|  |  |
| --- | --- |
| **Committee:** | Central Health and Disability Ethics Committee |
| **Meeting date:** | 27 August 2019 |
| **Meeting venue:** | Room GC.3, Ground Floor, Ministry of Health, 133 Molesworth Street, Wellington |

|  |  |
| --- | --- |
| **Time** | **Item of business** |
| 12:00pm | Welcome |
| 12:15pm | Confirmation of minutes of meeting of 23 July 2019 |
| 12:30pm | New applications (see over for details) |
| 12:30 – 12:55pm  12:55 – 1:20pm  1:20 – 1:45pm  1:45 – 2:05pm  2:05 – 2:30pm  2:30 – 2:55pm  2:55 – 3:20pm  3:20 – 3:45pm  3:45 – 4:10pm  4:10 -4:35pm  4:35 – 5:00pm | i 19/CEN/136  ii 19/CEN/138  iii 19/CEN/139  iv 19/CEN/141  v 19/CEN/142  vi 19/CEN/143  vii 19/CEN/144  viii 19/CEN/145  ix 19/CEN/146  x 19/CEN/147  xi 19/CEN/118 (response to provisional approval) |
| 5:00pm | General business:  Noting section of agenda |
| 5:15pm | Meeting ends |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Member Name** | **Member Category** | **Appointed** | **Term Expires** | **Apologies?** |
| Mrs Helen Walker | Lay (consumer/community perspectives) | 01/07/2015 | 01/07/2018 | Present |
| Mrs Sandy Gill | Lay (consumer/community perspectives) | 30/07/2015 | 30/07/2018 | Present |
| Dr Patries Herst | Non-lay (intervention studies) | 27/10/2015 | 27/10/2018 | Present |
| Dr Dean Quinn | Non-lay (intervention studies) | 27/10/2015 | 27/10/2018 | Absent |
| Dr Cordelia Thomas | Lay (the law) | 20/05/2017 | 20/05/2020 | Apologies |
| Dr Peter Gallagher | Non-lay (health/disability service provision) | 30/07/2015 | 30/07/2018 | Present |
| Dr Nora Lynch | Non-lay (provision of health & disability services) (co-opted) | 19/03/2019 | 19/03/2022 | Present (application 19/CEN/146 only) |
| Ms Helen Davidson | Lay (ethical/moral reasoning) | 06/12/2018 | 06/12/2021 | Present |

## Welcome

The Chair opened the meeting at 12:00pm and welcomed Committee members, noting that apologies had been received from Dr Cordelia Thomas.

The Chair noted that it would be necessary to co-opt members of other HDECs in accordance with the Standard Operating Procedures. Dr Nora Lynch confirmed her eligibility, and was co-opted by the Chair as a member of the Committee for the review of application 19/CEN/146.

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 23 July 2019 were confirmed.

## Noting Section:

## New applications

|  |  |  |
| --- | --- | --- |
| **1** | **Ethics ref:** | **19/CEN/136** |
|  | Title: | PHITT Trial |
|  | Principal Investigator: | Dr Mark Winstanley |
|  | Sponsor: | Children's Oncology Group |
|  | Clock Start Date: | 15 August 2019 |

Dr Mark Winstanley and Ms Sarah Hunter 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 paediatric hepatic malignancies hepatoblastoma (HB) and hepatocellular carcinoma (HCC) account for 1% of malignant tumours in children with an incidence that has been increasing.
2. This trial directly addresses the need for the next generation of clinical trials for hepatic malignancies, incorporating rational reductions in therapy that ameliorate both short and long-term side effects for patients with good prognoses while simultaneously optimizing curative potential with intensification and new agent integration to improve outcomes for those with poor prognoses.
3. A critical aspect of this trial is the opportunity to correlate histologic and biologic heterogeneity with response and outcomes in all risk categories, providing promise for future refinement to the newly proposed risk stratification schema.

