|  |  |
| --- | --- |
| **Committee:** | Northern A Health and Disability Ethics Committee |
| **Meeting date:** | 10 March 2015 |
| **Meeting venue:** | Novotel Ellerslie |

|  |  |
| --- | --- |
| **Time** | **Item of business** |
| 1.00pm | Welcome |
| 1.10pm | Confirmation of minutes of meeting of 10 February 2015 |
| 1.30pm | New applications (see over for details) |
|  | i 15/NTA/16  ii 15/NTA/17  iii 15/NTA/18  iv 15/NTA/19  v 15/NTA/21  vi 15/NTA/25  vii 15/NTA/20 |
| 4.25pm | General business:   * Noting section of agenda |
| 4.50pm | Meeting ends |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Member Name** | **Member Category** | **Appointed** | **Term Expires** | **Apologies?** |
| Dr Brian Fergus | Lay (consumer/community perspectives) | 01/07/2012 | 01/07/2015 | Present |
| Ms Susan Buckland | Lay (consumer/community perspectives) | 01/07/2012 | 01/07/2015 | Present |
| Ms Shamim Chagani | Non-lay (health/disability service provision) | 01/07/2012 | 01/07/2015 | Present |
| Mr Kerry Hiini | Lay (consumer/community perspectives) | 01/07/2012 | 01/07/2015 | Apologies |
| Ms Michele Stanton | Lay (the law) | 01/07/2012 | 01/07/2015 | Present |
| Dr Karen Bartholomew | Non-lay (intervention studies) | 01/07/2013 | 01/07/2016 | Present |
| Dr Christine Crooks | Non-lay (intervention studies) | 01/07/2013 | 01/07/2015 | Present |
| Mr Mark Smith | Non-lay (intervention studies) | 01/09/2014 | 01/09/2015 | Present |

## Welcome

The Chair opened the meeting at 1.03pm and welcomed Committee members, noting that apologies had been received from Mr Kerry Hiini.

The Chair noted that the meeting was quorate.

The Committee noted and agreed the agenda for the meeting.

The Committee discussed whether amendments with major changes to the study design should require peer review. The Committee agreed that in these cases, a letter would be send to the CI asking them if they are confident with the safety of the study.

## Confirmation of previous minutes

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

## New applications

|  |  |  |
| --- | --- | --- |
| **1** | **Ethics ref:** | **15/NTA/16** |
|  | Title: | The effect of high protein diets on weight loss and lean muscle mass in patients awaiting bariatric surgery |
|  | Principal Investigator: | Ms Jessica Robinson-de Wit |
|  | Sponsor: | University of Auckland |
|  | Clock Start Date: | 26 February 2015 |

Ms Jessica Robinson-de Wit and Mrs Sarah Mavor 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

* Ms Robinson de-Wit explained that this study will recruit 24 patients who are already booked in for bariatric surgery. Participants will be randomly allocated to one of two groups, either high protein or standard protein. There will be different calorie intakes for male and females. She said that baseline measures of height, weight and body composition will be taken and followed up at eight weeks. Participants will also complete a three day diet diary to demonstrate adherence to the diet.

Summary of ethical issues (resolved)

