dimech |
|  | Sponsor: | David Braley Cardiac, Vascular & Stroke Research I |
|  | Clock Start Date: | 25 May 2017 |

Dr Julian Dimech and a co-investigator were present in person for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. This study involves investigating whether patients with a hip fracture have better outcomes if they undergo surgery within 6 hours of admission.

Summary of ethical issues (resolved)

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

1. The Committee questioned how participants would be recruited. The Researcher explained that when patients present at ED and have their initial assessment they ED doctor will contact the researchers who then approach potential participants. The Committee questioned how long participants have to decide whether to be in the study. The Researcher confirmed that participants would need to consent within two hours of admission in order to be eligible for study participation, given that the study is investigating having surgery within 6 hours of admission compared to standard care.

Summary of ethical issues (outstanding)

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

1. The Committee questioned whether the study may have a detrimental impact on other patients, such as those having elective surgery. The Researcher explained that they have study specific resourcing to avoid a detrimental impact on other hospital patients. The Committee requested information from the locality confirming that other patients will still be able to receive standard care in reasonable timeframes.
2. The Committee questioned the justifications for including participants unable to provide informed consent. The Researcher explained that many of the participants in this study will be cognitively impaired and they believe it is essential to include these participants in order to obtain generalizable results.
3. The Committee raised paragraph 5.30 of the *Ethical Guidelines for Intervention* studies, which states: *“Vulnerable people should have the opportunity to be included in high-quality studies on questions that might affect their health, taking the following into account.*
   * *The study should ask questions that matter to the participant’s community, and the answers should benefit the community.*
   * *Studies should not be performed with vulnerable groups if they can be adequately performed with other groups.*
   * *Where a study with a vulnerable group is conducted, it should involve the least vulnerable people in that group (eg, older rather than younger children).*
   * *Intervention studies should be conducted only if the risk to vulnerable people is at an acceptable minimum. (See also paragraph 5.35 below.)*
   * *Study participation should be a matter of free and informed decision-making by study participants wherever possible. (See also the Code of Rights, Right 7(2) and (3); and the guidance referred to in paragraph 5.35 below.)”*
4. The Committee agreed that the study investigates a question that matters to the participants’ community and stand to benefit the community.
5. The Committee agreed that vulnerable participants, elderly adults who have suffered a hip fracture, are required for the study.
6. The Committee questioned whether the study could be conducted only in participants able to provide informed consent, a less vulnerable group. The Researcher stated that it was their belief that this is the case. The Committee requested further justification for this.
7. The Committee considered whether the risks associated with the study are at an acceptable minimum. The Researcher explained that the only expected risk was associated with having less time available for the pre-operative checks. The Committee agreed that the risks associated with study participation are at an acceptable minimum.
8. The Committee considered whether participation would be a matter of informed consent whenever possible. The Committee questioned how it would be determined whether participants have the capacity to provide informed consent, and how supported decision making would be facilitated for participants who have limited capacity but are able to provide some level of informed consent. The Committee requested a written protocol is provided for this.
9. The Committee noted that an HDEC may not approve an application that is inconsistent with NZ law, even if that application is consistent with ethical guidelines (*HDEC Standard Operating Procedures* paragraph 15). This includes the HDC Code of Rights, in this case the Committee raised Right 7 as a potential concern.
10. RIGHT 7
11. *The Right to Make an Informed Choice and Give Informed Consent*
    * 1. *Services may be provided to a consumer only if that consumer makes an informed choice and gives informed consent, except where any enactment, or the common law, or any other provision of this Code provides otherwise.*
