|  |  |
| --- | --- |
| **Committee:** | Northern B Health and Disability Ethics Committee |
| **Meeting date:** | 07 August 2018 |
| **Meeting venue:** | Novotel Ellerslie, 72-112 Greenlane Road East, Ellerslie, Auckland |

|  |  |
| --- | --- |
| **Time** | **Item of business** |
| 12:00pm | Welcome |
| 12:05pm | Confirmation of minutes of meeting of 03 July 2018 |
|  | New applications (see over for details) |
|  | i 18/NTB/118 **CLOSED**  ii 18/NTB/120  iii 18/NTB/124 **CLOSED**  iv 18/NTB/126  v 18/NTB/127  vi 18/NTB/129  vii 18/NTB/130  viii 18/NTB/133  ix 18/NTB/134  x 18/NTB/136  xi 18/NTB/137 |
| 6:00pm | General business:  Noting section of agenda |
| 6:05pm | Meeting ends |

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

## Welcome

The Chair opened the meeting at 12.30pm and welcomed Committee members, noting that apologies had been received from Mrs Jane Wylie and Dr Nora Lynch.

The Chair noted that it would be necessary to co-opt members of other HDECs in accordance with the Standard Operating Procedures. Dr Patries Herst confirmed her eligibility, and was co-opted by the Chair as members of the Committee for the duration of the meeting.

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 03 July 2018 were confirmed.

## New applications

|  |  |  |  |
| --- | --- | --- | --- |
| **1** | **Ethics ref:** | **18/NTB/118** **CLOSED** |  |
|  | Title: | Efficacy and safety of intravenous neridronic acid in CRPS |  |
|  | Principal Investigator: | Dr Barney Montgomery |  |
|  | Sponsor: | INC Research New Zealand Limited |  |
|  | Clock Start Date: | 26 July 2018 |  |

Dr Barney Montgomery (CI), Ms Dee Yang (PC) and Dr Wei Chung Tong (Co-Investigator) 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.

The Committee acknowledged the request for a closed meeting and confirmed that only members and secretariat support were in the room.

Decision

This application was *provisionally approved* by consensus.

|  |  |  |  |
| --- | --- | --- | --- |
| **2** | **Ethics ref:** | **18/NTB/120** |  |
|  | Title: | The CRYSTAL Study |  |
|  | Principal Investigator: | Dr Jim Stewart |  |
|  | Sponsor: | Micell Technologies |  |
|  | Clock Start Date: | 26 July 2018 |  |

Dr Jim Stewart (CI) ,Ms Robin Clarke (PC) and Mandy Fish (Research Co-ordinator) 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 MiStent is a metal alloy drug-eluting stent. It uses a bioabsorbable polymer to bind the drug to the stent and allows for the slow release of the drug into the lining of the artery wall.
2. The MiStent has been assessed in previous research studies. This research study compares the MiStent with two commercially available drug-eluting stent families - Xience and Promus. The study design tests the non-inferiority of MiStent to these two commercially available stents.
3. This is a randomised controlled trial and participants will be blinded to what stent they receive. All participants will be followed up for five years after stent implant.

Summary of ethical issues (resolved)

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

1. The Committee commended the Researcher(s) on their application. They found the submission to be straightforward and appreciated that.
2. The Committee recommended that the Researcher(s) reflect on what ethical issues they would face when conducting this study for example, management of data, protecting rights and interests of participants, informed consent.
3. The Committee noted that this study device was involved in two earlier trials, Dessolve I and Dessolve II. The Committee questioned why, following those trials, the device became available in Europe but not in New Zealand. The Researcher(s) believed this to be related to profitability.
4. The Committee questioned why the device was being brought back to New Zealand. Was there a difference in the device this time around? The Researcher(s) responded that to the best of their knowledge there is no real change and advised that this device trial was being run now to gain experience in a randomised controlled way against the standard stents.
5. The Committee queried if the Xience and Promus stents would be available to cardiologists in the standard care setting. The Researcher (s) confirmed that they would and it would be for the cardiologist to decide which one to use.
6. The Researcher (s) indicated that this study has not received ethical approval in other countries. New Zealand was going to be the first location for ethical approval. The study will be run out of three sites in New Zealand.
7. The Committee questioned how the Researcher(s) would mitigate any conflict of interests in the conduct of this study. The Researcher(s) advised that they did not foresee any as the choice for participation or not, should be straightforward. The Researcher(s) informed that none of the study team would gain financially from being involved in the study. The Committee requested that it be made clear in the PIS that regardless of choice to participate or not, participants’ standard care/treatment would not be affected in anyway.
8. The Committee questioned how consenting would be done. Where will it be and if participants would be given enough time to consider study information before providing consent? The Researcher(s) explained potential participants would be approached when they came into hospital for their standard of care angiogram appointment. The Clinical team would explain the angiogram procedure then the Research team would step in and introduce the study. The Researcher(s) acknowledged that in most situations participants would not have considerable time in which to consider the study information. There would be some patients who would have overnight to consider the study facts as their angiogram procedure would be done the day after. Others, relatively shorter times as their angiogram procedures would be done the same day.
9. The Committee requested that the acutely unwell, those that have confounding complicated factors and those whose competency may be questionable are excluded from recruitment.
10. The Committee questioned the form that data would be stored in. The Committee requested that data be stored in a de-identified form and linked to a study number for re-identification purpose when needed.

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 requested that evidence of Maori consultation be submitted for record purpose once completed.

The Committee requested the following changes to the Participant Information Sheet and Consent Form (PIS/CF):

1. It be made clear in the PIS that regardless of choice to participate or not, participants’ standard care/treatment would not be affected in anyway.
2. Please re-word the names of the groups in the line, “treatment versus control” (page 2) to “new versus standard”. Using treatment and control makes it sound like the MiStent will treat but the other stents will not.
3. The Committee questioned the participant payments being made. The Researcher(s) informed that payments will be made at the two follow up visits. They will be for travel cost and accommodation. The Committee requested that the PIS was clear about this and to ensure that there was no confusion that payments would not include for time.
4. Please include information that participants have the right to access and correct their data.
5. Please remove the last reason for stopping the study (last bullet point at the bottom of page 5).A study cannot be stopped purely for commercial interests. (NEAC Guidelines for Intervention Studies, paragraph 6.65).
6. The Committee noted the Consent Form includes a statement about notifying participants’ GPs should abnormal findings come to light. This however, has not been noted in the PIS. Please correct this. Additionally, is informing GPs of abnormal findings really optional? If not, please remove the yes/no options from this statement, in the Consent Form.
7. Please include where participant data will be stored.
8. Please add the sponsor’s address to the PIS and review the PIS to ensure New Zealand spelling rather than US.
9. The PIS to clearly state the difference in risk between the MiStent and the standard of care stents and should there be none, this should still be stated. Please also include the point of differences between the MiStent and the standard of care stents.