Summary of resolved ethical issues

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

1. The Committee queried the paucity of detail in the description of follow-up visits. The Researcher stated that this was because follow-up visits for those enrolled in the study were minimally different from standard of care for similar patients not enrolled in the study.
2. The Committee queried whether participants would receive further treatment if they relapse in the follow-up period. The Researcher stated that participants in this situation would be removed from the study to pursue treatment options.

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

1. The Committee suggested the addition of text to page six of the PIS, stating the intended duration of the study and that follow-up visits are not a deviation from the patients’ normal care.
2. The Committee requested that the Researcher amends the statement in the main PIS regarding optional studies, as well as the statement in the optional studies PIS, so that it is more clear what tissue sampling is optional and what is compulsory.

Decision

This application was *approved* by consensus, subject to the following non-standard conditions:

* Please amend the Participant Information Sheets with the suggested changes listed above.

|  |  |  |
| --- | --- | --- |
| **2** | **Ethics ref:** | **19/CEN/138** |
|  | Title: | Head Start 4 |
|  | Principal Investigator: | Dr Karen Tsui |
|  | Sponsor: | NEXT Consortium |
|  | Clock Start Date: | 15 August 2019 |

Dr Karen Tsui and Ms Paula Murray were present by teleconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. This is a prospective, randomised clinical trial to determine whether dose-intensive tandem Consolidation, in a randomised comparison with single cycle Consolidation, provides an event-free survival (EFS) and overall survival (OS) benefit for high-risk patients.
2. The study population will be high-risk patients with medulloblastoma, and patients with central nervous system (CNS) embryonal tumours completing "Head Start 4" Induction.
3. This study will further determine whether the additional labour intensity (duration of hospitalisations and short-term and long-term morbidities) associated with the tandem treatment is justified by the improvement in outcome.
4. It is expected that the tandem (3 cycles) Consolidation regimen will produce a superior outcome compared with the single cycle Consolidation, given the substantially higher dose intensity of the tandem regimen, without significant addition of either short-term or long-term morbidities.

Summary of resolved ethical issues

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

1. The Committee queried the target age-range of participants. The Researcher confirmed that they were aiming to recruit children under three years old, as they usually cannot be treated with radiation therapy, therefore leaving a gap in treatment for children below a certain age.
2. The Committee queried the cut-off age for recruitment into the study. The Researcher clarified that children were able to enrol in the study (provided they met other criteria) up to and including the day before their tenth birthday.

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

1. The Committee suggested that, as there is now a separate PIS for Future Unspecified Research (FUR), the amount of text regarding FUR in the main PIS can be reduced.
2. The Committee suggested that the use of personal pronouns at the bottom of page one of the FUR PIS could be interpreted as unnecessarily emotive or influential, and should be removed.
3. The Committee stated that all Consent Forms need to state that samples are being sent overseas, in addition to the statement in the PIS
4. The Committee stated that the reconsenting section of the PIS should be reworded for greater detail and clarity, particularly regarding how data is collected.

Decision

This application was *approved* by consensus, subject to the following non-standard conditions:

* Please refer to the requested changes to Participant Information Sheets and Consent Forms listed above

|  |  |  |
| --- | --- | --- |
| **3** | **Ethics ref:** | **19/CEN/139** |
|  | Title: | Nox 1 and 4 inhibition in type 1 diabetic kidney disease |
|  | Principal Investigator: | Professor Jonathan Shaw |
|  | Sponsor: | Baker Heart and Diabetes Institute |
|  | Clock Start Date: | 08 August 2019 |