      2. *Every consumer must be presumed competent to make an informed choice and give informed consent, unless there are reasonable grounds for believing that the consumer is not competent.*
      3. *Where a consumer has diminished competence, that consumer retains the right to make informed choices and give informed consent, to the extent appropriate to his or her level of competence.*
      4. *Where a consumer is not competent to make an informed choice and give informed consent, and no person entitled to consent on behalf of the consumer is available, the provider may provide services where -*
         1. *It is in the best interests of the consumer; and*
         2. *Reasonable steps have been taken to ascertain the views of the consumer; and*
         3. *Either, -*
            1. *If the consumer's views have been ascertained, and having regard to those views, the provider believes, on reasonable grounds, that the provision of the services is consistent with the informed choice the consumer would make if he or she were competent; or*
            2. *If the consumer's views have not been ascertained, the provider takes into account the views of other suitable persons who are interested in the welfare of the consumer and available to advise the provider.*
12. The Committee questioned how this study complies with Right 7 of the HDC Code of Rights. The Researcher explained that they will obtain consent from all participants able to provide informed consent and for those unable to provide informed consent they believe that study participation meets the ‘best interest’ test of Right 7(4). The Researcher also stated that where possible they will consult with family and friends of participants regarding whether the participant would want to be in the study if they could provide informed consent.
13. The Committee requested additional information on how this study meets the best interest test. The Researcher explained that they have reason to believe that undergoing surgery sooner after admission is beneficial to patients’ outcomes, and enrolment in this study gives participants a 50% chance of undergoing surgery substantially earlier. Additionally, participants are guaranteed an assessment soon after admission and additional monitoring, which they may not get as part of standard care. The Committee agreed that a 50% chance of receiving surgery earlier (which they accept as beneficial) means that study participation gives participants a chance at a benefit over non-participants. The Committee accepted that study participation meets the best interest test of Right 7(4). The Committee requested a protocol and suitable documentation is provided for recording the enrolment of participants unable to provide their own informed consent.
14. The Committee questioned how the researchers will ensure that the study meets Right 7(2) of the HDC Code of Rights, as participants must be assumed to be competent unless there are reasonable grounds for believing otherwise. The Researcher explained that it would be part of the clinical assessment. The Committee noted that the study protocol does not mandate a capacity assessment prior to consent being obtained, however, if it is expected that a number of participants will be unable to provided informed consent then a formal protocol for determining capacity to consent will be required.
15. The Committee questioned how the researchers will ensure that the study meets Right 7(3) of the HDC Code of Rights, as participants with diminished capacity may still have the ability to make an informed choice and this decision making should be supported, additionally participants without the capacity to provide informed consent should still be informed of the study to the extent appropriate for their level of competence. The Committee stated that suitable study documents must be provided to detail and support this process.
16. The Committee requested updated study documents are provided. This should include:
    * a study protocol which details how capacity to consent will be determined, and
    * how informing and obtaining consent from participants with limited capacity will be managed (a simplified Participant Information Sheet may be required), and
    * a way of recording the recruitment of participants unable to provide informed consent (including documenting that the enrolling clinician determined that participation is in the best interests of the participants, and whether family and friends of the participant were able to be consulted, and whether the participant was able to share their views).
17. The Committee noted that in New Zealand proxy consent (including from an EPOA or next-of-kin) for research is only legally acceptable in cases where the medical experiment would save the person’s life or prevent serious damage to the person’s health. This does not apply for this study.
18. The Committee questioned whether a historical control could be used for this study. The researcher explained that this is not suitable.