Decision

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

* Confirmation of Maori consultation approval (Ethical Guidelines Observational Studies, para 4.3)
* 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*).

|  |  |  |  |
| --- | --- | --- | --- |
| **3** | **Ethics ref:** | **18/NTB/124** **CLOSED** |  |
|  | Title: | NHFO2: 6 Minute Walk Study |  |
|  | Principal Investigator: | Dr James Harper |  |
|  | Sponsor: | Fisher & Paykel Healthcare Limited |  |
|  | Clock Start Date: | 26 July 2018 |  |

Dr James Harper (CI) and Irene Braithwaite 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.

The Committee acknowledged request for closed hearing and confirmed that only members and secretariat were in the room.

Decision

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

|  |  |  |  |
| --- | --- | --- | --- |
| **4** | **Ethics ref:** | **18/NTB/126** |  |
|  | Title: | Tuberculosis infection in Māori |  |
|  | Principal Investigator: | Professor Philip Hill |  |
|  | Sponsor: |  |  |
|  | Clock Start Date: | 26 July 2018 |  |

Professor Philip Hill 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. Prevalence study of latent tuberculosis infection in Maori in the Waikato region 750 Maori only participants from randomised selection of Statistics New Zealand Waikato mesh blocks, prison (Springhill), hospital visitor lists and from marae/hapu .
2. Primary objective is to "assess whether it is feasible to conduct a large representative tuberculin skin test (TST) survey for latent tuberculosis infection (LTBI), with appropriate investigation for tuberculosis (TB) disease in those who are TST positive, in urban and rural Maori people in NZ".
3. Questionnaire and TST - follow up cohort (TST positive) chest x-rays and referrals to clinical review for those with symptoms/positive or abnormal diagnosis via X-rays for all ages > 1.
4. It is thought that some of these TB cases occurring are not necessarily part of an ongoing outbreak (that some have described) but rather pockets of re-activation that cause isolated outbreaks.
5. Maori incidence of TB account for half of NZ’s domestic incidents.

An analysis was done using sequencing TB grown from the Maori population and the group of strain found was common to the colonial source that is found in Native American Indians and Native Canadian Indians. This strain did not come in with immigration.

1. Found very little effect of the immigration strain of TB on Maori because Maori do not tend to mix closely with immigrants. The TB strain in Maori were those found in the colonial period.
2. It is believed that these colonial period strains will be susceptible to antibiotics as they are a generation that developed prior to the introduction of antibiotics to New Zealand.

Summary of ethical issues (resolved)

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

1. The Committee stated that they understood this to be a feasibility study. The Researcher confirmed that it is a large feasibility study. The Researcher aims to have a reasonable representation of various age groups.
2. The Committee appreciated the idea of the study and acknowledged that it would be useful.

The Committee requested an explanation of the recruitment approach, in particular the cohort of participants. The Committee also wanted to know more about the mesh block approach and the reason for its use.

The Researcher explained that the mesh block approach had been used for the Maori Health Survey in the past and was refined for the New Zealand Health Survey.

The mesh block approach is a complicated way of getting representative sample from community survey. It uses pre-defined mesh blocks which are around 100 individuals/40-70 households all in the same geographical area. A process is then needed to identify Maori within these.

1. The Committee questioned what would be done if a large number of households refused to take part.

The Researcher stated the feasibility assessment would help to determine if this would be the case.

The research team are encouraged by the rates of acceptance in the ongoing National Health Survey and the Maori focused Mental Health Survey done earlier and advised that there is a parallel process to engage Maori in Waikato. This looks to get Maori views on presentation of information to prospective participants so it is received in a way that does not alienate them from wanting to participate due to poor quality of information given and how it is presented.

The Committee expressed support for this parallel process and thought it was a very good idea.

1. The Committee questioned if using the mesh block approach would exclude people who are not at home/do not live at home.

The Researcher explained that they will apply their standard process for going back and forth up to a certain number of times to try and catch occupants at home.

It is proposed that an alternative strategy also be considered as the population targeted can be transient, tend to not live in a home or move around a lot. The Researcher will apply the hui approach as a means to engage with Maori and to find ways to locate and ask them to take part.

1. The Committee queried how the rights of prisoners are supported by their inclusion and how their participation in the research is justified.

The Researcher explained that from a global perspective, prisons are a hot bed for TB but that they did not expect this to be so in New Zealand. However, the New Zealand TB guidelines does have a specific chapter covering prison populations. Maori have a relatively high representation in prisons, especially young Maori and it would be remiss of any TB study to not consider the prison population though it is not expected that prisoners will have a huge positivity rate.

1. The Committee questioned how the operational components of the study would be managed in the prison environment for example, how prisoners will be selected, where they will be seen, how they will be transported to clinic visits, what resources will be available to allow this to be done and how the safety of prisoners will be ensured once they are a part of the study.

The Researcher responded that they will work with Corrections. A clinic will be based in the prison for those who meet the criteria for being more clinically assessed and ex-rays and other hospital engagements will follow the protocol of prison staff and system for ensuring prisoner safety.

To focus on this safety, the research team plan to recruit in two batches that is, the first having half the recruited prisoners and the second the other half so if a high rate of infection is found in the first batch then the second batch will not be recruited

Corrections do not expect the research team to arrange security services to accompany prisoners and will be responsible for transport to and fro outside the prison, if needed. Corrections will also be responsible for the security of both prisoners and researchers whilst the study is conducted in the prison.

1. The Committee questioned if the rest of the prison population would also be screened in order to treat should a high rate of latent TB be found.

The Researcher stated that this is to be discussed with Corrections. One of things seen with recent outbreak investigations, the last in Gore, was the difficulty in forming boundaries of who should be investigated as contact. As investigations got further away from contact they were still getting positive testing for infection. As a result the researcher thought it may be better to engage the “reservoir of latent infection” as there is no easy answer for when to stop investigations

The Committee felt that the feasibility approach would be good to try and it could identify some of these issues.

