|  |  |
| --- | --- |
| **Committee:** | Northern B Health and Disability Ethics Committee |
| **Meeting date:** | 01 September 2015 |
| **Meeting venue:** | Novotel Ellerslie |

|  |  |
| --- | --- |
| **Time** | **Item of business** |
| 12:00pm | Welcome |
| 12:05pm | Confirmation of minutes of meeting of 04 August 2015 |
| 12:30pm | New applications (see over for details) |
|  | i 15/NTB/140  ii 15/NTB/156  iii 15/NTB/158  iv 15/NTB/147  v 15/NTB/149  vi 15/NTB/151  vii 15/NTB/152  viii 15/NTB/153  ix 15/NTB/154  x 15/NTB/155  xi 15/NTB/145  xii 15/NTB/146 |
|  | General business:   * Noting section of agenda |
| 5:30pm | Meeting ends |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Member Name** | **Member Category** | **Appointed** | **Term Expires** | **Apologies?** |
| Mrs Raewyn Sporle | Lay (the law) | 01/07/2012 | 01/07/2015 | Apologies |
| Mrs Maliaga Erick | Lay (consumer/community perspectives) | 01/07/2012 | 01/07/2015 | Present |
| Mrs Stephanie Pollard | Non-lay (intervention studies) | 01/07/2012 | 01/07/2015 | Apologies |
| Miss Tangihaere Macfarlane | Lay (consumer/community perspectives) | 19/05/2014 | 19/05/2017 | Present |
| Mrs Phyllis Huitema | Lay (consumer/community perspectives) | 19/05/2014 | 19/05/2017 | Present |
| Mrs Kate O'Connor | Non-lay (other) | 01/07/2013 | 01/07/2016 | Present |
| Ms Raewyn Idoine | Lay (consumer community perspective) | Co-opt STH | Co-opt STH | Present |
| Dr Nora Lynch | Non-lay (health/disability service provision) | 01/07/2015 | 01/07/2018 | Present |
| Dr Sarah Gunningham | Non-lay (intervention studies) | Co-opt STH | Co-opt STH | Present |
| Dr Devonie Waaka | Non-lay (intervention studies) | Co-opt STH | Co-opt STH | Present |

## Welcome

Note: Mrs Raewyn Sporle is absent for the meeting and Ms Raewyn Idoine has been co-opted to Chair the meeting.

The Chair opened the meeting at 12:30pm and welcomed Committee members, noting that apologies had been received from Mrs Raewyn Sporle and Mrs Stephanie Pollard.

The Chair noted that it would be necessary to co-opt members of other HDECs in accordance with the SOPs. Dr Sarah Gunningham and Dr Devonie Waaka confirmed their eligibility, and were co-opted by the Chair as members of the Committee for the duration of the meeting.

The Chair and Committee welcomed the new Northern B ethics committee member, Dr Nora Lynch, and the new HDEC advisor, Fox Swindells.

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 04 August 2015 were confirmed.

## New applications

|  |  |  |
| --- | --- | --- |
| **1** | **Ethics ref:** | **15/NTB/140** |
|  | Title: | Retrospective Review of progression of Low Grade Appendiceal Mucinous Neoplasms |
|  | Principal Investigator: | Dr Shuai Yuan |
|  | Sponsor: |  |
|  | Clock Start Date: | 30 July 2015 |

Dr Lance Yuan 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. The Researcher(s) explained that the study investigates a specific subset of tumours of the appendix - Low grade Appendiceal Mucinous Neoplasms (LAMN).
2. There is controversy about how to manage this sub-set of tumours. There is clinical disagreement on why they are caused and therefore what the correct follow up measures should be.
3. This protocol outlines a plan to review patients with LAMN from 1995 to present, in Auckland City Hospital. A pathologist, Dr Chow, will screen existing samples that are stored in the pathology department to ensure they are eligible to be reviewed. The sample data will be correlated with historical medical information will and follow up data. This data is usually stored within Auckland District Health Board. All files will have patient IDs.
4. The Researcher(s) hope to establish some basic parameters for correct follow up of patients with LAMN.