Prof Jonathan Shaw & Ms Anne Reutens was present by teleconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. This study will test whether a new medication under investigation, called GKT137831, is effective and safe. It will be added to current optimal standard of care treatment for diabetic kidney disease in people who have type 1 diabetes and a persistent abnormal amount of albumin in the urine.
2. The primary purpose of this study is to help answer this question:
   * What effect does GKT137831 have on urine albumin levels?
3. The secondary purpose of this study is to help answer these questions:
   * What effect does GKT137831 have on kidney function?
   * Is GKT137831 safe and tolerable?
   * What effects does GKT137831 have on metabolite levels and other markers of diabetic kidney disease?
4. GKT137831 is a molecule which inhibits the enzyme NADPH oxidase (NOX). NOX produces substances such as superoxide or hydrogen peroxide, which are called free radicals. Those free radicals are – when present in small quantities – involved in normal cellular functions. However, they become toxic if they are present in excess amounts. The study drug blocks the activity of a subset of NOX enzymes which could be causing diabetic kidney disease.
5. The study is a trial with a total of 142 people, 71 people per arm: Group 1 GKT137831; Group 2 placebo
6. Up to 284 participants will be screened with 142 randomised. The treatment period is for 48 weeks with total study duration for the participant of up to 56 weeks. There will be 10 study visits. Analyses will include urine albumin:creatinine ratio, HbA1c, renal and liver function, full blood examination, thyroid stimulating hormone, fasting glucose, fasting lipids, pregnancy test if applicable.
7. There will also be blood tests to examine how the study drug is handled by the body (pharmacokinetics), blood and urine tests to see the effect on inflammatory markers and other biomarkers of response to the drug, and optional blood tests to look at epigenetic effects and RNA.

Summary of resolved ethical issues

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

1. The Committee queried whether the peer review was still relevant, due to its presentation as reviewer questions only, and the time between its completion and the current application. The Researcher stated that all reviewer questions were answered as part of the funding process; the receipt of the grant indicates that all reviewer questions were answered and actioned satisfactorily.

Summary of outstanding ethical issues

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

1. The Committee stated that Māori consultation must take place as part of the locality assessment process and should be clear about tissue samples being sent overseas. Local sites should have established processes for this to take place.
2. The Committee stated that Scientific Review from SCOTT should be sent to the Committee once it has been completed.

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

1. The Committee stated that page seven of the main PIS is amended, under the heading “Informing Doctors”. Please change the text to state that researchers will be informing participant’s GPs, but that they suggest the participants additionally do so themselves.
2. The Committee stated that page seven of the main PIS should be amended to state that samples will be stored for future research with the participant’s consent.
3. The Committee stated that page eight of the main PIS should be amended to state that, with consent, some samples will be stored for the purpose of future research.
4. The Committee stated that the amended sample storage statement listed in point 12 should be reflected with separate optional consent in the Consent Form.
5. Please amend the PIS for Future Unspecified Research to include information on whether the donor may be contacted in the future, whether information arising from future research will be made available to donors and that the donor won’t own any IP that may arise from future research; how samples will be stored when they are disposed of, and any cultural issues that may arise from that.
6. The Committee stated that the Consent Form should be amended so that tick-boxes are only present next to optional parts of the research

Decision

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

* Please provide evidence of Māori consultation
* Please provide evidence of scientific review by SCOTT, once available
* Please make the requested changes to the Participant Information Sheets and Consent Forms listed above

After receipt of the information requested by the Committee, a final decision on the application will be made by Ms Helen Davidson and Dr Peter Gallagher.

|  |  |  |
| --- | --- | --- |
| **4** | **Ethics ref:** | **19/CEN/141** |
|  | Title: | Youth Wellbeing Study 3.0: How do adolescents think, feel, and behave? |
|  | Principal Investigator: | Professor Marc Wilson |
|  | Sponsor: | Victoria University of Wellington |
|  | Clock Start Date: | 16 August 2019 |