1. The Committee raised the point that prisoners may have low literacy rates and asked that this be considered when providing them with information. Please ensure the information will be easily understood, especially if they want to take part.

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 requested that the sponsor of the study be identified.
2. The Committee advised that ethnicity information is collected to iwi level as this would be useful for analysis.
3. The Committee questioned how “household” is defined and wanted to know how it is decided who is the head of the household. Would this person be the person that opens the door, the oldest male/oldest female? Are they self-identifying? Please clearly outline how you manage this interaction and who that person will be and what you will do if some household want to participate and some do not. Also what you will do if it is mix ethnicity family (eg, dad and children are Maori and mum identifies as New Zealand European – does it count as Maori household?)
4. .The Committee emphasised that in research in New Zealand one person cannot decide for another person whether they take part in research. The Committee requested that the recruiting process in households is thought through properly as there is a definite ethical issue when one person determines whether access is allowed to their household in order to request study participation from the household.

The Committee asked for details of the recruitment and individual consent approach for the households

1. The Committee queried how ‘visitors to hospital’ would be recruited.

The Researcher stated this group was decided after consultation with Te Puna Oranga, Waikato. It would be additional to the mesh block method of recruiting (as this alone may not be sufficient). It is hoped that it will provide access to Maori that will not be picked up by mesh block method. The research team would identify Maori in-patients and put a process in place where they would consult staff looking after them on the appropriateness of approaching their visiting relatives. If it is decided that it is alright then the research team will apply the process outlined in the protocol.

1. The Committee appreciated that this recruitment process was decided following consultation but wanted the approach to be more clearly detailed. The Researcher should consider how a visitor will be approached given the first conversation with them will be “we are only looking for Maori participants and you are visiting someone who is Maori but you may or may not be Maori.”

The Committee are worried about the use of visitors in hospital as they are not there for treatment, are not patients but are visiting their whanau and may be focused on this rather than other things and unless they are approached to be part of research around ‘visiting patients in hospital’, it is unusual to use this cohort for research on another topic. This second degree of association should be approached in a way that is sympathetic.

The Committee understands that it can be very hard to get a population view and that it is challenging to recruit in this population but question the appropriateness of using this group of people in terms of their expectations of what will happen to them when visiting whanau in hospital.

1. The Committee requested that children and young adults be provided with Assent and Consent forms. These should use simplified and age appropriate language. These forms should have a set for 12-15 years olds and 7-11 year olds and the consent forms should be completed by their parent/guardian.
2. The Committee noted that the Hapu, Iwi and Marae settings will be critical to recruiting and will be important stake holders for the research. The Committee saw this as a good opportunity to establishing strong connections.

The Researcher advised that the process for recruitment will remain the same and the process for finding recruits will be driven by consultation. The Researcher planned to undertake consultation with this group and provide the outcome to HDECs.

The Committee requested the specifics for how this would occur.

.The Committee were concerned that those on the Iwi list would be worried about how their details would be spoken about and used and urged the Researcher to consider this.

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

1. The Committee requested that the option for withdrawal be stated in the PIS section. It must be voluntary and should state that participants can withdraw verbally. Written notification is not needed should a participant want to withdraw from research.

Decision

This application was *declined* by consensus, as the Committee did not consider that the study

would meet the following ethical standards.

* Investigators should identify perceived, potential or actual conflict of interest they may have in relation to any others involved in the study. Such conflicts of interest can compromise the design or conduct of a study or the reliability of its results, thereby exposing the study participants or others to needless risk or inconvenience.*(Observational Studies, paragraph 4.18)*
* The definition of ‘household’ and how recruitment is made as well as the protection of rights and interests of participants requires more thought (*Observational Studies, section 5*)
* Suitable information sheets and assent forms are required (*Observational Studies, paragraph 6.21*) This includes an information sheet and consent form for participants able to provide their own informed consent (this includes all participants aged 16 years or older and may include some younger participants if they are deemed competent), an information sheet and assent for children, and a very simple information sheet and assent form for young children that should very simply explain their participation in the study. Guidance on assent can be found at <http://ethics.health.govt.nz/guidance-materials/assent-guidance>.
* Issues relating to Māori cultural and ethical values should be addressed in discussion with Māori concerned (*Ethical Guidelines for Observation Studies* 4.4)

The Committee suggests that the response to this decline decision is submitted for Northern B HDEC’s attention. Please submit your response in line with a Northern B HDEC meeting.

The Committee suggests that your study is done in two part. First, focus on the Kaupapa Maori research around consultation which can inform the feasibility study. This can be a small piece of research around 3 months. Document all focus groups, consultations, conversations had and how the protocol has been altered.

Two, conduct the investigation and population feasibility study.

|  |  |  |  |
| --- | --- | --- | --- |
| ***5*** | ***Ethics ref:*** | ***18/NTB/127*** |  |
|  | *Title:* | *Peripartum depression, olfaction, and eating behaviour* |  |
|  | *Principal Investigator:* | *Dr Mei Peng* |  |
|  | *Sponsor:* | *University of Otago* |  |
|  | *Clock Start Date:* | *26 July 2018* |  |

*Dr Mei Peng and Hazel Potterton (Co-Investigator) 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 if there is a causation relationship between olfactory changes in pregnant women and peripartum depression.*
2. *There is not much research looking at olfactory changes in women experiencing peripartum depression.*
3. *Understanding olfactory function changes in peripartum women is important as this function is vital for food intake, choice and quality of life.*
4. *Declines in olfactory function can lead to poor appetite and poor nutrition state which is concerning for peripartum women and newborns.*

*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 favourable peer review submitted and acknowledged that the Researcher(s) had addressed concerns raised. There was one point that was not too clear. Were the recruitment of controls and depressed being done simultaneously?*

*The Researcher(s) confirmed that following peer review, they would recruit these two groups simultaneously.*

1. *The Committee were concerned about the wellbeing of participants should they become really depressed during the study. Will there be appropriate staff on hand to address this should it arise? The Researcher(s) reported that a psychiatric liaison nurse would be available to them if needed. The Committee indicated that it may be a good idea to also consult with the Otago Medical School on this issue. The Researcher(s) stated that they would keep an eye on participants during de-briefs at the end of each session and would make sure participants were made aware of mental health services they could access.*

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 advised that data collected for the study be held in a potentially identifiable form where it is allocated a study ID/number and linked to a code (refer Ethical Guidelines Observational Studies, paragraph 6.4, page 13: <https://neac.health.govt.nz/streamlined-ethical-guidelines-health-and-disability-research> )
2. The Committee requested protocols be prepared for staff making home visits. The protocols should cover safety and Tikanga Maori concepts during home visits. These would be a good template for future studies.
3. The Committee recommended not using the signage “Peripartum Depression Study” when providing directions to the testing sessions. This would help to manage stigma. Please reconsider the wording used on this signage.