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 this study is primarily an audit, but explained that the researcher would like to contact patients and or their family in the event that follow up data is missing from the ADHB records.
2. The Committee asked whether the researcher knew how many cases of missing information there may be, and whether not seeking the missing data would significantly bias the data. The Researcher(s) explained that it was difficult to know until the audit had been completed. The Researcher(s) stated if it were only 2-3 patients it would not be a major concern. But it could be the case that there are many incomplete files, due to patients leaving the Auckland region. We would want to know what happened with these patients, and it is very important for scientific validity to include them.
3. The Committee queried how many participants are needed. The Researcher(s) stated they need all the data, it is not a study where there is a power calculation – the researchers picked 200 as this is how many we have in our system. It is important to make the data series as large as possible. The Researcher(s) stated the disease is rare, 1-5% rate, with 200 records in Auckland region since 1995.
4. The Researcher(s) confirmed only data from adults would be included.
5. The Committee explained that the 3-month timeline is ambitious. The Researcher(s) stated he was confident it was manageable.
6. The Committee discussed harm minimisation plans, including an option to phone the GP of cases where data is incomplete, and ask them about the patient to avoid causing undue stress or harm. The Researcher(s) stated that they thought this was a good idea.
7. The Committee asked whether the researchers had considered patients who had transferred to private practice for follow up. The Researcher(s) stated that generally if people are lost to follow up we would be able to find that sub-set of people, due to their likelihood of going through some form of public practice. The Committee stated they are aware of patients that have private practice for most things, so potentially not including private practice participants should be noted as a limitation of the study.
8. The Researcher(s) explained there are multiple clinicians who will be following this patient population up. The Committee stated there would be purely private patients who will not be identified through these means. The Researcher(s) stated that they hope that we have enough people from Auckland city hospital for the purposes of the study.
9. The Committee queried what the length of follow up the hospital recommends, noting researchers should not necessarily consider them as lost to follow up if the hospital discharges them. The Researcher(s) stated they would review clinical notes for ‘cured of disease and therefore discharged’ as a way of avoiding mislabelling someone as lost to follow up. The Researcher(s) noted they would not know if the patient had relapsed.
10. The Researcher(s) clarified the participants, if alive, should all be under active follow up.
11. The Researcher(s) other audits suggest 30% of patients are subsequently out of ADHB systems.
12. The Committee noted R.3.9.1 should be answered ‘no’.
13. The Committee queried whether Maori consultation would be required, and asked the Researcher(s) to talk to their research office. This would also assist in addressing queries of relevancy for Maori in the ethics applications, which were answered poorly.
14. The Researcher(s) talked about the potential to re-open cases if we identify something in our research that will be relevant for participants. The Committee noted this would be a clinical practice issue.

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 some studies cite a 45% survival after 6 years. The Committee explained that there is a high chance you will be contacting family members who have had someone die which may cause harm or undue stress. What measures do you have in place to mitigate this potential for causing harm? The Researcher(s) explained the plan was to make an initial contact to the listed contact person from hospital records. The Committee noted this was not appropriate.
2. The Researcher(s) explained that if avoiding contacting patients and families would be better for the study and if this is acceptable to ethics we would like to do this.
3. The Committee queried if the researchers could do a cross reference with the incomplete outcome cases and the death registry, to know whether the person had died or not. The Committee noted that including those who have died would also be scientifically relevant. This was the primary ethical issue of the study and the Committee noted it had not been thought out.
4. The Committee is comfortable in approving the audit. The Committee expects an amendment to be submitted. This amendment will outline how many incomplete records there are, the process planned to follow this information up, including any patient information and cross referencing plans.

Decision

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

* Amend protocol to make the study as phase 1 and phase 2. The study design must minimise risk of harm (*Ethical Guidelines for Observation Studies* *para 5.5*).

This following information will be reviewed, and a final decision made on the application, by Dr Sarah Gunningham and Mrs Mali Erick.

|  |  |  |
| --- | --- | --- |
| **2** | **Ethics ref:** | **15/NTB/155** |
|  | Title: | Early detection markers and risk factor analysis for Human papillomavirus associated oropharyngeal cancer |
|  | Principal Investigator: | Ms Rebecca Lucas-Roxburgh |
|  | Sponsor: |  |
|  | Clock Start Date: | 20 August 2015 |

Ms Rebecca Lucas-Roxburgh and Dr Jacqui Benshop or Dr Laryssa Howe were present by teleconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. The study investigates early detection markers and risk factors for Human papillomavirus (HPV)
2. HPV causes nearly all cases of cervical cancer. Studies indicate that HPV may account for 75% of oropharyngeal cancer.
3. The Researcher(s) have conducted research that suggests that one third of people in New Zealand are HPV positive.
4. The study has two aims. The first is to try and identify early detection markers for oropharyngeal cancer. This involves taking tissue samples and comparing them against those who are positive and negative for HPV. It will aim to identify pre-cancer legions. Secondly the study will look at risk factors for positive and negative HPV. This part of the study involves questionnaires.
5. The Researcher(s) explained that there is no significant data on these topics. The primary goal is to improve understanding of the disease.

Summary of ethical issues (resolved)

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

1. A.1.5 – questionnaire is a ‘working draft’. The Committee queried what this meant. The Researcher(s) stated that they have consulted widely with patients and surgeons about the acceptability and readability of the questionnaire. If we receive feedback we can make changes prior to using it with study participants. The Committee noted any substantial changes must be approved by HDEC prior to use.
2. The Committee noted the peer review raised a concern about the number of participants in the study. The Researcher(s) stated that they have talked with the peer reviewer and taken her advice on board. To mitigate her concern there is now no follow up period in the study, which lets us get more samples. We have been informed that the sample size and time frame will work out and be sufficiently powered.