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

1. The Participant Information Sheet for relatives contains information which implies consent is being given on behalf of another person for research, which is not acceptable in New Zealand.
2. Please re-title the Participant Information Sheet.
3. Please consider whether all New Zealand researchers need to be listed in the Participant Information Sheet.
4. Please add a heading to the Participant Information Sheet regarding what is involved in participation.
5. Please use bullet points in the PIS to break up the information density.
6. Please reword the statement “determine your vital status at one year” in page 5 of the Participant Information Sheet.
7. Please reformat the contact information in the Participant Information Sheet and add the HDEC contact details.
8. Please revise the Consent Form to more accurately reflect the HDEC template, this should involve amalgamating all clauses rather than requiring the participant to sign in 2 places.
9. Please remove all language from all study documents relating to proxy consent.
10. In the Consent Form if someone is mentally able to consent but can’t sign their name because of a physical incapacity with the dominant arm, then a mark/signature made with the non-dominant hand can be witnessed as theirs without having someone "sign on their behalf".
11. Please revise the Baseline Questionnaire instructions, as patients with a hip fracture will be unable to stand upright to have their height measured.
12. Please remove the statement from the poster about participants receiving additional monitoring not given outside the study.
13. Please remove the reference to family and friends being among future people who may benefit from this research.

Decision

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

* As above, please provide more information on how this study will comply with Right 7 of the *HDC Code of Rights.*
* As above, please provide more information on how this study complies with paragraph 5.30 of the *Ethical Guidelines for Intervention Studies.*
* 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 Nora Lynch and Mr John Hancock.

|  |  |  |
| --- | --- | --- |
| **8** | **Ethics ref:** | **17/NTB/94** |
|  | Title: | He Korowai Manaaki |
|  | Principal Investigator: | Associate Professor Beverley Lawton |
|  | Sponsor: | University of Otago |
|  | Clock Start Date: | 25 May 2017 |

Dr Bev Lawton, Francesca Storey, Dalice Sim, Dr Stacie Geller, and Dr Fiona Cram were present by teleconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. This study investigates whether an augmented maternal care pathway, which includes extra appointments, improves outcomes for pregnant women and their babies.

Summary of ethical issues (resolved)

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

1. The Committee questioned how it was decided to use all practices in this area for the intervention arm of the study. The Researcher explained that the local iwi requested that all pregnant women in their area receive the intervention.
2. The Committee questioned whether patients who did not meet a clinician in their first trimester would still be eligible to participate in the rest of the study. The Researcher confirmed that they would be.
3. Please use Statistics New Zealand's ethnicity classifications when collecting ethnicity data to ensure the options available are suitable for New Zealand participants. These classifications are: New Zealand European, Maori, Samoan, Cook Islands Maori, Tongan, Niuean, Chinese, Indian, Other (such as Dutch, Japanese, Tokelauan) please state.

Summary of ethical issues (outstanding)

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

1. The Committee questioned the justification for the use of health information without consent for the historical control group. The Researcher explained that they believe that the value of the study outweighs the risks associated with this privacy breach.
2. The Committee referred the researcher to paragraph 6.43 of the *Ethical Guidelines for Observational Studies* and requested that a response is provided justifying this use of health information in line with these guidelines:

Access to identified or potentially identifiable data for research without the consent of the people the data identifies or makes potentially identifiable may be justifiable when:

* + 1. the procedures required to obtain consent are likely to cause unnecessary anxiety for those whose consent would be sought; or the requirement for consent would prejudice the scientific value of the study; or it is impossible in practice to obtain consent due to the quantity or age of the records; and
    2. there would be no disadvantage to the participants or their relatives or to any collectivities involved; and
    3. the public interest in the study outweighs the public interest in privacy.