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

* Ms Robinson de-Wit advised that the main supervisor will be Dr Andrew McCormick.
* The Committee noted that if baseline measures of creatinine and urea are not taken, there will be nothing to compare them with.
* The Committee asked if the three day dietary diary would only be done once and not before participants start the diet. Mrs Mavor explained that it is routine for the dietitian to obtain a diet history before participants begin the weight loss programme. Information collected in the diary will be to check compliance and will not be analysed for macronutrients.
* The Committee asked what would happen if a participant reverts back to old dietary habits after the diet and while waiting for surgery. Mrs Mavor explained that it is generally expected that weight loss is maintained. She said that bariatric surgery patients are generally motivated and that once they achieve the required weight loss, they are put on the surgery waiting list.
* The Committee asked if the researchers would also be doing skinfold as well as circumference measures. Ms Robinson de-Wit advised that they will not measure skin folds because the significant variability in any given individual’s measurements when taken by different people is well- known to researchers. She plans to assess lean and fat mass using bio-impedance scales but has yet to purchase these..
* The Committee asked how participants would be identified. Ms Mavor explained that patients would be recruited from the bariatric clinic. Ms Robinson-de Wit will call patients before their dietician visit and send them forms if they are interested. The Committee noted that it would be good if the consent form could be signed in front of the doctor or dietician.
* Mrs Mavor explained that when patients are referred to the bariatric clinic, they come to a generalised group session which explains the general risks and benefits of bariatric surgery. If patients want to continue with the surgery route, they are then booked in for an individual appointment with a surgeon and given a weight loss goal.
* Mrs Mavor advised she does not anticipate any clinical safety issues with a higher protein diet as this is still less protein than many healthy New Zealanders typically consume.
* The Committee noted that the peer reviewer had expressed concern about the timeframe in terms of achievability of the study as a Masters project. Ms Robinson de-Wit explained that she would be taking baseline measurements along with the follow up at eight weeks and then writing her thesis which is due in September. She explained that data will be then be looked at by Dr McCormick and secondary results would be followed up by a registrar. This needs to be included in PIS.
* The Committee noted that the PIS needs to be clear around what components of the study are for Ms Robinson de-Wit’s Masters. It also needs to be clear that participants will be followed up until the end of the study, even if some elements are not part of the Masters.
* The Committee commended the researcher for a PIS that was short yet readable.
* Ms Robinson de-Wit agreed to include kilojoules in brackets after references to calories as this is what is on standard packaging.

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

* Please remove “we are currently awaiting ethics approval” on page 1 of the PIS.
* Please amend “we have chosen you to participate” to “we are asking you to participate because you are eligible for bariatric surgery” (page 2 of the PIS).
* Please include a statement in the PIS about what parts of the study will be conducted by Ms Robinson de-Wit and what parts by a registrar.
* Please include an email contact for the researcher (page 2 of the PIS).
* Please include the urine test in the PIS, and that the urine test is being done to determine compliance with the diet.
* Please amend “you would be eligible for compensation from ACC” to “you may be eligible for compensation from ACC” (page 3 of the PIS).
* Please review for missing words, grammar and jargon (for example, CMDHB, randomisation).
* Please make it clear what is standard care for participants ie is the comparator diet standard care or not?
* Please include contact details for a nurse specialist who participants can contact if they have any concerns about the diet.
* Please remove “in my first language” (first point of the consent form) as interpreters will not be provided.

Decision

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

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

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

|  |  |  |
| --- | --- | --- |
| **2** | **Ethics ref:** | **15/NTA/17** |
|  | Title: | Microwave ablation of liver tumours |
|  | Principal Investigator: | Dr. Adam Bartlett |
|  | Sponsor: | University of Auckland |
|  | Clock Start Date: | 26 February 2015 |

Dr Peter Swan 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

* Dr Swan explained that while microwave ablation is widely used to treat liver cancer, it is not as good as it could be. He said that for surgery the local recurrence of tumour rate is around 2%, but with microwave ablation it varies from 5 to 20%. Dr Swan explained that these figures vary because there may be a lot more factors than just the type of tumour being operated on that are important in recurrence. This study seeks to identify the factors that are important in microwave ablation, with the aim of allowing microwave ablation to be offered as a first option as an alternative to surgery.

Summary of ethical issues (resolved)