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 queried if there is a sponsor - A.5.1 – The Committee noted that the postgraduate office might be willing and or appropriate to be the sponsor, as they may initiate, finance and monitor the study. Please clarify.
2. The Committee noted the locality would be DHB. The Researcher(s) confirmed this was correct.
3. The Researcher(s) and the Committee discussed what information and testing is involved with this patient population around the time of study participation.
4. The Committee noted that some people would fill out questionnaires before they are notified they have cancer and some after. The Committee noted recall of risk factors would be affected by when the questionnaire is administered. Have the researchers considered standardising this? The Researcher(s) stated that there is an assumption that when they are approached the participant will have a visible non-healing legion. The participant would then either find out it is a malignancy or not. The Committee noted one way would be to only administer questionnaires to those who have been informed they have cancer. The Committee noted people who have the disease would work hard to recall exposures. The Researcher(s) stated in terms of the questionnaires, we are comparing HPV positive and HPV negative. In terms of the risk factor analysis all patients will have cancer. The Researcher(s) stated if a participant has a benign cancer they would not be included. The Committee noted it is more about recall and timing of questionnaire administration.
5. The Researcher(s) stated they could wait until they get the pathology report, and then send the questionnaires.
6. The Committee confirmed it would be better to initiate questionnaire contact after diagnosis.
7. The Committee clarified the process: Consenting, giving information at biopsy, getting brushing, then if cancer is diagnosed – send questionnaire out. A letter should accompany this questionnaire. Add this information to the Participant Information Sheet.
8. The Committee suggested the diagnosing Dr could send the letter, on their letterhead.

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

1. The Committee noted that data is not anonymous, as often referred to, but is de-identified. The Committee explained identifiably of data and referred the researchers to the National Ethics Advisory Committee Guidelines for Intervention Studies section 7.2. The Researcher(s) confirmed that the data is de-identified. The Committee requested that the Participant Information Sheet is amended to state de-identified, not anonymous, and explain what happens regarding the data coding for participants.
2. The Committee queried the time to consent. Is it correct that the potential participant needs to make a decision about participation while they are waiting for their biopsy? The Researcher(s) explained that was correct – this short consent period was required due to the need for the biopsy brushing to be collected. The Researcher(s) explained that this short consent window was mitigated by having clear options about withdrawal, for instance, participants can withdraw and their tissue will not be used, and they would not be sent a questionnaire. The Committee noted this is not clear, at all, in the Participant Information Sheet. The process for participants is further confused as it states ‘you do not need to decide today if you want to participate’. Amend the document to reflect your plan for consent then potential withdrawal option.
3. Add information on Maori views on use of tissue. For instance: 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 Maori 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.
4. Page 3 – ‘remove other studies’ at the top – sub heading.
5. Please remove the tick boxes. Only have yes/no option if the statement is truly optional. The Committee stated that summary of results is optional but the remainder are not.
6. Please add information ‘what happens if I change my mind’ in Participant Information Sheet.
7. Add information about any different use of the stored samples would require further consent, and seek consent to be contacted about such use.
8. The Committee noted tonsil cancer and oropharyngeal cancer are used interchangeably. IS this correct? The Researcher(s) confirmed yes oropharyngeal cancer includes other mouth cancers.
9. Be consistent with oropharyngeal cancer terminology and describe what it is.

Decision

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

* Please amend the information sheet and consent form, and assent forms, taking into account the suggestions made by the Committee (*Ethical Guidelines for Observation Studies* *para 6.11*).
* Amend the protocol to clearly show who will receive questionnaires and when. The study design must minimise risk of harm (*Ethical Guidelines for Observation Studies* *para 5.5*).
* Clarify whether the study is sponsored.

This following information will be reviewed, and a final decision made on the application, by Dr Devonie Waaka and Mrs Mali Erick.

|  |  |  |
| --- | --- | --- |
| **3** | **Ethics ref:** | **15/NTB/158** |
|  | Title: | Comparison of the blood levels of two forms of tranexamic acid 500 mg tablets in healthy male and female volunteers |
|  | Principal Investigator: | Dr Noelyn Hung |
|  | Sponsor: | Southern Cross Pharma Pty Ltd |
|  | Clock Start Date: | 20 August 2015 |

Dr Tak Hung and Mrs Linda Folland 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 bioavailability study in healthy participants, male and female. Study drug has a short half-life – less than 2 hours. Treatment period will be approximately 13 hours.
2. Side effects of this drug are minimal.
3. The Committee stated the Participant Information Sheet was much improved.

Summary of ethical issues (resolved)

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

1. The Committee queried the period of time between reading signing the consent form and receiving experimental drug. The Researcher(s) stated it is variable. Screening must occur within 21 days of consent. Typical process would be - give consent, next day basic screening, and then medical screening. Likely administering the drug the following weekend. In summary, anywhere between 1-3 weeks.
2. The Committee asked what happens if participants do not have a GP (international students). The Researcher(s) stated student health is involved; this ensures someone can follow up with participant.
3. The Committee noted on page 3 – ‘no drug or medicine, including oral contraceptives’. Does this statement include paracetamol? The Researcher(s) confirmed it did, explaining that the researchers need to know about all drugs a participant has taken. The Committee noted it reads as exclusion criteria. The Researcher(s) stated it is actually just to know the context for why participant was on paracetamol – it is a safety mechanism. The Committee stated they could revisit the wording to make this clear.