Prof Marc Wilson was present by teleconference and Dr Jessica Garisch 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. Non-suicidal self-injury (NSSI) has been defined by the International Society for the Study of Self-Injury as the deliberate, self-inflicted destruction of body tissue without suicidal intent and for purposes not socially sanctioned (ISSS, 2007). This application extends (with Marsden funding) upon our previously HRC-funded research (with HDEC approval 12/NTB/35) investigating why some young people never engage in NSSI, why some young people start NSSI, and why some of those who engage in NSSI stop while for others it becomes an ongoing coping strategy (see attachment ‘How this protocol differs’ for a description of differences).
2. Specifically, with the support of collaborating secondary schools, we will continue to survey the same cohort of young people (age 13 years and older) at least once a year for at least three years. As this is a longitudinal study, identity of participants will be confidential (and not anonymous). The survey includes questions assessing a range of demographic, social, and psychological ‘variables’. Social variables include extent of social network, bullying experience, and others. Psychological variables include both protective (e.g., self-esteem, happiness, optimism, connectedness to family and school) and risk factors (e.g., deficits in emotional understanding, depression, anxiety).
3. Additionally all participants complete questions assessing suicidality (whether they have seriously considered suicide in the last two weeks), and whether they have thought about or engaged in self-injury. Those who give cause for concern are identified to their guidance counsellors.
4. This application is based heavily upon that previously approved (12/NTB/35) and reflects changes for which we sought an amendment (12/NTB/35/AM06) that was declined on the grounds that “the proposed research is a new study sufficiently distinct from that approved”.

Summary of resolved ethical issues

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

1. The Committee queried how well researchers will get to know he participants over the course of this study, and how that differs from the previous study. The Researcher stated that participants will be enrolled for the duration of their time in high school. The present study differs because a smaller number of schools will be involved and students can join at any year, not just the first year of high school.
2. The Committee queried whether any participants will be twelve years old or younger. The Researcher stated that it is possible, however recruitment will occur at the end of the school year, so all children will have turned thirteen by the time they join the study.
3. The Committee queried whether there were any known risks to participation in the study. The Researcher stated that measures of affect were administered immediately prior to and immediately following the main survey, and that in the previous study no increase in distress or self-injury has been found.
4. The Committee queried how the risk to participants who are experiencing significant distress will be managed. The Researcher stated that the survey captures recent and clinically significant distress; the results automatically notify researchers as soon as the survey is completed, who will then inform relevant guidance counsellors. Children and parents are informed of this process for managing distress during the onset/assent process. Additionally, students will be able to self-identify any distress. Clinical judgement on the part of the researchers, as well as any existing relationships between students and guidance counsellors, will also be taken into account. Two Clinical Psychologists will also be available to help triage students and perform risk assessments as needed.
5. The Committee queried whether participants are aware of the types of questions they will be answering prior to their assent. The Researcher stated that children are informed that they will be asked a range of questions, including about bullying, self-injury, relationships and attachments.
6. The Committee queried how many parents do not consent to their adolescents under the age of 16 participating in the research. The Researchers stated that of the consent forms that are returned, approximately one in forty do not consent.
7. The Committee queried whether the children who do not participate will experience any stigma. The Researchers stated that groups of children will complete the survey at the same time on school computers. Any children not participating will be able to do other school work on the computer during this time.
8. The Committee queried how data is stored and de-identified. The Researcher stated that the data is de-identified and coded once it is removed from the survey site, with a separately stored study key in case data needs to be recombined.

Summary of outstanding ethical issues

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

1. The Committee requested that they would like to review the blurb provided to students prior to their assent and participation.
2. The Committee requested to see the information video that is provided to students prior to their assent and participation.
3. The Committee stated that evidence of consultation with Māori must be provided.

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

1. The Committee stated that a contact number for HDEC should be provided on the PIS, in case participants or parents have any concerns.

Decision

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

* Please provide the student blurb for the Committee to review
* Please provide the student information video for the Committee to review
* Please provide evidence of consultation with Māori
* Please provide an updated PIS that includes the HDEC contact number

After receipt of the information requested by the Committee, a final decision on the application will be made by Mrs Helen Walker and Dr Patries Herst.

|  |  |  |  |
| --- | --- | --- | --- |
| **5** | **Ethics ref:** | **19/CEN/142** |  |
|  | Title: | tune.in: an app to help young people meet their health behaviour change goals |  |
|  | Principal Investigator: | Associate Professor Sarah Hetrick |  |
|  | Sponsor: | The University of Auckland |  |
|  | Clock Start Date: | 16 August 2019 |  |