1. The Committee stated that in order to approve an application it must be clearly stated how this requirement is met by a study involving the use of health information without consent. As this was not justified with this application the Committee were unable to approve the use of health information without consent for the historical controls in this study.
2. The Committee questioned why the researchers believe that the clinics and practitioners are the participants in the study, rather than the pregnant women who will be receiving the study intervention. The Researcher explained that the goal of their study is to alter clinic behaviour rather than patient behaviour, and whether the study protocol is adhered to will be reported. The Committee stated that although clinics and practitioners may be participating in the study, the pregnant women are participants in this intervention study as the intervention will alter the care they receive and their outcomes, and the outcomes of their children, will be recorded.
3. The Committee explained that as the pregnant women in this study are participants they must be fully informed about the study and able to make a decision regarding their participation. The Committee questioned why the Researchers are not intending to obtain informed consent. The Researcher explained that they were concerned that the practitioners may not offer enrolment to some women if consent is required, especially high risk women who may stand to benefit the most from the study and have the most important results.
4. The Committee stated that people are entitled to make free and informed decisions about their participation in a study (*Ethical Guidelines for Intervention Studies* paragraph 6.8).
5. The Committee noted that an HDEC may not approve an application that is inconsistent with NZ law, even if that application is consistent with ethical guidelines (HDEC Standard Operating Procedures paragraph 15). This includes the right to not be subjected to medical or scientific experimentation without that person's consent (section 10 of the New Zealand Bill of Rights Act 1990). Additionally, the study must be consistent with the HDC Code of Rights, including Right 6 (the right to be fully informed) and Right 7 (the right to make an informed choice and give informed consent).
   1. Right 6 1(d) states that *every consumer has the right to the information that a reasonable consumer, in that consumer's circumstances, would expect to receive, including notification of any proposed participation in teaching or research, including whether the research requires and has received ethical approval.*
   2. Right 7(1) and 7(6)(a) state that *services may be provided to a consumer only if that consumer makes an informed choice and gives informed consent, except where any enactment, or the common law, or any other provision of this Code provides otherwise*, and *where informed consent to a health care procedure is required, it must be in writing if the consumer is to participate in any research.*
6. The Committee stated that legally and ethically to receive approval the study must obtain informed consent from all participants.
7. The Researcher raised concerns about the effect of informing the women about the study altering their behaviour and compromising the study results. The Committee referred the researchers to the section in the *Ethical Guidelines for Intervention Studies* on Deception and Concealment (paragraphs 6.30 and 6.31). If it is intended to conceal some information from participants these ethical guidelines must be met, and participants must still receive the information a reasonable consumer would expect to receive.
   1. *To maintain study validity, it may sometimes be appropriate to withhold information from participants until after study completion, or to conceal certain aspects of study design. Some examples of these circumstances are where:*
      * + *participants are not told the purpose of tests performed to monitor their adherence to the study protocol*
        + *prospective participants are asked to consent to remain uninformed of the purpose of some procedures until the study is completed*
        + *participants are not told that some information has been withheld until the study has been completed, because their knowledge of this aspect of the study would jeopardise its validity.*
   2. *When an investigator believes deception or concealment is scientifically justified, the following criteria apply.*
      * + *There are no suitable alternative methods.*
        + *Participants are not exposed to increased risk of harm.*
        + *The extent of deception or concealment is defined in the study protocol.*
        + *Adequate and prompt disclosure is made, and debriefing is provided, as soon as appropriate and practicable.*
        + *Participants are entitled to require the withdrawal of study data that were obtained from them without their knowledge or consent.*
        + *The deception or concealment will not compromise the relationship between the community and the investigators or research.*
        + *The investigator justifies the deception or concealment to an ethics committee.*
8. In addition, the Committee identified that the pregnant women’s children will become study participants after they are born if it is intended to collect information about them. After birth the parents or legal guardians must provide informed consent to the collection and use of information from or about their child. A separate Parent Information Sheet must be provided.
9. The Researchers questioned whether informed consent needed to be obtained or if it would be sufficient to just inform the participants of the study. The Committee referred the researcher to paragraph 6.8 of the *Ethical Guidelines for Intervention Studies* and Right 7 of the HDC Code of Rights, reiterating that people are entitled to make free and informed decisions about their participation in a study.
10. The Researcher raised concerns about practitioners not offering the Participant Information Sheet to all potential participants. The Committee stated that if patients are not offered the Participant Information Sheet and provide informed consent then they cannot be included in the study or receive study specific interventions, they must only be provided with standard care.

Decision

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

* Paragraph 6.43 of the Ethical Guidelines for Observational Studies justification must be provided regarding the use of health information without consent in line with these guidelines:
* *Access to identified or potentially identifiable data for research without the consent of the people the data identifies or makes potentially identifiable may be justifiable when:*
* *the procedures required to obtain consent are likely to cause unnecessary anxiety for those whose consent would be sought; or the requirement for consent would prejudice the scientific value of the study; or it is impossible in practice to obtain consent due to the quantity or age of the records; and*
* *there would be no disadvantage to the participants or their relatives or to any collectivities involved; and*
* *the public interest in the study outweighs the public interest in privacy.*
* People are entitled to make free and informed decisions about their participation in a study (*Ethical Guidelines for Intervention Studies* paragraph 6.8).
* Please provide suitable information sheets and consent forms for pregnant women and also for parents or legal guardians to consent to the inclusion of their children in this study after birth (*Ethical Guidelines for Intervention Studies* paragraph *6.22*).