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

1. Please collect ethnicity during screening visit, not during consent. The Committee noted this is a consent form not a data collection form.

Decision

This application was *approved* by consensus.

|  |  |  |
| --- | --- | --- |
| **4** | **Ethics ref:** | **15/NTB/147** |
|  | Title: | Comparison of Sotagliflozin versus placebo as an addition to Insulin in patients with type 1 Diabetes |
|  | Principal Investigator: | Dr Ian Rosen |
|  | Sponsor: | Covance New Zealand Ltd |
|  | Clock Start Date: | 20 August 2015 |

Dr Ian Rosen and Mrs Catherine Howe were present in person for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. The study is to determine whether blood sugar control can be improved by adding the experimental agent on top of standard care (insulin).
2. This is a new, novel, medication developed for diabetes. The study drug has not been used in type 1 diabetes patients before.

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 the FDA warning. The Researcher(s) stated they go into great detail with potential participants. The Researcher(s) confirmed regular monitoring is in place for this risk.
2. The Committee requested an explanation on how the study meets equipoise standard. The Researcher(s) explained randomisation methods. The Committee explained what equipoise (balance of benefit and risk between study arms) is and requested that in future the application addresses equipoise rather than randomisation.
3. The Committee queried why females were asked to wash their genitals before sex but not after, and queried the discrepancy between males and females (participant instruction material). The Researcher(s) noted that was a valid point and would review the documentation.
4. The Committee queried whether any patients have their doctor as their researcher (R.5.4). The Researcher(s) explained the form had an error in it. It would be likely that treating clinicians would also be researchers.
5. P.4.1 – please indicate incidence of diabetes in Maori rather than referring to the treaty of Waitangi. The Researcher(s) acknowledged that it was a mistake. This comment also refers to F.1.1 and F.1.2.

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 application states 77 participants would be recruited but insurance certificate for 66. Please amend.

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

1. The Committee queried the statement on commercialisation – is this necessary for New Zealand audience? The Committee requested this is removed or justified.
2. The Committee queried if there are any risks with fathering a child while on study – can drug be passed through sperm? The Researcher(s) stated males must use recognised form of contraception, or their partners. The Committee noted that this information must be in the Participant Information Sheet.
3. The Committee queried what happens to patients at 32 weeks. Is there possibility of extending treatment? Or would participants go back on standard care and potentially to previous levels of blood sugar. The Researcher(s) stated if medication were not commercially available they would return to treatment they were on. The Committee requested that post study access is explicitly outlined.

Decision

This application was *approved* with nonstandard conditions by consensus.

|  |  |  |
| --- | --- | --- |
| **5** | **Ethics ref:** | **15/NTB/149** |
|  | Title: | CARSK Study |
|  | Principal Investigator: | Associate Professor Helen Pilmore |
|  | Sponsor: |  |
|  | Clock Start Date: | 20 August 2015 |

Associate Professor Helen Pilmore was not present for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. The study involves patients who are on kidney transplant waiting lists from New Zealand, Australian and Canadian.
2. The study aims to determine if routine, current practice, screening for heart artery blockers are useful or whether they create more problems than they solve.
3. For future applications please explain the peer review process, the Committee accepts the peer review but would like more information on it and who was involved.
4. The Committee commended the answers on F.1.1 and F.1.2.

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 queried whether Auckland District Health Board is the sponsor. Please talk to the research office and clarify sponsor status.
2. The Committee queried why the control group receive more screening than standard of care? If it is a control group it should reflect standard of care. Please justify or amend.
3. The Committee noted the plans to minimise conflict of interest were well thought out.
4. (P.2.7) states that ‘important new information’ would be discussed at the 6 monthly appointments. The Committee noted if this information is important they should telephone the participant and see whether they wanted to continue participation in the study.
5. Please explain who the New Zealand member of the data safety monitoring committee is.

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

1. The Committee noted the study procedures (page 2) of Participant Information Sheet have doubled up. Paragraph 2 and 3 are the same as paragraph 5 and 6.
2. Queried the statement on page 3 about the data safety monitoring committee ‘ensuring’ participant safety’. Please remove – this is an overstatement of the role of a data safety monitoring committee.
3. Page 1 – ‘blockages’ – please explain, in what? For instance - specify heart vessel.
4. Please clarify what interpreters are available and make this clear.
5. Please make informing the GP of study participation a mandatory option i.e. statement not yes/no box.

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 clarify the sponsored status of the study.

This following information will be reviewed, and a final decision made on the application, by Dr Devonie Waaka and Mrs Mali Erick.

|  |  |  |
| --- | --- | --- |
| **6** | **Ethics ref:** | **15/NTB/151** |
|  | Title: | Exploring the role of an individualised healthcare transition document for young people with disabilities transitioning from Paediatric services to Primary Care. |
|  | Principal Investigator: | Dr Emma Cluett |
|  | Sponsor: |  |
|  | Clock Start Date: | 20 August 2015 |

Dr Emma Cluett 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. The Researcher(s) explained that this was a small research project was being undertaken as part of the Royal Australasian College of Physicians fellowship.
2. The study is a single arm intervention study. The intervention is a formal transition document for young people with disability.
3. There is a gap in knowledge in the transition process in New Zealand and internationally.
4. The study will involve 15 participants from Counties Manakau.
5. Outcome data points will be utilisation of the document and transition readiness. Secondary measure will be sought by following up interactions with primary care and interactions with tertiary services. The researchers will be seeking feedback from GPs.
6. Primary function of the project is to collect information to provide advocacy.