A/Prof Sarah Hetrick and Ms Liesje Donkin were present by teleconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. This is an open trial aiming to test an app designed to support young people to make positive behavioural changes (i.e. goal attainment and emotional management). We will assess how well young people engage with the app, its acceptability to young people, and its potential efficacy.
2. Participant referral via school counsellors or mental health services is designed to maximise recruitment, particularly for Māori and Pasifika young people. The enrolment process will be the same for all volunteers and all study procedures will be carried out online to time reduce burden. Participants will provide informed consent, eligibility screening and complete baseline assessments electronically.
3. Participants will be included in the study if they are twelve to twenty-five years old at the time of consent/assent, have been identified by a health professional as potentially benefiting from the proposed app, and have access to a smart phone that can run the proposed app.
4. Participants will be excluded if they are not able to sufficiently understand the nature of study involvement or can provide online informed consent; if they are at an acute risk of harm or distress, or parental consent is not obtained for participants aged twelve to fifteen years.

Summary of resolved ethical issues

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

1. The Committee queried whether recruitment will occur through GPs. The Researcher stated that recruitment would occur only through Child & Adolescent Mental Health Services (CAMHS) and school guidance counsellors.
2. The Committee queried the age group that required parental consent. The Researcher stated that participants under sixteen years old would require parental consent.
3. The Committee queried whether follow-up would occur outside of normal business hours. The Researcher stated that participants will all already be enrolled in a mental health service, therefore the safety plan outlined by the Researcher would only be actioned if the primary plan put in place by the mental health service provider was to fail.
4. The Committee queried the design of the study, as some measures appeared to look at efficacy. The Researcher confirmed that this is a feasibility study, and that measures of efficacy are indicative only and cannot be used to make any claims until a randomised controlled trial has been done.

Decision

This application was *approved* by consensus.

|  |  |  |
| --- | --- | --- |
| **6** | **Ethics ref:** | **19/CEN/143** |
|  | Title: | The relationship between spine adipose index and deep infection after posterior fusion of the lumbar spine |
|  | Principal Investigator: | Dr Vikesh Gupta |
|  | Sponsor: |  |
|  | Clock Start Date: | 16 August 2019 |

Dr Vikesh Gupta 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. Measuring the subcutaneous thickness of the lumbar spine at the operated level on MRI scan. We will then form the spine adipose index by dividing this measurement by the size of the vertebral body. We will compare the spine adipose index in patients who developed deep infections of the spine after posterior fusion of the lumbar spine to control patients (those who did not develop infection), matching both groups for demographic factors and known risk fa tors for developing infection after spine surgery.
2. Our research aims to identify whether spine adipose index is an independent risk factor for developing deep infection, and whether it is a better predictor than BMI for deep infection lumbar fusion surgery using the posterior approach.

Summary of resolved ethical issues

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

1. The Committee queried the precise reasoning behind not seeking explicit consent for this study. The Researcher stated that the study will be taking place at a teaching hospital, where standard practice is to obtain verbal consent from patients to use their data for research studies at the time of treatment. The Researcher also stated that the study will be looking at historical data that may not have complete or updated contact information, and that none of the findings will impact care as treatment will have already completed for all patients whose data will be used.
2. The Committee queried whether the data will be de-identified. The Researcher confirmed that it will be.
3. The Committee queried the number of locations involved in the study. The researcher stated that up to four hospitals would provide records.
4. The Committee queried the target sample size for this study. The Researcher responded that they estimated about 1,500 cases will be included in the study.
5. The Committee queried whether consultation with Māori had been undertaken. The Researcher stated that the consultation process had been started at respective localities.

Decision

This application was *approved* by consensus, subject to the following non-standard conditions:

* Please provide evidence of consultation with Māori to HDEC once it has been completed

|  |  |  |
| --- | --- | --- |
| **7** | **Ethics ref:** | **19/CEN/144** |
|  | Title: | Diet and Diabetes |
|  | Principal Investigator: | Miss Christina Lampey |
|  | Sponsor: |  |
|  | Clock Start Date: | 16 August 2019 |

Miss Christina Lampey was present by teleconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. This study aims to investigate the nutritional intake of children with diabetes by requesting a 2-5 day food diary from the cohort and comparing with the international recommendation intake and comparing the macronutrient intake with diabetes control (HbA1C), insulin regime, type of blood glucose monitoring device and growth/ BMI.