|  |  |  |
| --- | --- | --- |
| **9** | **Ethics ref:** | **17/NTB/86** |
|  | Title: | Oral Prednisone for the Treatment of Acute Sore throat |
|  | Principal Investigator: | Dr Ivan Koay |
|  | Sponsor: |  |
|  | Clock Start Date: | 25 May 2017 |

Dr Ivan Koay was present in person for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. This study involves patients who present to their GP with an acute sore throat being treated with prednisone (a steroid).
2. Participants will have a swab of their throat taken and if clinically indicated will receive antibiotics as per standard care once the swab results are returned, however these patients will have received 48 hours of the steroid by the time the swab results are available. Patients who receive antibiotics will be withdrawn from the study as this study investigates the effect of prednisone in patients with sore throats who are not taking antibiotics.

Summary of ethical issues (resolved)

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

1. The Committee noted that it must be recorded what analgesics participants are taking.
2. The Committee stated that the patients who end up taking 48 hours of prednisone and then change to antibiotics would be an interesting sub group, however, the study recruitment and analysis must account for that drop in numbers.
3. The Committee questions the recruitment process. The Researcher explained that participants will be recruited from an urgent care clinic where a triage nurse will record their symptoms.If they meet inclusion criteria will be given information about the study by the nurse and can think about whether they want to be in the study.
4. The Committee questioned whether identifiable data may be shared with other researchers. The Researcher confirmed that the only data that may be shared will be in a de-identified form.
5. The Committee questioned whether this study is commercially funded. The Researcher explained that this is an investigator led study. The Committee questioned whether anyone may get any commercial benefit from the study. The Researcher explained that this is not expected or likely.
6. The Committee and the Researcher discussed the manufacturer of the study drug and placebo. The Researcher explained that the manufacturer would help with the randomisation process.
7. The Committee suggested that to help support the study results that participants should be asked before they are unblinded to guess whether they are in the study or placebo arm.
8. The Committee questioned whether the receptionist is involved in consenting participants. The Researcher confirmed that they were only involved in checking the readability of the Participant Information Sheet.
9. The Committee questioned whether the Researcher has been involved in conducting a Randomised Controlled Trial before. The Researcher stated that they had in the UK before. The Committee noted that a lot of work is involved in running this kind of trial.

Summary of ethical issues (outstanding)

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

1. Please clarify in the protocol what outcomes are being measured and when follow ups will be completed.
2. The Committee suggested that some exclusion criteria are added to the study to exclude patients with unstable diabetes or a venous or arterial ulcer on their leg. Please revise the study protocol to reflect this.

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

1. The Committee requested that the Participant Information Sheet is revised in line with the HDEC Participant Information Sheet template.
2. Please specify the kind of steroid in the Participant Information Sheet.
3. The Participant Information Sheet indicates that the study involves a one off dose, however it actually involves two doses, please revise this for accuracy.
4. Please revise the risk section to remove reference to risks that are not relevant as participants are only taking prednisone for two days.
5. The Committee requested the compensation wording is updated for accuracy, they suggested the following statement: *“If you were injured in this study, which is unlikely, you would be eligible* ***to apply*** *for compensation from ACC just as you would be if you were injured in an accident at work or at home. This does not mean that your claim will automatically be accepted. You will have to lodge a claim with ACC, which may take some time to assess. If your claim is accepted, you will receive funding to assist in your recovery. If you have private health or life insurance, you may wish to check with your insurer that taking part in this study won’t affect your cover.”*
6. Please add information to the Participant Information Sheet about what will happen to participants’ data.
7. Please provide a consent form.
8. Please provide a copy of the patient diary.