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

1. Please include contact details for Maori support and independent health and disability health advocate (see HDEC PIS template at <https://ethics.health.govt.nz/> ).
2. Please explain the term peripartum.
3. The Committee noted a reference to New World vouchers and suggested that New World is not mentioned as it sounds like New World is being marketed. This can be replaced with the term, “grocery voucher” The Committee suggested that grocery vouchers also be offered in the first visit in case participants do not come back to the second.
4. The Researcher(s) confirmed that participants’ GPs would be notified of their attendance in the study. Please add this information to the PIS and a line in the CF indicating the same. This line can either indicate GP notification to be optional therefore yes/no tick box is include otherwise this line can indicate GP option is compulsory so a yes/no tick box will not be needed.
5. The Committee were concerned that risks to taking part were not mentioned. Please list these. Please access the HDEC PIS template for guidance (<https://ethics.health.govt.nz/> )
6. Please add the exclusion criteria as outlined in the protocol for example, no asthmatics, no suffers of allergies affecting breathing and smell.
7. Health Information should be retained for a minimum period of 10 years (Health (Retention of Health Information) Regulations 1996). Please ensure this is clear in your documentation.
8. Please indicate that extra support such as a psychiatric liaison nurse will be available during the study and include contact details for mental health services to the contact section of the PIS.
9. The Committee questioned why asthmatics were being excluded from the study. Was it because the smell sticks could trigger an asthma attack? The Researcher(s) confirmed this to be the case. The Committee requested the addition of the exclusion criteria to the PIS as outlined in the protocol. Participants could also be asked to not wear perfume when attending study visits.

Decision

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

* Please ensure participant identity is protected (*Ethical Guidelines Observational Studies, paragraph 6.4, page 13*)
* Please provide protocols for the staff making home visits that cover safety and Tikanga Maori visits *(Ethical Guidelines for Observational Studies, para 5.11)*
* Please do not use the words ‘Peripartum Depression Study’ when providing directions to the testing sessions. Please reconsider the wording. *(Ethical Guidelines for Observational Studies, para 4.9)*
* Please amend the information sheet and consent form, taking into account the suggestions made by the Committee (*Ethical Guidelines for Intervention Studies* *para 6.22*).

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

|  |  |  |  |
| --- | --- | --- | --- |
| **6** | **Ethics ref:** | **18/NTB/129** |  |
|  | Title: | Eye disease in Obstructive Sleep Apnoea |  |
|  | Principal Investigator: | Dr Rasha Al-Taie |  |
|  | Sponsor: |  |  |
|  | Clock Start Date: | 26 July 2018 |  |

Dr Rasha Al-Taie (Co-ordinating Investigator) and Dr Lucy Lu (Primary Contact) were 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. Study of whether persons (aged 7+) who are diagnosed with Obstructive Sleep Apnea have a higher rate of a specific eye problem.
2. Respiratory doctors who diagnose OSA will refer patients to the study which involves one short visit to the eye clinic at Manukau. If eye problem detected then referral for further treatment will be made (early treatment is very desirable).

Summary of resolved ethical issues

1. The Committee noted that Maori are overrepresented in OSA and both Maori and Pasifika peoples tend to present with more severe forms of OSA. Please consider fair representation of Maori and Pasifika people in your recruiting targets.

Summary of ethical issues (outstanding)

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

1. Please identify the sponsor of this study.
2. The Committee found the submitted documentation to be inadequate for children. There needs to be two children assent forms (7-11 year olds and 12-15year olds). For more information please refer to the Assent Form instructions and checklist document at <https://ethics.health.govt.nz/guides-templates-forms-0> .
3. The Committee suggests when preparing Assent forms for the younger children to include some fun pictures that will appeal to the children and make them more age appropriate.
4. The Committee noted the absence of a Parent/Guardian Participant Information Sheet/Consent Form. This is to provide information on the study to parents/guardians of child participants and obtain their permission for their child to participate. Please provide a copy for the Committee to review.
5. Please provide petrol vouchers for parents for transporting their children to the study site.
6. Please consider a koha for the children to acknowledge their willingness to take part.
7. Please consider Tikanga Maori concepts when conducting this study for example, touching of heads.
8. Please ensure Maori consultation is made. The only time consultation is not necessary is if Maori are not expected to take part in the study.

The Committee questioned how the Researcher(s) would deal with abnormal findings when and if these are found.

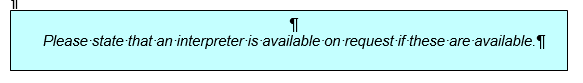
1. The Committee queried if participant GPs would be notified of abnormal findings.

Participants should be informed of the process followed by the research team should abnormal findings be made.

1. Please use the HDEC PIS/CF template as found at <https://ethics.health.govt.nz/home> under the Quick Links section.

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

1. Please include the line “Before you decide you may want to talk about the study with other people, such as family, whānau, friends, or healthcare providers. Feel free to do this.”
2. Please only include the yes/no options against the statements found in the 7-15 year old assent form if they are truly optional (ie,should participants circle “no” they can still take part in the study). Please also ensure these statements are relevant.
3. Please add the following interpreter option to the top of your Consent Forms.

Decision

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

* Please provide suitable information sheets and assent forms. This includes an information sheet and consent form for parents of participants unable to provide informed consent, an information sheet and consent form for participants able to provide their owned informed consent (this includes all participants aged 16 years or older and may include some younger participant if they are deemed competent), an information sheet and assent form for children, and a very simple information sheet and assent form for young children that should very simply explain their participation in the study *(Ethical Guidelines for Intervention Studies, para 6.22).*
* Please ensure Maori consultation is made ( *Ethical Guidelines for Observational Studies, para 4.3*)
* Please consider payments for costs involved in taking part (eg,petrol, parking, travel) and acknowledgement of wiliness to participate (*Ethical Guidelines for Interventional Studies, para 6.34*)
* Please amend the information sheet and consent forms, taking into account the suggestions made by the committee (*Ethical Guideline for Observational Studies, para 6.10*).