Summary of resolved ethical issues

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

1. The Committee queried whether this study was part of the requirements to complete a program of tertiary study. The Researcher stated that it is not currently, however it may be used to create a Master’s thesis, subject to university approval.
2. The Committee stated that the PIS should be amended to disclose that this study is for completion of a Master’s degree, should that eventuate.
3. The Committee queried why all children were under the age of sixteen. The Researcher stated that this was because patients are transferred to adult services once they turn sixteen years old.
4. The Committee queried how blood will be sampled. The Researcher stated that blood samples had been obtained historically, with consent for Future Unspecified Research (FUR).
5. The Committee queried how recruitment would occur. The Researcher stated that patients could be recruited from the FUR database.
6. The Committee queried how data will be managed. The Researcher stated that blood data will be linked to the diaries, then de-identified.
7. The Committee queried whether consultation with Māori has taken place. The Researcher stated that the process has been started with their Research Office.

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

1. The Committee stated that the PIS should be restructured to follow the HDEC template, and encouraged the Researcher to seek support from colleagues and the HDEC Secretariat when completing the new version of the PIS.

Decision

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

* Please provide an updated Participant Information Sheet that includes greater detail and follows the HDEC template, available to download on the HDEC Website. Please consult with HDEC Secretariat for assistance if any uncertainties arise.

After receipt of the information requested by the Committee, a final decision on the application will be made by Mrs Helen Walker and Dr Peter Gallagher.

|  |  |  |
| --- | --- | --- |
| **8** | **Ethics ref:** | **19/CEN/145** |
|  | Title: | Efficacy and Safety of Selonsertib in Participants With Moderate to Advanced Diabetic Kidney Disease |
|  | Principal Investigator: | Dr Michael Collins |
|  | Sponsor: | Gilead Sciences |
|  | Clock Start Date: | 16 August 2019 |

Ms Jean Chen & Dr Michael Collins 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. Diabetes is the leading cause of chronic kidney disease in the developed world. With current standard of care treatment, many patients will continue to have decline in kidney function. Selonsertib is expected to delay the time to development of outcomes such as dialysis, kidney transplant and death.
2. This study will investigate whether Selonsertib can slow the decline in kidney function, reduce the risk of kidney failure, or reduce the risk of death due to kidney disease in subjects with diabetic kidney disease. The secondary objectives of this study are to evaluate the effect of Selonsertib on heart disease and death, and to assess the safety and tolerability of Selonsertib in subjects with diabetic kidney disease (DKD). Participants will receive Selonsertib or placebo in addition to their standard of care therapy for their diabetes and diabetic kidney disease.
3. Participants will be required to complete an at least five week run in phase (at least one week of placebo, and 4 weeks of Selonsertib). If they remain eligible after the run-in phase participants will be randomised to receive Selonsertib or Placebo orally once daily.
4. Participants will remain on the study treatment until death, kidney transplantation, treatment discontinuation (e.g., unacceptable toxicity or subject’s refusal of treatment) or study completion (target number of endpoint events met, estimated treatment duration of 21 months).

Summary of resolved ethical issues

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

1. The Committee queried whether participants will know that they are taking placebo during the run-in period. The Researcher stated that they will be aware, and that the purpose of this is to let them run off anything they were previously taking, and also to help monitor any changes in kidney function. Following this will be the vetting process for participants, then they will be randomised to the study drug or placebo group.