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

* Dr Swan explained that this study will be on patients already scheduled to have a liver resection or liver transplant. This study will involve two experiments on the piece of the liver that is being removed, before it is removed. No ablation will be performed on the piece of the liver left after the operation (the future liver remnant). He said that a surgery technique to stop bloodflow to the area, the Pringle Manoeuvre (PM), will be used during the experiments. This will involve an extra five minutes for the surgery (approximately two minutes extra for each of the experiments). Dr Swan advised that the PM is standard practice for liver operations and is usually performed for 15 minute intervals, several times over the course of a procedure. Some units use the PM selectively while others use it on everyone, and its use may also be determined intraoperatively. He said that there are no known adverse effects from the PM.
* The Committee asked if it was possible that participants could get the PM as part of this study when it would not normally be used on them, which would make this study an intervention. Dr Swan advised that most surgeons would never say that they would not use the Pringle Manoeuvre as it was one of the techniques that may or not be used. He said that there was subset of people who may not get one but this would not be known until they have had surgery.
* Dr Swan advised that the risks of the study were a slightly longer operation for participants.
* Dr Swan advised that there is no difference in outcomes when the PM is used.
* Dr Swan confirmed that patients can get their liver specimen after the experiments back if they want, as they can in usual clinical practice.
* Dr Swan confirmed that all of the liver resection patients would have cancer, while only some of the patients receiving liver transplants would.
* The Committee asked for confirmation on the recruitment process. Dr Swan explained that people having a resection are often identified and booked up to four weeks in advance of their surgery. Dr Swan is in contact with the liver surgeons and consultants and all are aware of the study and have given their permission for their patients to be approached. He said that patients meeting the inclusion and exclusion criteria will be approached, ideally the day before surgery. Dr Swan said it would be emphasised that if people do not want to take part in the study that this will not influence their planned procedure.
* Dr Swan advised that with transplant patients it is not always possible to approach participants the day before for informed consent but it will be either him or Dr Adam Bartlett who does the approaching.

Summary of ethical issues (outstanding)

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

* Please explain why ethnicity is being collected at the end of the PISCF rather than collected from hospital records as all other data is? If this is going to be kept please ensure that the New Zealand Census question 2001 is being used to collect ethnicity data as per the requirements of the *Ethnicity Data Protocols for the Health and Disability Sector*.

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

* Please include in the PIS that participants are scheduled for an operation and the researchers want to test a procedure which will not alter the standard of care. Please also include that there will no therapeutic benefit and that there is not much additional risk.
* Please amend Northern B HDEC to Northern A HDEC.
* Please include that participants can only withdraw up until they are ready to be operated on.
* Please amend “you would be eligible for compensation from ACC” to “you may be eligible for compensation from ACC”.
* Please include information on the study duration and how long participants have to get their samples back.
* Please include in the first paragraph that this study is PhD research for Dr Swan.
* Please remove “after” from the bullet point “I consent to members of the research team having access to my data and/or clinical records, during, or after, the study” (page 2 of the consent form).

Decision

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

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

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

|  |  |  |
| --- | --- | --- |
| **3** | **Ethics ref:** | **15/NTA/18** |
|  | Title: | BARISTa: Biomarkers And Recovery In STroke |
|  | Principal Investigator: | Assoc Prof Cathy Stinear |
|  | Sponsor: | University of Auckland |
|  | Clock Start Date: | 26 February 2015 |

Associate Professor Deborah Young and Dr Suzanne Ackerley 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

* Dr Young explained that this study will take a coordinated approach to collecting blood and urine samples and clinical data of stroke patients. This will allow researcher to use samples to look at biomarkers for predictors of stroke and how participants will recover from a stroke. She said that samples and data will be collected from 100 stroke patients and 50 healthy controls.

Summary of ethical issues (resolved)

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

* The Committee asked for clarification on the consent process. Dr Ackerley advised that stroke patients will be screened and the researchers will determine through interactions with patients whether they can provide informed consent. She said that they work closely with speech and language therapists and provide alternative ways of communication, for example writing rather than verbalising. Dr Ackerley explained that another study she is involved in requires participants to consent for themselves at 72 hours post stroke, but the testing for this study is quite different.
* The Committee asked what proportion of patients would be able to provide consent. Dr Ackerley advised that a large proportion could provide consent.
* The Committee asked how critical it is for the testing to take place within 48 hours. The researchers confirmed that it is important for the biomarkers of interest.
* The Committee discussed the ethical concerns about observational research (particularly biobanking) with patients with reduced ability to consent (even with family assent) and asked what would be the implications of only including patients who are able to consent for themselves. Dr Ackerley noted that it would take away a small group of stroke patients and the group would not be quite as representative. She also noted that palliative stroke patients do not get approached. She agreed they would only recruit participants who were able to consent.
* The Committee noted that data is more likely to be potentially identifiable rather than de-identified and participants should be advised accordingly.