Summary of ethical issues (resolved)

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

1. The Committee queried if this is a trial, noting that the application suggests that everyone receives the document as standard practice - there is an assumption that this document already works.
2. The Researcher(s) clarified that only people who consent to this study will receive the transition document. There is no standard of care or gold standard.
3. The Committee asked how the study would be conducted. The Researcher(s) stated transition progress is currently unstructured and fluid. This informal nature is part of the problem. To assess our formal process we will carry out a previously validated questionnaire, before the transition document is administered. Then participants will receive the document. We will formally run through it until they understand it. We will then conduct another follow up session 1-2 months later.
4. The Committee queried if there was any use of a control arm of those who have transitioned who did not use the form? The Researcher(s) explained rationale for single arm design, citing it was easier, that it was a pilot, there were time constraints and limited financial resources. The Researcher(s) noted if this were a larger study the researchers would use a control.
5. The Committee noted study is hypothesis generating.
6. The Committee queried who speaks to family or participants about the study, noting the contradiction in the application. The Researcher(s) explained that researcher obtains consent (which avoids coercion if approached by treating clinicians) but paediatrician introduces the study with them (avoids disclosure of information to researcher without consent). The Committee noted this is best practice.
7. The Committee queried if this is a living document. The Researcher(s) stated no - explained that currently there is no access or funding to create a CONCERTO document. The Researcher(s) noted the study could generate a need for this. The formal transition document would be static but could develop into one that is used by multiple parties.

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 discussed the child assent forms and requested age appropriate Participant Information Sheets in the event that a participant could consent for himself or herself. See HDEC guidance at <http://ethics.health.govt.nz/guidance-materials/assent-guidance>
2. The Committee noted Maori consultation would be required, as per the Health Research Council Guidelines for Research Involving Maori.
3. The Committee suggest talking to Auckland District Health Board research office in regards to consultation.
4. The Committee queried the sponsor status of the study. Please consult with research office.

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

1. Add more space for participants to sign.
2. The Committee suggested shortening the study title.
3. The Committee suggested removing the statement about families finding the transition difficult.
4. The Committee noted having children sign is important.
5. The Committee noted he/she instead of they – as this is a small sample size this should be feasible.
6. Add contact numbers – health and disability commission, Maori support numbers.
7. HDEC suggested looking at HDEC template Participant Information Sheet for information to include.
8. Amend ‘certificate’ of consent to ‘consent form’.

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 age appropriate information sheets and assent forms for younger participants and amend the existing information sheets and assent/consent form, taking into account the suggestions made by the Committee (*Ethical Guidelines for Intervention Studies* *para 6.22*).
* Clarify the sponsored status of the study.

This following information will be reviewed, and a final decision made on the application, by Dr Sarah Gunningham and Mrs Tangihaere MacFarlane.

|  |  |  |
| --- | --- | --- |
| **7** | **Ethics ref:** | **15/NTB/152** |
|  | Title: | Skin changes following fat grafting |
|  | Principal Investigator: | Ms Michelle Locke |
|  | Sponsor: | The University of Auckland |
|  | Clock Start Date: | 20 August 2015 |

Ms Michelle Locke was present by teleconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. The Committee noted the application was of a very high quality.

Summary of ethical issues (resolved)

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

1. The Committee queried if the tissue punch biopsy would be in same spot as the elective surgery. The Researcher(s) stated no, but close to it - probably side by side.
2. The Committee asked if there would be two larger scars from research participation. The Researcher(s) confirmed there would be, but they may be excised after their surgery. The Researcher(s) explained if they did not participate in research the participants would have 3-4mm long scar that would usually heal well and go almost un-noticed. The punch biopsy leaves a 7mm scar, which is a little bit bigger than the standard care scar. In terms of what the research participation adds it does not pose a significant difference.
3. The Researcher(s) explained that they will two roles, clinician and researcher.
4. The Committee stated with their medical hat on they can collect data and collect samples but when in the researcher role there was a need to work with de-identified data and tissue. Please ensure identifiable information is coded prior to research use.
5. The Committee queried why the researchers were not offering study results for participants. The Researcher(s) stated they could, adding it will take many years to get the results. The Committee noted that was typical and that they thought it would be appropriate to offer. The Researcher(s) noted participants may be hard to track them down would leave area on Participant Information Sheet for the option.

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

1. Add information on Maori views on use of tissue. For instance: 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 Maori 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 *approved with non-standard conditions* by consensus.

|  |  |  |
| --- | --- | --- |
| **8** | **Ethics ref:** | **15/NTB/153** |
|  | Title: | Validation of White Blood Cell Lineage Specific DNA methylation markers |
|  | Principal Investigator: | Dr Miles Benton |
|  | Sponsor: | Institute of Environmental Science and Research |
|  | Clock Start Date: | 20 August 2015 |

Dr Miles Benton was present by teleconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. The study investigates how methylation relates to gene expression.
2. There will be 6 male 6 females, selected within university or Malaghan Institute – students, clinicians. The participant understanding of the research will already be high.