Decision

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

* Please respond to the outstanding ethical concerns detailed above.
* 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 Nora Lynch and Miss Tangihaere Macfarlane.

|  |  |  |
| --- | --- | --- |
| **10** | **Ethics ref:** | **17/NTB/97** |
|  | Title: | IN.PACT AV Access Study |
|  | Principal Investigator: | Associate Professor Andrew Holden |
|  | Sponsor: | Medtronic |
|  | Clock Start Date: | 25 May 2017 |

Professor Andrew Holden and Helen Knight was present in person for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. This study investigates the use of a drug coated balloon compared to a standard balloon for the treatment of stenoses (narrowing of veins) within AV fistulas.
2. Drug coated balloons are standard therapy in lower limb stenosis, it is hoped that they will also be beneficial for these patients.
3. The Committee commended the high quality of the Participant Information Sheet.

Summary of ethical issues (resolved)

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

1. The Committee questioned how participants will be recruited, given that not all patients undergoing this surgery will end up being eligible for study participation and it cannot be known in advance which patients will be eligible. The Researcher explained that they will consent all willing patients before surgery and then some will not be included in the study if they do not meet the inclusion criteria.
2. The Committee questioned whether study data may be used outside of this study. The Researcher stated that the de-identified study data is sent to the study sponsor who may use this data for other research projects.
3. The Committee noted that the study should not be stopped by the study sponsor for commercial reasons.
4. The Committee questioned how many participants are expected to be Māori. The Researcher explained that over 50% of people receiving this treatment are Māori, so they expect a lot of Māori participants.
5. The Committee questioned the exclusion criteria of patients anticipating a kidney transplant in the next 6 months. The Researcher explained that this is likely to be patients with less co-morbidities, and patients with more co-morbidities will be eligible for the study.

Summary of ethical issues (outstanding)

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

1. Please add page numbers to the Participant Information Sheet.
2. In the Participant Information Sheet please revise ‘standard care’ to a more lay friendly term, such as ‘usual care’.
3. Please add any available information on safety concerns to the Participant Information Sheet, this may be for the use of drug coated balloons in other conditions if none is available for this specific condition.
4. Please revise the risk section of the Participant Information Sheet to only include relevant risks. For example potential risks to participants’ kidney is listed, however, these participants already have poor kidney function. The Committee stated that only study specific risks should be included in the Participant Information Sheet, any risks associated with standard care should not be included in the study Participant Information Sheet and should be explained as part of routine care.
5. The Committee raised concerns about using the term ‘treatment’ when discussing study participation as an option, and requested the researchers carefully consider this to ensure that no benefit is implied by study participation.

Decision

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

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

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

|  |  |  |
| --- | --- | --- |
| **11** | **Ethics ref:** | **17/NTB/90** |
|  | Title: | Effect of Intravenous compared with oral supplement on the quality of life in patients with inflammatory bowel disease |
|  | Principal Investigator: | Dr Stephen Inns |
|  | Sponsor: |  |
|  | Clock Start Date: | 19 May 2017 |

Dr Stephen Inns was present by teleconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. This study investigates IV v. oral iron supplement on the quality of life of patients with IBD who are iron deficient but not anaemic.

Summary of ethical issues (resolved)

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

1. The Committee questioned whether there is evidence that any form of iron supplement is beneficial for iron deficient, non-anaemic patients with IBD. The Researcher explained that this study follows a study which found some quality of life benefit from iron.
2. The Committee noted that participants would not be blinded to their group allocation, as they will be able to tell if they are receiving oral or IV iron. The Committee questioned how the placebo effect would be controlled for, given this lack of blinding combined with subjective quality of life measures. The Researcher explained that given their study goals it would be difficult to have objective measures.
3. The Committee questioned whether alternative study designs, such as a double blinded trial, have been considered to address these issues. The Researcher explained that they are unable to do this as they cannot access placebo infusions or tablets, especially considering that they would not be able to mimic the side effects that participants can easily identify.
4. The Committee stated that scientific validity is an ethical concern. Scientific soundness is ethically important, projects without scientific merit needlessly expose participants to risk and misuse their time, and waste resources (*Ethical Guidelines for Intervention Studies* paragraph 5.5).
5. The Committee questioned whether the suggestions from the peer reviewer’s comments have been incorporated. The Researcher explained that they have been included in the version of the study protocol that was submitted for HDEC review.
6. The Committee questioned whether participants would be subject to a pregnancy test. The Researcher explained that if a participant thought they may be pregnant they would be tested, however there are no safety concerns from iron in pregnancy so pregnancy testing would not be done on all female participants.
7. The Committee questioned whether participant must provide stool samples. The Researcher confirmed that they will if they have not had a recent endoscopy.