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

|  |  |  |  |
| --- | --- | --- | --- |
| **7** | **Ethics ref:** | **18/NTB/130** |  |
|  | Title: | Otoacoustic emissions as a potential hearing screen for preschool children. |  |
|  | Principal Investigator: | Dr Pat Tuohy |  |
|  | Sponsor: | Ministry of Health |  |
|  | Clock Start Date: | 26 July 2018 |  |

Dr Emma Williams was present by teleconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of ethical issues (resolved)

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

Some

1. The Researcher(s) explained the main issues with old test is that some children just cannot comply due to their behaviour or development language so about 4-6% will not even be tested. The results of the test may be difficult to interpret requiring around 11-12% to be re-screened and a lot of the children will be lost to follow up as parents do not bring them back to screening or they do not understand. The final issue with the test is you could have around 4% being referred to an audiologist when only 1% in the general population would have a hearing impairment. There seems to be a high rate of false positives associated with this test.
2. The Committee questioned how parents would find out about the research component being offered during the b4 school test.

The Researcher(s) explained that as part of the b4 school test, a phone call/ text is usually made to parents within the week before to inform them. The Researcher(s) planned to give verbal information about the research, at this point.

An information sheet will be provided on the day. The consent process will happen in two parts (i) by the b4 school test nurse who does the routine consent process and then with (ii) the vision & hearing screening technician who conducts the hearing screen test with the child. This stage allows for second verbal consent and opportunity to ask questions

1. The Committee questioned if a preliminary letter could be sent now/at least at an earlier stage. The Researcher(s) informed that the organisers did not think it would be feasible as they do not know very far in advance when children would come in for their b4 school test. The Researcher(s) stated that ideally they would like to send out a preliminary letter for every child who might have a b4 school test but the majority of them would not meet their trial time of 6-8 weeks so a lot of people will get unnecessary information.

The Committee recognised that the preliminary letter approach would not work in this case and focused on the alternate approach; parents show on the day for the b4 school test and are provided information on the research study during this appointment.

The Researcher(s) confirmed that the pre-warning for the research would be made in the b4 school test reminder text/phone call. While waiting for their appointment with a nurse, written information on the research would be handed out. Parents can talk to the nurse briefly about the research and if they have further questions/want to hear more about it, they can talk to the hearing & vision screening technician. The Researcher(s) will be on site at the beginning of the screening session but not for the whole session.

1. The Committee queried if parents could be directed to a website containing information on the research when the b4 school test texts/ phone calls are made. A link to the website could be added to the text message. The Committee also suggested providing the option to have the research information emailed to parents.

The Committee suggested that the Researcher(s) consider expanding their options for communicating the research information to parents.

1. The Committee questioned how parents for whom English is not their first language would be included in the research.

The Researcher(s) advised that they would look into translating a simplified version of Participant Information Sheet (PIS) into Te Reo and a few Pacific languages based on which is the most common in the Hutt area.

1. The Committee asked if the Researcher(s) have access to funds to help cover the cost of translators. The Researcher(s) reported that they have applied to the Hutt Hospital Foundation and will make a submission to Cure Kids.
2. The Committee queried if Researcher(s) would be working with All Well Child providers or just Plunket. The Researcher(s) stated that they would be working with Plunket & Tamariki Ora who are working jointly to provide the b4 school test in the Hutt area.
3. The Committee queried if there was a Maori/Pasifika peoples provider for the b4 school test. The Researcher(s) advised that it is a universal test and not set up to specifically target certain population groups.
4. The Committee advised that this study requires a written information sheet and recommended using the HDEC PIS/Consent Form template. Having a brief PIS/CF is good and it should be easy to understand. The main thing to consider is that parents will be clear that the research is separate from the b4 school test and is optional. The PIS/CF should include risks for example; managing privacy risks for kept data as well as state how long data is kept and where it will be kept.
5. The Committee questioned if Maori consultation had been made and reminded the Researcher(s) that if Maori are part of the study then consultation is required. The Committee suggested the Maori Research team at Ministry of Health be approached for the consultation.
6. The Committee noted the declaration that no cultural issues are associated with this study and asked if practitioners will have awareness of the tapu nature of the head for Maori and Pasifika people.

The Researcher(s) appreciated the comment made and advised that they looked forward to the Maori consultation to help them address this and any other foreseeable cultural issues.

Summary of ethical issues (outstanding)

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

1. Please ensure the study has a PIS/CF and it’s advisable that you use the HDEC PIS/CF template (https://ethics.health.govt.nz/ under the Quick Links section).
2. Make sure it is clear that the research is different from the b4 school test.
3. Please ensure Maori consultation is made.
4. Please consider expanding options for communicating the research information to parents during first point of contact (ie, text/phone call reminders for the b4 school test appointments.

Decision

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

* Please prepare a PIS/CF for the study *(Observational Study, paragraph 6.11*)
* Please ensure Maori consultation is made (*Observational Study, paragraphs 4.3-4.4*)
* A vast amount of parents will only realise that the research is separate from the check, on the day of the appointment. This is acceptable relative to the risks of the study but these steps need to be detailed. Please capture the details in the protocol.

This following information will be reviewed, and a final decision made on the application, by Dr Patries Herst and Mr John Hancock.

|  |  |  |  |
| --- | --- | --- | --- |
| **8** | **Ethics ref:** | **18/NTB/133** |  |
|  | Title: | BTI-201: Study of plasma gelsolin (rhu-pGSN) added to standard of care in people hospitalised with acute community acquired pneumonia (CAP) |  |
|  | Principal Investigator: | Dr Catherina Chang |  |
|  | Sponsor: | BioAegis Therapeutics Inc. |  |
|  | Clock Start Date: | 26 July 2018 |  |