Summary of ethical issues (resolved)

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

1. The Committee queried how the researcher would know participants are healthy. The Researcher(s) stated the participants’ only need to be reasonably healthy; adding it will be self reported information. The Researcher(s) referred to the exclusion criteria.
2. The Committee noted Participant Information Sheet is written for a non-lay audience but concluded that the participants would be able to understand it due to their involvement with research.
3. The Committee queried are you intending to keep samples for future research? The Researcher(s) stated no. The Committee noted it states you are in application. The Researcher(s) clarified that they decided not to.

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

1. The Committee asked about the tissue going overseas. The Researcher(s) explained the need for DNA to go overseas for analysis. The Committee noted this is on consent form but not the Participant Information Sheet. Please add some brief information on the Participant Information Sheet.
2. Remove tick boxes on the consent form, as they are not truly optional. Make them statements.

Decision

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

|  |  |  |
| --- | --- | --- |
| **9** | **Ethics ref:** | **15/NTB/154** |
|  | Title: | Effects of dairy protein at rest and after exercise |
|  | Principal Investigator: | Dr Cameron Mitchell |
|  | Sponsor: | Fonterra Co­operative Group |
|  | Clock Start Date: | 20 August 2015 |

Dr Cameron Mitchell and Prof David Cameron-Smith 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 Researcher(s) explained that the study hopes to generate evidence to address sarcopedia – loss of muscle mass from aging. Loss of muscle mass can have significant health impacts.
2. The Researcher(s) stated this project is part of government funded primary growth partnership that focuses on targeted food interventions.
3. The Researcher(s) explained that the study is a non-inferiority study that addresses the study question - what is minimal effective dose for efficacy.

Summary of ethical issues (resolved)

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

1. The Researcher(s) described the fluid, muscle biopsy and the exercise intervention. The Researcher(s) explained the muscle biopsy and its risks. The Researcher(s) stated the average incision would leave fine white scar. Complications in scientific literature are exceedingly rare. The Researcher(s) anecdotally have only had situation of complications, which was bleeding for 20 minutes. The Researcher(s) explained in most situations ice and bed rest is adequate to recover from the biopsy.
2. The Committee noted the researcher had substantial experience in conducting muscle biopsies. The issue was more related to the clinical oversight in case something went wrong. The Committee was satisfied provided that clinicians were able to be present quickly for any adverse events.
3. The Researcher(s) confirmed no storage of tissue beyond the length of the study would occur.
4. The Researcher(s) confirmed tissue is stored for study, tissue will be stored with participant number and will be able to be linked to participant details.
5. The Researcher(s) noted insurance would be renewed.

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 the 250-dollar reimbursement was low when considering the number of procedures and time and inconvenience involved in participation. The Researcher(s) agreed.
2. The Committee requested a new reimbursement figure and requested a rationale behind the new figure.
3. The Committee noted that the advertisement constituted inducement, due to its wording. Amend to ‘you will be reimbursed for your time and inconvenience’.
4. The Committee noted that it should be clear for participants that this will be taxable income and may impact any benefits they are receiving.
5. The Committee asked who conducts the biopsies. The Researcher(s) stated Dr Mitchell (CI). The Researcher(s) explained that Dr Mitchell is not a medical doctor, however Dr Paul Hoffman, a qualified doctor, is across the hall. The Committee queried how many biopsies Dr Mitchell has done. The Researcher(s) explained, 200 in New Zealand and up to 1000 in total, where I have been involved in the process. The Committee accepted that Dr Mitchell had satisfactory experience to conduct the biopsy. However the Committee raised concerns about the lack of safety procedures in case of an unexpected adverse event.
6. The Committee queried if people are screened for bleeding disorders. The Researcher(s) stated yes, both as exclusion criteria and in terms of verbal screening.
7. The Committee queried local anaesthetic – 1% Lidocaine. The Committee asked what the maximum could be given to one person. The Researcher(s) was not able to give the exact number, but stated that they would ensure it was correct.
8. The Researcher(s) stated we always operate within a clinician on call.
9. The Committee raised issue of anaphylaxis - very small risk – but is important to have good processes in place.