Summary of ethical issues (outstanding)

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

1. Please add to the Participant Information Sheet the requirement to provide a stool sample if the participant has not had a recent endoscopy.
2. Please consider the HDEC Participant Information Sheet Template and revise the Participant Information Sheet to ensure that all required information is included, including that participants’ hospital records will be accessed and their GP informed of their participation.
3. Please add a short lay title to the Participant Information Sheet.
4. Please revise the Participant Information Sheet to remove all typographical errors.
5. Please clarify the randomisation process in the Participant Information Sheet.
6. Please clarify in the Participant Information Sheet that participants should take all tablets as directed and return the containers.
7. Please add any possible side effects of iron, including the differences for IV (such as pain at the injection site).
8. Please remove the statement ‘no chance of being harmed’ from the Participant Information Sheet as this is possible.
9. The Committee requested the compensation wording is updated for accuracy, they suggested the following statement: *“If you were injured in this study, which is unlikely, you would be eligible* ***to apply*** *for compensation from ACC just as you would be if you were injured in an accident at work or at home. This does not mean that your claim will automatically be accepted. You will have to lodge a claim with ACC, which may take some time to assess. If your claim is accepted, you will receive funding to assist in your recovery. If you have private health or life insurance, you may wish to check with your insurer that taking part in this study won’t affect your cover.”*
10. Please add the HDEC contact numbers to the Participant Information Sheet.

Decision

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

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

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

|  |  |  |
| --- | --- | --- |
| **12** | **Ethics ref:** | **17/NTB/93** |
|  | Title: | Intravenous and Intraperitoneal lignocaine |
|  | Principal Investigator: | Professor Andrew Hill |
|  | Sponsor: | The University of Auckland |
|  | Clock Start Date: | 25 May 2017 |

Dr Wiremu MacFater was present in person for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. This study involves comparing two standards of care, Intravenous and intraperitoneal lignocaine, to improve pain management after laparoscopic colon resections.
2. The Committee commended the high quality of the application, especially for a student researcher.

Summary of ethical issues (resolved)

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

1. The Committee noted that the study had good stopping rules and an independent data safety monitoring committee which is appropriate for this study.
2. The Committee questioned whether participants will be cared for in the ward and whether the use of ECG monitors is standard care. The Researcher explained that they are purchasing new equipment for the study, and will have two doctors on site who will be altered through an automated alarm system to any safety concerns as an extra safety measure.
3. The Committee questioned whether any specific drugs participants may be taking would exclude them from the study. The Researcher explained that as both study treatments are standards of care then screening for this is part of existing care.
4. The Committee noted that in the study protocol Intravenous and intraperitoneal are not always used accurately. Please ensure this is altered for accuracy.
5. The Committee questioned the Māori cultural consultation process. The Researcher explained their process, including how study results will be communicated with Māori.

Summary of ethical issues (outstanding)

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

1. Please reword the opening sentence of the Participant Information Sheet which states that surgery inflicts injury.
2. Please clarify in the Participant Information Sheet that participants will have two lines (IV and intraperitoneal), one with saline and another with lignocaine.
3. Please clarify in the Participant Information Sheet approximately what time of day participants will be followed up after discharge as some may be back at work.
4. Please clarify in the Participant Information Sheet that participants cannot withdraw once their data has been analysed.
5. Please clarify the information about the magnitude of the risk of infection.
6. Please clarify in the Participant Information Sheet that study data will be retained for 10 years following the end of the study.
7. Please revise the information about pain level reporting, as participants are required to report their pain levels the day before and after surgery but both say to consider their pain levels of the previous two days, however this timeframe would overlap.
8. Please add page numbers and the study title or reference number to the footer of the Participant Information Sheet.
9. Please revise the Participant Information Sheet to remove all typographical errors.