Mrs Christine Tuffery was present by teleconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. This is a phase Ib/IIa study to evaluate the safety, pharmacokinetics and pharmacodynamics of a Recombinant Human Plasma Gelsolin (rhupGSN) added to Standard of Care in patients hospitalized for acute community acquired pneumonia (CAP). Gelsolin occurs naturally in the blood to modulate inflammation while at the same time boosting the body’s ability to fight infection.
2. Plasma gelsolin functions through pleiotropic mechanisms of action, scavenging toxic actin, binding inflammatory mediators, and enhancing pathogen clearance. Potential participants will be screened as soon as possible after presentation to hospital. All participants will receive standard of care treatment in addition to study treatment. rhupGSN will be administered via intravenous push.
3. There is a Single Dose (SD) and a Multiple Ascending Dose (MAD) arms in the study. Each dosing cohort will include 6 rhupGSN: 2 placebo patients. Dose escalation will involve 3 dose levels of rhupGSN (6, 12, and 24 mg/kg). The MAD arm involves 3 doses of study drug given on 3 consecutive days. The first MAD cohort will start after the first SD cohort is shown to be safe.
4. Dose escalation will only occur after safety information at day 7 on all participants in the prior cohort has been reviewed for the SD and MAD arms. Participants will attend follow up visits on day 7 and day 28.
5. Data and Safety Monitoring Board will review safety data during the course of the study. Safety and tolerability assessments include; physical examinations (including vital sign measurements), AE assessments, concomitant medication assessments, safety laboratory testing and ECGs and other testing as per standard of care.
6. Optional future unspecified research.
7. The study is going to SCOTT review.

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) explained the study drug and its potential benefits, noting it is an early phase study. This is the first time it is used in patients with pneumonia.
2. The Committee asked the researcher about recruitment, noting only least vulnerable should be included. In particular, how is recruitment in this context being managed? The Researcher(s) explained that they have done acute studies before, and note the issue with informed consent and recruitment in this context. The Researcher(s) explained that family is involved as much as possible. The Researcher(s) noted while there are tight timeframes for recruitment, they aim to recruit at the latter end of the time frame, so potential participants are less sick, adding that standard of care can already be administered, which also helps reduce burden.
3. The Committee asked about capacity to consent - will all participants provide their own consent. The Researcher(s) stated that they would, confirming also that family is involved to support decision making but not to provide consent on behalf of others.
4. The Researcher(s) confirmed they are excluding patients who are really unwell.
5. The Committee asked how long participants have to consider participation, noting timelines are pushed to the other end of the window of recruitment. The Researcher(s) stated within 24 hours of presentation to hospital. The Researcher(s) noted an answer is required as soon as possible, which is not ideal, but is a reality of the research context.
6. The Committee asked what would happen if family is not present. The Researcher(s) stated if they were concerned about the patient (in terms of not being confident in participating without talking with family) we would not pursue recruitment, or give family a phone call.
7. The Committee asked whether interpreters are provided. The Researcher(s) stated they were not.
8. The Researcher(s) confirmed Maori consultation has occurred.

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 about application questions (P.4.1) and (F.4.1), are there any statistics or prevalence of Maori or other ethnicities in this context. The Researcher(s) stated they are over represented, but did not have figures available. The Researcher(s) stated they expected recruitment of Maori to be higher. The Committee noted that the application would benefit from this information.

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

1. The Committee commended the researchers on the easy to read participant information sheet.
2. Pg. 2 – please do not use flip of coin to explain the randomization process for a 4 arm trial.
3. Reproductive information on page 8 – this is very confusing, particularly about contraception methods, however the whole section needs a close review. Make sure what is acceptable and what is not, is clear, and look at men vs women information, as it is currently different. The paragraph ‘if you do become pregnant during the study’ – this is not likely, please review.
4. Pg.11 second bullet. NEAC ethical guidelines do not permit stopping trials early for commercial interest. Remove this from the participant information sheet.
5. P.6 change "sites in Australia" to sites in New Zealand.
6. If plan is to tell GP about participation in the study, please add to participant information sheet (in consent form only).

Future unspecified research participant information sheet:

1. No cultural statement, or destruction of samples details. Please review the HDEC template for future unspecified research participant information sheet and fill in missing areas. For example, all future research subject to ethics review, but may not be in New Zealand.
2. The Committee asked whether it was possible for genetic research to be future unspecified research, adding if it is possible please add more detail about it.
3. Remove ‘will not be used for commercial research’ as this is not necessarily true in future.

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 address how the study may benefit Māori and how cultural issues that may arise for Māori participants in the study will be managed (*Ethical Guidelines for Intervention Studies* *para 4.7*).

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

|  |  |  |  |
| --- | --- | --- | --- |
| **9** | **Ethics ref:** | **18/NTB/134** |  |
|  | Title: | Continue data gathering from previous selenium study. |  |
|  | Principal Investigator: | Dr. Nishi Karunasinghe |  |
|  | Sponsor: |  |  |
|  | Clock Start Date: | 26 July 2018 |  |

Dr. Nishi Karunasinghe 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) have successfully completed a selenium supplementation study with Auckland men (n=572) that was initiated in 2006 and was officially closed on the 13th February 2017. A total of 528 men have given consent to storing their blood and DNA for future New Zealand accredited ethics committee approved studies.
2. The Researcher(s) discussed, with the Norther B Ethics Committee, the value of more studies with stored blood/DNA samples taking into account original participant consents for such work.
3. The NTB Ethics Committee noted in prior correspondence that most of the samples did have consent for future unspecified research.
4. The Researcher(s) were asked to close the NTY 06/07/060 study, but request permission for a new study under a new ethics application (communication attached). The importance of the factors proposed to be assessed are summarised in 'Protocol-New Selenium Study' dated 17.07.2018 (attached). The Researcher(s) wish to carry out the following:
   * Questionnaire based prospective monitoring of previous study participants.
   * Collect additional biomarkers from stored blood and DNA samples in collaboration with experts in proteomics, and trace mineral and DNA methylation work based in New Zealand and overseas.
   * Store remainder of blood and DNA samples for further work.
   * Align and analyse current and previously collected (demographic, lifestyle, biomarker, and genetic) data for various outcomes. Previous selenium supplement study being continued with only those of the cohort who consented FUR.

Summary of ethical issues (resolved)

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

1. The Committee asked about the extension study. The Researcher(s) provided an overview of the prior study and HDEC interactions with the researcher. The Researcher(s) then explained what opportunities had led to the current application, namely interest in the samples from international researchers.
2. The Researcher(s) explained the benefits associated with this new research, including the international researchers offer to conduct assay development free of charge. The Researcher(s) added that locally this would cost 150k, and explained that this current study is a collaboration.
3. The Researcher(s) explained the different tests and types of tissue that need to be sent overseas for this work.
4. The Researcher(s) and the Committee noted nearly all prior participants had consented for future unspecified research. Also, the prior consent was all to do with genetics. The Committee determined that the proposed use is consistent with consent given.
5. Can participants who have samples destroyed, complete the questionnaire? The Researcher(s) confirmed they could.
6. Letters of support from Papaarangi Reid and Kerry Hiini are dated 2005 and 2006 respectively. The Researcher(s) noted contacted Sarah Jane Pane has provided review, which is recent.