Summary of ethical issues (outstanding)

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

* Please justify the sample size and inclusion of non-stroke patients, particularly as the numbers in the protocol (50:25) are different than in the application (100:50).
* Please provide any questionnaires that non-stroke patients will complete.
* The Committee noted that there needs to be a separate PIS and consent form for biobanking as this raises different ethical issues. The researchers also need to supply the information required for the committee to approve the establishment of a biobank. Please refer to the Guidelines for the Use of Human Tissue for Future Unspecified Research Purposes at http://www.health.govt.nz/publication/guidelines-use-human-tissue-future-unspecified-research-purposes-0 and section 13 of the Standard Operating Procedures for Health and Disability Ethics Committees at <http://ethics.health.govt.nz/operating-procedures> for further information. This should also include information on intellectual property, commercialisation, the process on the death of a donor and whether any incidental and clinically significant findings will be communicated. A suggested template can be found on the HDEC website.
* The committee invites the researchers to consider whether consenting participants for Future Unspecified Use (the separate PISCF) could be done at a late date (eg 3-6 months, at one of the follow ups), as the ethical issues are different and to allow time for informed consent for the patient and their family.

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

* Please remove “in my first language” (first point of the consent form) as interpreters will not be provided.
* Please include information on the six month assessment in the PIS.
* Please remove yes / no boxes on consent forms for those statements that are not truly optional.

Decision

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

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

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

|  |  |  |
| --- | --- | --- |
| **4** | **Ethics ref:** | **15/NTA/19** |
|  | Title: | Study of CTX-4430 in Acne Patients |
|  | Principal Investigator: | Assoc Professor Marius Rademaker |
|  | Sponsor: | Celtaxsys Australia, Pty Ltd |
|  | Clock Start Date: | 26 February 2015 |

Mrs Anneke Marais, Ms Eileen Bisley and Dr Lynda Bluck were present by teleconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

* The researchers explained that this study will look at the safety and efficacy of a drug to treat acne. They confirmed that this drug will not be used to treat Cystic Fibrosis.

Summary of ethical issues (resolved)

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

* The Committee asked why the medication will not be available when the study finishes. The researcher explained that prior to the completion of the study patients will see a dermatologist who will make sure that they are put on another treatment if they require ongoing medication for their acne.
* The Committee asked for clarification on the photography aspect of the study. The researchers explained that some people are self-conscious and do not want to be identified. Participants’ eyes will be covered and they will wear hospital caps in the photos. This will ensure that there is no possibility of identifying participants.
* The Committee noted that there had been no independent peer review. The researchers advised that the protocol had been reviewed by key opinion leaders and agreed to send their comments to the Committee.
* The researchers confirmed that there was no data on the prevalence of acne in Maori.
* The Committee asked if there was any formal arrangement for monitoring safety. The researchers advised that participants will be monitored by a clinical trials coordinator and a registered nurse at the Tristram Clinic in Hamilton. This is a day stay hospital which has emergency equipment and specialists.
* The Committee noted that the study was also taking place in Australia and asked whether ethical approval had been received. The researchers explained that the study had been submitted for ethical approval in Australia at the same time and that the review will take place this week.

Summary of ethical issues (outstanding)

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

* Please clarify why details of the study will not be put on the ANZCTR website.

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

* Please identify the central laboratory in Australia where test samples will be sent, along with the length of time that samples will be kept (page 7 of the PIS).
* Please clarify what blood samples are being kept for (page 7 of the PIS).
* Please make it clear that there will be no benefit to individuals in taking part in this study.
* Please include the possible risks due to changes in cardiac and respiratory function and information on why an ECG is being provided.
* Please include the main inclusion criteria in the PIS.