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

1. The Committee noted phenylalanine is not a protein. Please state what it is in the IV fluid clearly in the Participant Information Sheet as some people believe they are allergic to phenylalanine (whether they are or not is irrelevant).
2. Add some basic inclusion exclusion criteria on bleeding risks.
3. The Committee stated please remove info on Fonterra’s milk production from the beginning of the document. This is not an advertisement for Fonterra.
4. Add risks involved in cannulation.
5. Add information on Maori views on use of tissue. For instance: 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 Maori 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.
6. Add more information about ACC equivalent coverage that will be provided in the event of an injury.
7. Make the 5 biopsy component clearer, it is currently buried in text (between pages 2-3).
8. Item 3 on CF – remove this statement. There is no power for sponsor to be able to access the health information, both generally but particularly if someone withdraws from the study. Please also limit access to information for the purposes for this study. Remove ‘any further research’ and ‘even if you withdraw’.
9. Please contact Papaarangi Reid – as the Committee notes the researchers need Maori consultation – see Health Research Council Guidelines for Research Involving Maori.
10. Clearly state what is paid for, for instance taxis, and that you can’t walk or bike post intervention.
11. Remove initialling each page requirement.
12. Add explicit consent option for sending tissue back to participants.
13. Add Liggins Institute logo to letterhead.
14. Amend to NTB HDEC as the reviewing ethics committee.
15. Please collect ethnicity data. Collect this information using the New Zealand Census template.

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*).
* Provide further details of safety arrangements, including a list of named clinicians who will be involved to monitor the study for adverse events, real time. Every intervention study should have appropriate oversight of the conduct of the study to ensure the safety of the participants and the integrity and validity of the study data (*Ethical Guidelines for Intervention Studies* *para 6.38)*
* Provide an updated reimbursement figure, with rationale. Amend advertising to focus less on the monetary figure and instead state participants will be reimbursed (*Ethical Guidelines for Intervention Studies* *para* 6.32 – 6.37)

This following information will be reviewed, and a final decision made on the application, by Dr Sarah Gunningham and Raewyn Idoine.

|  |  |  |
| --- | --- | --- |
| **10** | **Ethics ref:** | **15/NTB/156** |
|  | Title: | A research study to find out if the study drug, reslizumab, is safe and can help people with uncontrolled asthma |
|  | Principal Investigator: | Dr Conroy Wong |
|  | Sponsor: | PPD Australia Pty Ltd |
|  | Clock Start Date: | 20 August 2015 |

Dr Conroy Wong and Mrs Catherine Howe were present in person for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. The study will investigate whether a new administration of resilzumab (study drug) is safe and therapeutic for people with uncontrolled asthma.
2. Previous study looks at efficacy of intravenous study drug. The study showed a 50% reduction of inflammation in the lungs, which is a key element of asthma exacerbation.
3. The study drug was found to be very safe.
4. This study will assess subcutaneous delivery of the study drug.
5. The Committee noted HDEC don’t have access to clinical trial agreement. Please confirm no restriction of publication of negative results. The Researcher(s) confirmed there were no restrictions about publication of negative results.

Summary of ethical issues (resolved)

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

1. The Researcher(s) clarified that stating there was no requirement for Māori consultation was an error.
2. R.1.1 – procedures and risks – no risks of study drug itself – in Participant Information Sheet there are only two risks – anaphylaxis and myalgia. The Researcher(s) stated from publish studies there is no difference between placebo and study drug, other than the two raised. 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 asked for more information the data safety monitoring committee arrangements for the study. Have you discussed this aspect of the study with SCOTT? The Researcher(s) explained that there are standard monitoring for studies in place, such as reporting of adverse events as they happen. The Committee noted it was not common for international multi centre studies to not have a safety committee overseeing events. Please follow up the safety monitoring arrangements – HDEC expects some form of data safety monitoring.
2. Please clarify the number of children involved in the 6 cited trials.
3. Please clarify if there are any risks with males fathering children, and risks to unborn children.

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

1. Please add information about the dose of the study drug.
2. Add line between content and footer – it is currently merging.
3. Please make it clear that the study drug is not approved anywhere in the world, including New Zealand.
4. The Committee noted that the assent form was high quality, and requested that the adult Participant Information Sheet was written better as comparatively it was repetitive and confusing.
5. Remove double up (for example, lung function and vital signs). This will reduce number of pages.
6. The Committee recommends the use of a table to reduce duplication.
7. Explain what systemic immunosuppressant are.
8. The Committee queried whether study doctor/site gets reimbursed, or make a profit? Page.16 - make this clear for participants.
9. Quantify risks, for instance fewer than 1-100 rather than less than 1%
10. On last paragraph – bullet point 3 – change to breast-feeding a child from ‘nursing a child’.

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*).
* Provide details of the Data Safety Monitoring Committee’s composition and monitoring plan *(Ethical Guidelines for Intervention Studies para 6.50).*

This following information will be reviewed, and a final decision made on the application, by Dr Devonie Waaka and Mrs Phyllis Huitema.

|  |  |  |
| --- | --- | --- |
| **11** | **Ethics ref:** | **15/NTB/145** |
|  | Title: | A study to evaluate if a new drug is superior to placebo and will result in a longer period without tumour progression in patients with relapsed non-Hodgkins's lymphoma after treatment with standard |
|  | Principal Investigator: | Dr Marie Hughes |
|  | Sponsor: | Bayer New Zealand Limited |
|  | Clock Start Date: | 20 August 2015 |

Taina von Blaramberg was not present by teleconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. The Committee noted the language on anonymisation is very formal.
2. The Committee noted application is of a poor quality.