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 how researchers will know if participants are well (alive) before calling. The Researcher(s) stated they plan to contact using current email and information. If money is sought, maybe public notices or Facebook, but admitted they had no substantive process to address this risk. The Researcher(s) noted this group is very close, as well as very engaged with the research team.
2. The Committee noted there needed to be a process to ensure recruitment did not cause undue emotional distress.
3. The Committee explained that NHI search is possible with name and D.O.B, using Ministry of Health HealthUI systems.
4. The Researcher(s) explained benefit of seeking NHI, adding it was not to look at hospital records, but for follow up reasons.
5. Please explore the Ministry of Health process to identify NHI and then mortality data, and add this process to the protocol.
6. Please provide independent peer review.
7. The questionnaires need customising for a New Zealand audience (e.g. ethnicity), and please also ensure that all questions are relevant to this study.
8. The Committee asked who is reviewing results to determine that they are clinically relevant, so they are then sent to GP. Who determines that results are potentially a health issue. Please consider whether results will be relevant if they are this old, and consider who makes this determination.
9. The Committee contested that serum selenium levels hasn’t changed over the last decade and would need to be tested again before making such a statement. The Researcher(s) noted it is good idea to re-test, but there are funding issues. The Committee noted that it must be clear that it was a base line 15 years ago in any reports/publications. The Researcher(s) cannot assume levels have not changed and can only relate baseline Selenium levels to the questionnaire data.
10. The Committee note the limitation of the study.
11. The Committee suggested that Uni-services is the sponsor. Please contact them about this.
12. Add questions about selenium supplements to questionnaire, and diet.
13. How long will questionnaires take to complete? Please add this information to the participant information sheet.
14. Remove religions – not relevant for New Zealand audience. Review whole questionnaire with this in mind.
15. Please use Statistics New Zealand's ethnicity classifications when collecting ethnicity data to ensure the options available are suitable for New Zealand participants. These classifications are: New Zealand European, Maori, Samoan, Cook Islands Maori, Tongan, Niuean, Chinese, Indian, Other (such as Dutch, Japanese, Tokelauan).
16. Remove any questions in the questionnaire that are not relevant.
17. Keep NHI separate from questionnaire.

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

1. Explain reason why collecting NHI (that is sensitive to the reason) in the participant information sheet.
2. Review to ensure all relevant and pertinent information covered i.e. somewhat light on tissue transportation aspect. Ensure inclusion of Maori Health Support contact details. Ask Uniservices for Maori support details.
3. Consent form, please review for relevancy (for example pregnancy, GP, tissue going overseas etc).
4. Add sponsor details.
5. Review to remove instructions from the template from the participant information sheet.
6. Add more information on data and confidentiality.
7. Remove ACC statement.
8. Explain questionnaires, how long they might take, that you don’t need to answer all questions, some may make you feel uncomfortable etc.

Decision

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

* Please amend the information sheet and consent form, taking into account the suggestions made by the Committee (*Ethical Guidelines for Observation Studies* *para 6.11*).
* The study design must minimise risk of harm – please provide a process to ensure recruitment does not cause undue harm, and update the protocol to include this information (*Ethical Guidelines for Observation Studies* *para 5.5*).
* Peer review is an important aspect of ethical review and is used to assure New Zealand's Health & Disability Ethics Committees of the scientific validity of a research proposal. There is a HDEC peer review template available at <http://ethics.health.govt.nz/home>

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

|  |  |  |  |
| --- | --- | --- | --- |
| **10** | **Ethics ref:** | **18/NTB/136** |  |
|  | Title: | Study of KPL-301 for treatment of Giant Cell Arteritis compared with placebo. |  |
|  | Principal Investigator: | Dr Nigel Gilchrist |  |
|  | Sponsor: | Kiniksa Pharmaceuticals Ltd |  |
|  | Clock Start Date: | 26 July 2018 |  |

Dr Nigel Gilchrist and Larissa Roberts 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 Phase 2 randomized, placebo-controlled Proof of Concept study will evaluate the efficacy and safety of KPL-301 co-administered with a 26-week corticosteroid taper in patients with Giant Cell Arteritis (GCA). The study will consist of a screening period (up to 6 weeks), a double-blind placebo-controlled 26-week period during which subjects will receive blinded KPL-301 or placebo, alongside a 26-week corticosteroid taper, until the last subject has reached the 26-week time point and the results from the 26-week time point have been analyzed, followed by an Open-Label Extension for an additional 26-week period.
2. Comprehensively documented study Phase II - efficacy of KPL-301 versus placebo, coadministered with a 26 week steroid taper, for maintaining sustained remission for 26 weeks in subjects with new onset or elapsing/refractory giant cell arteritis (GCA). (giant cell arteritis - inflammation in lining of arteries - causes severe headaches. Usual care steroids) potential OLE.
3. The Committee noted there is lots of input required from participants (study diaries etc) - potential payoff of reducing steroid use.
4. Optional genetics and biopsy sub studies.

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 SCOTT review is being sought. The Researcher(s) stated it is going well.

Summary of ethical issues (outstanding)

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

1. P.12 The Committee asked whether patients are compensated for their significant time investment in this study when there is commercial benefit to the sponsor. The Researcher(s) explained that participants are reimbursed fully for study related costs.
2. Make it clear in participant information sheet that participants are compensated for travel, parking expenses etc. proof reference for expenses can be removed.
3. Standard treatment vs gradual coming off of steroids in protocol - will patients on the placebo be likely to have a resurgence from their GSA? Will they be untreated? The Researcher(s) explained that all participants are on standard of care.
4. The Researcher(s) confirmed Maori consultation is underway.