Decision

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

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

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

|  |  |  |
| --- | --- | --- |
| **5** | **Ethics ref:** | **15/NTA/20** |
|  | Title: | M15-310: A study of Ombitasvir/Paritaprevir/Ritonavir, Dasabuvir and Sofosbuvir with or without RBV in patients with chronic Genotype 1 HCV |
|  | Principal Investigator: | Prof Edward Gane |
|  | Sponsor: | AbbVie Ltd |
|  | Clock Start Date: | 26 February 2015 |

Dr Christian Schwabe and Mrs Carolyn Harris were present by teleconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

* The Committee asked for a brief explanation on the aims of this study. Dr Schwabe explained that this study would look at a combination of antivirals in patients with genotype 1 Hepatitis C virus, with the main aim to find how short the treatment duration could be.
* Dr Schwabe noted that standard treatment duration is currently 12 weeks. If this can be reduced to six or four weeks it will result in a significant cost reduction.

Summary of ethical issues (resolved)

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

* The Committee asked whether there should be an independent DSMB given that this was a phase 3 study of a new medicine. Dr Schwabe explained that sofosbuvir is approved for use in New Zealand and that the three other drugs under review are about to be approved. He said that all drugs are considered to be safe and well tolerated.
* The Committee asked for clarification on the compulsory DNA testing. Dr Schwabe explained that IL28B testing is used to categorise patients into easier and more difficult to treat patients. In the days of interferon and the first generation of antivirals, this testing was a very important predictor of deciding the appropriate treatment regimen and duration.
* Dr Schwabe explained that Professor Gane is usually involved in the development of protocols and sits on the global advisory board for AbbVie.
* The Committee were concerned about the lack of independence in the study around safety monitoring. Dr Schwabe explained that the main component is whether patients will relapse and the protocol has stringent criteria around this. If more than one patient in the first cohort relapses, they will not move onto the next cohort. He said that there is a lot of trust in the sites to provide good data. Dr Schwabe noted that if there is a very stringent stopping criteria in the protocol, the safety monitoring becomes a little less critical.
* The Committee asked if an independent person reviews data at any point in the study after researchers get results. Dr Schwabe advised that there are teleconferences involving the Principal Investigator and medical monitors and there is close real time monitoring of the studies. He confirmed that the medical monitor works for AbbVie.
* The Committee commended the researchers for the inclusion of a separate PIS for future unspecified research.
* The Committee commended the researchers for the paragraph in the PIS on cultural issues which they considered to be the best they had seen.
* The Committee asked for clarification on restrictions on publication (B.4.3). Dr Schwabe explained that once the sponsor makes the initial presentation, the investigator can send an abstract to the sponsor. He said that the sponsor wants to be aware of what data will be disseminated and that there is no suggestion that the sponsor will veto this abstract.
* The Committee asked for clarification on what was meant by absolute confidentiality cannot be guaranteed (page 21 of the PIS). Mrs Harris explained that while everything is done to maintain confidentiality, such as coding data by initials and date of birth, there is the small possibility that this may not be case in countries with slightly different laws.
* Dr Schwabe confirmed that Professor Gane is the main contact if participants have any concerns and that participants get a card which has his mobile number on it.
* The Committee asked if the researcher anticipated any changes to the study design. Dr Schwabe advised that it was hard to predict what is going to happen to this study or whether the sponsor will change the study design.

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

* Please review for American spelling and references.
* Please clarify or remove reference to paying study doctor (page 1 of the optional sub-study PIS).
* Please include that New Zealand HDEC review won’t happen if samples are sent overseas and include information on intellectual property (optional sub-study PIS).
* The Committee noted that the tone of the PIS is weighted in the direction of protecting the sponsor as opposed to informing the participant. Please review and consider more user friendly language, remove jargon, abbreviations and repetition and include cohorts as a diagram.
* Please be clear about what the future blood samples will be used for (section 10, page 19 of the PIS) and if this is distinct from the optional study then clarify this here, and include where samples will be sent and how long they will be kept for.