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 Nora Lynch and Miss Tangihaere Macfarlane.

## Substantial amendments

|  |  |  |
| --- | --- | --- |
| **1** | **Ethics ref:** | **12/NTB/42/AM18** |
|  | Title: | Tissue Bank and Database |
|  | Principal Investigator: | Professor Swee T Tan |
|  | Sponsor: | Mr Christopher Adams |
|  | Clock Start Date: | 06 June 2017 |

Professor Swee T Tan and two research nurses were present by teleconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. Previously HDEC approval had been granted to move the storage of tissue samples retained in this tissue bank to a new location. This approval required that re-consent be obtained from participants for the ongoing storage and use of their tissue.
2. This amendment has been submitted as the researchers have only been unable to contact 200 of 1000 participants, and, although all contacted have agreed to the ongoing storage and use of their tissue, the researchers are applying to continue storing the tissue of the remaining 800 participants without re-consenting them.

Summary of ethical issues (resolved)

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

1. The Committee questioned how many participants are expected to be deceased. The Researcher explained that 2/3 of the tissue samples are from cancer patients and 40-50% of these patients are expected to be deceased.
2. The Committee questioned whether the researchers could check against the mortality index to confirm whether participants are deceased. The Researcher explained that this is not practical or realistic in this case.
3. The Committee questioned when these samples were collected between. The Researcher explained that they would have been collected between 2002 and 2013.
4. The Committee questioned whether tissue may be used for profit, and how it is determined who can use tissue from the Tissue Bank. The Researcher explained that their governance committee determines how the tissue can be used, and this tissue is only used by researchers within their organisation, and for studies they collaborate on.
5. The Committee noted that it is challenging to review these kind of amendments as it is unclear from the study documents what is current, due to the large number of amendments. The Committee suggested that in future applications it is clarified exactly what version of documents is current, and a copy of these is provided for ease of reference.

Summary of ethical issues (outstanding)

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

1. The Committee questioned whether formal Māori consultation has been undertaken when moving the storage of these samples, and in relation to this ongoing use without re-consent. The Researchers explained that they have consulted with a Māori member of the governance committee and follow the Te Ara Tika Guidelines. The Committee requested some documentation of the process and what was considered during the Māori consultation.
2. The Committee requested some examples of the Participant Information Sheets and Consent Forms that participants would have been consented with.
3. The Committee questioned whether participants would be informed that their tissue may be sent overseas. The Researcher stated that some would have been. The Committee questioned whether, if they agree to the ongoing storage and use of these samples without re-consenting the participants, the samples could be flagged and only used within New Zealand. The Researcher confirmed that this could be arranged.
4. The Committee questioned whether the researchers believe that participants consented to this ongoing storage and use of their tissue when they initially consented. The Researcher explained that the participants understood that they were providing their tissue samples for ongoing research related to their condition. The Committee questioned whether a condition could be placed on this tissue to ensure it is only used for research related to the condition it was originally collected in relation to. The Researcher confirmed that this would be possible.
5. Please provide some documentation for the above restrictions on the use of this tissue.

Decision

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

* Please respond to the outstanding ethical concerns detailed above.
* Please provide examples of the Participant Information Sheets and Consent Forms that participants would have been consented with *(Ethical Guidelines for Observational Studies para 6.10)*
* Please provide updated governance documents detailing the requested restrictions to be placed on tissue under the scope of this amendment.

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

## General business

1. The Committee noted the content of the “noting section” of the agenda.
2. The Chair reminded the Committee of the date and time of its next scheduled meeting, namely:

|  |  |
| --- | --- |
| **Meeting date:** | 04 July 2017, 12:00 PM |
| **Meeting venue:** | Novotel Ellerslie, 72-112 Greenlane Rd East, Ellerslie, Auckland |

The following members tendered apologies for this meeting.

* Mrs Jane Wylie

1. **Problem with Last Minutes**

The minutes of the previous meeting were agreed and signed by the Chair and Co-ordinator as a true record.

The meeting closed at 6:15pm.