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

1. The Researcher(s) addressed relationship with TB testing and the study drug. Please add this detail in lay language in the participant information sheet.
2. Study cannot be stopped for commercial reasons - note 'other reasons' in consent form p14 6. Please remove.
3. Widen the margins to increase white space, this makes it easier to read.
4. Add sponsor details and name on the front of the participant information sheet.
5. The Committee noted that consent for data on children can only be collected after consent is given by the parents, after the child is born.
6. p.1 change to NTB HDEC.
7. p.8 state where overseas (for tissue samples),
8. Please consider using the updated HDEC participant information sheet template for ACC wording.
9. For consent form, remove Y/N boxes that are not truly optional.
10. In general, the Committee recommends use of standard HDEC templates for PIS and CIF forms
11. The statement in the PIS forms that patient data may be sent to countries without data protection safeguards and rights and that the sponsor et al shall seek to maintain confidentiality only within the limits of local laws is inadequate in the Committees view. The sponsor should seek to maintain New Zealand standards or equivalent or better for New Zealanders health data sent offshore – The Committee note the long (15 year) period for data retention (as compared to 10 year NZ standard). The Researcher(s) noted they would strengthen the wording.
12. Explain acronyms before use ie GCA, 'what does participation involve' should be an opportunity to explain what the potential participant will experience as a participant. I think this has been missed, instead, explains the trial design. Remove 'treatment' in what treatment will I receive. This is not a treatment, it is an experimental study drug and at best should be called a medication.
13. Reword first paragraph of risk/benefit section p8, very confusing.

Genomic PICF:

1. Please remove this sentence: the study doctor wants to confirm that you agree to be part of a genomic study, as part of the main study p1. This is potentially coercive.
2. The Committee suggested participants are offered to ‘discuss participation with family, whanau’ since this is genetic information, not 'anyone you choose'
3. p1 Move paragraph 2 to top.
4. Check repetition between paragraphs 1 and 2 Explain 'genomic' before 'pharmacogenomics' is discussed i.e. genomic means xyz
5. p2 make it clear if withdrawn whether blood will still be used in genomic research p4 7.

Biopsy collection PICF

1. Use of 'your study doctor wants you to' again but seems less coercive in this context. It can stay in this section.
2. Please add some consideration about tikanga around interventions touching the head in form.

Pregnant partner ICF

1. The Committee asked whether there should be a pregnant participant information sheet as well, currently just one for pregnant partners.

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*).
* Explain what happens to health information (*Ethical Guidelines for Intervention Studies* *para 7.7)*

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

|  |  |  |  |
| --- | --- | --- | --- |
| **11** | **Ethics ref:** | **18/NTB/137** |  |
|  | Title: | A Multicenter, Double-Masked, Randomized, Dose-Ranging Trial to Evaluate the Efficacy and Safety of Conbercept Intravitreal Injection in Subjects with Neovascular Age-related Macular Degeneration |  |
|  | Principal Investigator: | A/Prof Philip Polkinghorne |  |
|  | Sponsor: | INC Research New Zealand Limited, a Syneos HealthT |  |
|  | Clock Start Date: | 26 July 2018 |  |

Associate Professor Philip Polkinghorne and Ms May Mendoza were not present for the 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 global research study is a phase 3 trial for patients with wet Age-related Macular Degeneration (AMD) who have not received treatment before, and that anti-vascular endothelial growth factor (VEGF) injection is considered an appropriate treatment for them. VEGF is a protein that promotes blood vessel growth, which is one of the main causes of wet AMD. Therefore, an anti-VEGF medication works by stopping this protein from being made in the eye.
2. The anti-VEGF medication being trialed is called Conbercept. The aim of this trial is to evaluate the efficacy and safety of 0.5 mg and 1.0 mg conbercept IVT injection compared with active control, Aflibercept IVT injection (2.0 mg, Eylea®), in patients with AMD. Eylea® is an approved medication in New Zealand to treat AMD.
3. AMD is a leading cause of severe and irreversible vision loss in people over the age of 65 and it can affect both eyes and can cause legal blindness.
4. Approximately 1140 eligible men and women over the age of 50 will participate in the 96 week study and will receive double blind treatment in a 1:1:1 ratio to one of the following three treatment arms: 0.5mg conbercept, 1.0 mg conbercept or 2.0 mg/eye Aflibercept (Eylea)for 92 weeks.
5. The duration of the study is approximately 96 weeks with a screening period of less than or equal to 14 days, followed by a treatment period of 92 weeks (last assessment at 96 weeks) with primary efficacy analysis at 36 weeks.

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 there are some sham injections to maintain blind.
2. The Committee noted a benefit of participation is the chance to get some treatment at no cost.

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 there are a lot of visits, and noted there should be plans to reimburse travel. (p.3.3.1). Amend participant information sheet to state ‘may be reimbursed’ to ‘will be reimbursed’ regarding travel expenses.
2. The Committee asked if it was necessary to pregnancy test in 50+ year olds, and when inclusion is post menopause or sterile. Please remove pregnancy and contraception wording from study documentation.
3. (p.4.1) Identify incidence of disease in Maori in order to ascertain potential benefit. What is the burden of AMD in Maori? If there are none, in future please state that there are none.
4. The Committee asked about the consultation, as it was not clear who the "Maori adviser" is. (p.4.3.1) Provide and upload update regarding Maori consultation.

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

1. Add global sponsor address front page, up front. Also at clause 18 pg 19. Amend may be reimbursed to will be reimbursed re travel expenses. Note that there should not be a requirement to provide receipts.
2. Note that the study cannot be stopped for commercial reasons. Please remove this as per NEAC guidelines.
3. Please remove the requirement for withdrawing from the study in writing, verbal withdrawal is acceptable.
4. Ensure inclusion of contact details for Maori health/cultural support.
5. Consent form: Add sponsor address front page, up front.
6. add '1 in 10 people' etc against the risks (common, less common, rare) p.11/12;
7. stopping commercial interests (p.17);
8. Compensation statement p. 19 – this must be both not no-fault and ACC equivalent levels of compensation. Please see the updated wording on the HDEC template participant information sheet.
9. Consent form – please remove y/n boxes unless optional.
10. Add lay title and a table of the visits.
11. The Committee noted that the privacy information on page 18 was too relaxed. Please review and provide more protection for participant’s data.

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 address how the study may benefit Māori and how cultural issues that may arise for Māori participants in the study will be managed (*Ethical Guidelines for Intervention Studies* *para 4.7*).

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

## General business

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

|  |  |
| --- | --- |
| **Meeting date:** | 04 September 2018, 12:00 PM |
| **Meeting venue:** | Novotel Ellerslie, 72-112 Greenlane Road East, Ellerslie, Auckland |

The following members tendered apologies for this meeting.

* Miss Tangihaere Macfarlane will be away for next 2 meetings,04 September & 02 October.

The meeting closed at 5.40pm