Decision

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

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

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

|  |  |  |
| --- | --- | --- |
| **6** | **Ethics ref:** | **15/NTA/21** |
|  | Title: | NiPPeR |
|  | Principal Investigator: | Professor Philip Baker |
|  | Sponsor: | Auckland UniServices Limited |
|  | Clock Start Date: | 26 February 2015 |

Professor Philip Baker and Associate Professor Timothy Kenealy 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

* Professor Baker explained that as an obstetrician, the challenge for him is that pregnancy outcomes of pre-term birth, pre-eclampsia and gestational diabetes are not improving. He said that the optimal time for improving these outcomes is pre-pregnancy or early pregnancy.
* This study will begin a nutritional intervention before pregnancy to improve outcomes. Professor Baker said the aim of the study is to improve glycaemic control in pregnancy. He said that there is nothing in the nutritional supplement that has any clinical risk for the baby and he is comfortable with the doses that will be used.
* Professor Baker noted that the ethical challenge is the burden on the participant.

Summary of ethical issues (resolved)

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

* The Committee noted that this study had a long duration and is asking a big commitment from the mother and father. Professor Baker explained that this is a unique cohort and there is a massive impetus to continue following it up. He said that all of the principal investigators have done long term follow up studies in different jurisdictions and have experience of retaining participants. He noted that some of these studies under represented vulnerable groups and wants this study to represent minority groups appropriately. He noted that retention will be a big deal and that there are techniques and strategies for enhancing retention.
* In terms of sample management Professor Baker noted that the researchers will be working with a Swedish company, which will individually bar code every aliquot and link it to a data set. This will allow every aliquot to be tracked.
* Professor Baker noted that this study is funded from a combination of commercial and public funding.
* Professor Baker advised that he had discussed the power calculations with several statisticians who had convinced him that the calculations were reasonable and that they would show the minimum effect that the study is powered to detect. Professor Baker noted that on the basis of the literature, he would expect larger changes in glucose control.
* The Committee asked for clarification on Professor Peacock’s comments on the peer review around powering for neo-natal outcomes. Professor Baker provided a document justifying this and the Committee confirmed they were happy with the power calculations.
* The Committee asked how realistic it was for women to take the drink twice a day.
* Professor Baker noted that as researchers they are not allowed to taste the product but it has gone through various tasting trials. He said that the product is provided in sachets and mixes up to a glass.
* The Committee asked what impact this study will have on usual pregnancy care for women. Professor Baker explained that each woman will have their own LMC. He said that he has discussed the study with midwives who are supportive.
* The Committee asked if there will be additional ultrasounds for women. Professor Baker advised that there will be. The Committee asked whether it would be required for women to have a nuchal scan and an anatomy scan as women currently go through an informed consent process with their GP or LMC to choose whether or not to have these screening tests. Professor Baker advised that they would require this. It was agreed that this would be included in the PIS. In addition dating scans and the growth scans in the study are not usual care, this will also need to be clarified in the PIS, and could the investigators please confirm that the women will not be paying for any of these additional scans. Associate Professor Kenealy advised that the questionnaires are nearly complete and are having minor amendments made to make it suitable for a New Zealand audience. He said that the post pregnancy questionnaires will be finalised before the first participants are recruited. Please ensure study IDs are on questionnaires and not names.
* The Committee asked how participants will get the product. Associate Professor Kenealy said that this was not yet finalised but it was though that it would be delivered to women’s homes.
* Professor Baker advised that the protocol has been revised based on the peer reviewers’ comments.
* The Committee noted that there needs to be a separate PIS and consent form, as well as additional information provided to the committee, for future unspecified research as this has different legal, ethical and cultural risks. Please refer to the Guidelines for the Use of Human Tissue for Future Unspecified Research Purposes at <http://www.health.govt.nz/publication/guidelines-use-human-tissue-future-unspecified-research-purposes-0> and section 13 of the Standard Operating Procedures for Health and Disability Ethics Committees at <http://ethics.health.govt.nz/operating-procedures> for further information. A suggested template can be found on the HDEC website.
* Please remove the reference in the pamphlet to the UK site being sponsored by the University of Auckland.