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 queried what the main differences were between applications 145 and 146.
2. A.1.6 (both studies) states ‘no ethical issues’. The Committee noted this is not acceptable. Please provide an overview of the ethical risks in this study in a cover letter and adequately mitigate them.
3. Is this also an open label extension study application? Please clarify.
4. How many 28-day cycles will there be?
5. P.4.1 – people in clinical trials do better – this is not a fact, Cochrane review has disputed this claim.
6. Please do not call placebo a treatment (PIS title).
7. People on placebo who aren’t responding will be switched to study drug? When?
8. Please reword information on anonymisation to be more acceptable to a lay reader.
9. Add information on Maori views on use of tissue. For instance: 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 Maori 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.
10. The Committee suggest moving contact details to end of the Participant Information Sheet.
11. The Committee queried what parties are referred to (European union on CF).
12. Will Participant Information Sheet and consent form be on letterhead?
13. Please clarify what is happening with human tissue? Particularly with sending it overseas? Is this communicated adequately to participants?
14. Tracked changes not acceptable (Participant Information Sheet) – for future applications please submit final versions.
15. Referring to other state jurisdictions is not acceptable or relevant for New Zealand participants. Please remove these references and make the Participant Information Sheet appropriate for a New Zealand audience.
16. Why did a previous ethics committee decline this application? Please provide a letter explaining the reasons and what has been done to address these concerns.
17. The Committee requested information on prevalence of disease in Maori.

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*).
* Provide further information on the study design, *in particular when participants will receive study drug if on placebo arm* (*Ethical Guidelines for Intervention Studies para* 5.4)
* Investigators should consider the features of a proposed study in light of these ethical considerations, and should then satisfactorily resolve any ethical issues raised by the study. Not all ethical considerations weigh equally (*Ethical Guidelines for Intervention Studies para* 4.2)
* Address outstanding ethical issues.

This following information will be reviewed, and a final decision made on the application, by Ms Kate O’Connor and Ms Raewyn Idoine.

|  |  |  |
| --- | --- | --- |
| **12** | **Ethics ref:** | **15/NTB/146** |
|  | Title: | A study to evaluate if a new drug in combination with rituximab or placebo will result in a longer period without tumour progression in patients with relapsed indolent non-Hodgkins's lymphoma after tr |
|  | Principal Investigator: | Dr Marie Hughes |
|  | Sponsor: | Bayer New Zealand Limited |
|  | Clock Start Date: | 20 August 2015 |

Taina von Blaramberg was present by teleconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. The Committee noted the language on anonymisation is very formal.
2. The Committee noted application is of a poor quality.

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 queried what the main differences were between applications 145 and 146.
2. A.1.6 (both studies) states ‘no ethical issues’. The Committee noted this is not acceptable. Please provide an overview of the ethical risks in this study in a cover letter and adequately mitigate them.
3. Is this also an open label extension study application? Please clarify.
4. How many 28-day cycles will there be?
5. P.4.1 – people in clinical trials do better – this is not a fact, Cochrane review has disputed this claim.
6. Please do not call placebo a treatment (PIS title).
7. People on placebo who aren’t responding will be switched to study drug? When?
8. Please reword information on anonymisation to be more acceptable to a lay reader.
9. Add information on Maori views on use of tissue. For instance: 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 Maori 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.
10. The Committee suggest moving contact details to end of the Participant Information Sheet.
11. The Committee queried what parties are referred to (European Union on CF).
12. Will Participant Information Sheet and consent form be on letterhead?
13. Please clarify what is happening with human tissue? Particularly with sending it overseas? Is this communicated adequately to participants?
14. Tracked changes not acceptable (Participant Information Sheet) – for future applications please submit final versions.
15. Referring to other state jurisdictions is not acceptable or relevant for New Zealand participants. Please remove these references and make the Participant Information Sheet appropriate for a New Zealand audience.
16. Why did a previous ethics committee decline this application? Please provide a letter explaining the reasons and what has been done to address these concerns.
17. The Committee requested information on prevalence of disease in Maori.

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*).
* Provide further information on the study design, *in particular when participants will receive study drug if on placebo arm* (*Ethical Guidelines for Intervention Studies para* 5.4)
* Investigators should consider the features of a proposed study in light of these ethical considerations, and should then satisfactorily resolve any ethical issues raised by the study. Not all ethical considerations weigh equally (*Ethical Guidelines for Intervention Studies para* 4.2)
* Address outstanding ethical issues.

This following information will be reviewed, and a final decision made on the application, by Ms Kate O’Connor and Ms Raewyn Idoine.

## General business

1. The Committee noted the content of the “noting section” of the agenda.
2. Formatting of lay language title – (insert lay title here) not adding ‘Lay title:’
3. Noted that page numbers on agendas would be helpful – check with printer.
4. The Chair reminded the Committee of the date and time of its next scheduled meeting, namely:

|  |  |
| --- | --- |
| **Meeting date:** | 06 October 2015, 12:00pm |
| **Meeting venue:** | Novotel Ellerslie, 72-112 Greenlane Road East, Auckland |

The following members tendered apologies for this meeting.

* Mrs Mali Erick

1. **Problem with Last Minutes**

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

The meeting closed at 5.00pm