Summary of ethical issues (outstanding)

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

* Please provide further information on how appropriate priority group representation will be ensured given that the primary outcome condition of interest has a higher prevalence in Maori, Pacific and Asian women, and part of the ethical imperative is ensuring that research has relevance and benefit to those women.
* The Committee noted that the PIS assumes that participants are heterosexual, please review the wording.

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

* Please include at the start of the PIS that a primary outcome is the 28 week glucose level.
* Please clarify if any of the elements of the study are optional.
* Please remove reference to having more scans being a benefit.
* Please make it clear to participants in the PIS that hair will be cut and not pulled out.
* Please provide more information on reimbursement.
* Please include more information on the possible longitudinal nature of the study.
* Please include that participants’ LMC will also informed that they are taking part in the study (page 5 of the PIS mentions GP and doctor but not LMC).

Decision

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

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

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

|  |  |  |
| --- | --- | --- |
| **7** | **Ethics ref:** | **15/NTA/25** |
|  | Title: | Observational study of microangiopathy |
|  | Principal Investigator: | Dr Mark Smith |
|  | Sponsor: | CDHB |
|  | Clock Start Date: | 26 February 2015 |

No researchers were present for discussion of this application.

Potential conflicts of interest

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

Dr Christine Crooks declared a potential conflict of interest, and the Committee decided that she would not take part in the discussion.

Summary of Study

* The Committee noted that the aim of the study is to establish a biobank in Australia for 30 people with the rare condition microangiopathy. Six samples will be provided from New Zealand.
* The Committee noted that there would be no individual benefit to participants.

Summary of ethical issues (resolved)

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

* The Committee noted that for clarity to participants there should only be one PIS as the biobanking is not optional, and is in fact the purpose of the research – in this case separating the consents has the potential to confuse participants.
* The Committee noted that given the rarity of the condition, that participants may be potentially identifiable, and this possibility should be included in the PIS.
* The Committee noted that there was better information on the PIS for genetic samples. They also noted that the withdrawal conditions were different for each PIS.
* The Committee noted the last sentence on page 3 of the PIS for genetic samples “If you withdraw or discontinue from the study…unless you specifically ask that they be destroyed” should be removed. Participants have the right to withdraw from the study (including withdrawal and destruction of their samples) without additional impediment that this statement implies.

Summary of ethical issues (outstanding)

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

* The Committee were concerned about wording in the application that suggested consent would be sought from vulnerable people who may not be able to consent for themselves (mention of family consent/assent, and the possibility of children). Could the investigators please explain this further and if this is then case then a strong justification on why this would be required.

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

* Please combine the two PIS and make it clear that biobanking is not optional. Please also provide to the committee more detail on the elements required by the Standard Operating Procedures to approve the establishment of a biobank. Please refer to the Guidelines for the Use of Human Tissue for Future Unspecified Research Purposes at <http://www.health.govt.nz/publication/guidelines-use-human-tissue-future-unspecified-research-purposes-0> and section 13 of the Standard Operating Procedures for Health and Disability Ethics Committees at <http://ethics.health.govt.nz/operating-procedures> for further details on the information to be included. This should include information on whether there is any commercial involvement, what the management of clinically significant and incidental findings will be, the process on death of a donor, and the actual withdrawal given that the samples will be stored outside of New Zealand. A suggested template can be found on the HDEC website.
* Please include information on how confidentiality, privacy, informational and cultural risks will be managed.
* Please clarify what the medical records are (page 2 of the main PIS).
* Please review PIS for jargon and include language for a lay audience.
* Please include Maori cultural support, a New Zealand contact for withdrawal and HDC advocacy contact details.
* Please clarify the sentence “you will not have any claim to the DNA…” (page 2 of the PIS).

Decision

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

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

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

## 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:** | 14 April 2015, 08:00 AM |
| **Meeting venue:** | Novotel Ellerslie, 72-112 Greenlane Rd East, Ellerslie, Auckland |

No members tendered apologies for this meeting.

The meeting closed at 4.50pm.