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

1. The Committee stated that the contact details on page eighteen of the PIS should be moved to the end of the PIS.
2. The Committee stated that the second to last point on the Consent Form regarding receiving results should be reworded to “I want to receive a summary of results”.
3. The Committee stated that the Consent Forms need to state that samples are being sent overseas

Decision

This application was *approved* by consensus, subject to the following non-standard conditions:

* Please refer to the requested changes to the Participant Information Sheets and Consent Forms listed above

|  |  |  |
| --- | --- | --- |
| **9** | **Ethics ref:** | **19/CEN/146** |
|  | Title: | Investigation of the endometrial cancer genomic profile in New Zealand women |
|  | Principal Investigator: | Dr Claire Henry |
|  | Sponsor: |  |
|  | Clock Start Date: | 16 August 2019 |

Dr Claire Henry & Ms Sara Filoche 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. Endometrial cancer (EC) has been a neglected disease, and this is to our detriment - it is now one of the leading causes of women’s mortality and morbidity in Aotearoa, New Zealand (NZ) and incidence is on the rise, particularly in younger women.
2. EC incidence, morbidity and mortality rates in women who identify as Māori and Pasifika are much greater than those who identify as European/Other. Whilst promised to enhance clinical management, the ‘genomics era’ has not impacted health outcomes of women with EC.
3. The current treatment strategy is standard for all women with EC in that they will receive surgery and subsequent radiation or chemo therapy if tumours are high grade and stage. There are no genomic biomarkers clinically used to aid diagnosis and prognosis of EC. This is particularly important when assessing patients with high heterogeneity or grade 3 tumours, which have variable outcomes and may result in under or over treatment, particularly with chemo or radiation therapy.
4. Therefore this study, for the first time, will investigate the genomic profile of EC in NZ women. Specifically, researchers will aim to:
   * Determine the prevalence of genomic subtypes of EC in NZ women.
   * Consider care management and outcome in relation to genomic status.
   * Consider whether integrating genomic profiling with clinical care is feasible and beneficial (cost analysis).

Summary of resolved ethical issues

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

1. The Committee queried where clinical data was being obtained from. The Researcher stated that data would be obtained from the Cancer Registry and hospital records, and confirmed that a clinician would be extracting data from hospital records.
2. The Committee queried whether the proposed study was an audit or observational research, as the genotyping used is not currently in clinical practice, is not standard of care and is not a recognised quality assurance. The Researcher confirmed that the proposed study is observational research and not an audit.

Summary of outstanding ethical issues

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

1. The Committee stated that the protocol should be amended to reflect that this is an observational study and to account for the use of data and tissue without consent, in compliance with the Code of Health and Disability Services Consumers’ Rights (1996).
2. The Committee stated that the managing clinician must confirm that no genomic data generated by the researchers will be of clinical use, before agreeing to genomic data not being returned to the hospital.
3. The Committee stated that causal relationships are unlikely to be established with the current sample size, and should be changed to an exploratory question.
4. The Committee stated that, if the study is to not be exploratory, then a statistician should be recruited to help calculate study power, in addition to being present for the cost efficacy analysis section of the study.

Decision

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

* Please provide an amended protocol, with the suggested changes regarding use of data and tissue without consent added.
* Please provide evidence that the study question will not investigate causal relationships with the current sample size, except for exploratory purposes only.
* Please provide evidence the managing clinician has confirmed that they do or do not consider the genomic data generated by this study to be of clinical use, and whether they will or will not require this data to be provided to the hospital.
* If the researchers decide not to alter the study to an exploratory design, please provide evidence that a statistician has been recruited to the research team.
* The Committee recommended that the Researcher consult with the HDEC Secretariat if there are any aspects of the requested changes that they are uncertain of.

After receipt of the information requested by the Committee, a final decision on the application will be made by Ms Helen Davidson and Dr Nora Lynch.

|  |  |  |
| --- | --- | --- |
| **10** | **Ethics ref:** | **19/CEN/147** |
|  | Title: | (duplicate) Hyperbaric Oxygen Therapy for the treatment of acute sensorineural hearing loss |
|  | Principal Investigator: | Dr Ben Thomson |
|  | Sponsor: |  |
|  | Clock Start Date: | 16 August 2019 |

Potential conflicts of interest

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

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

Summary of Study

1. This study will be conducting a prospective trial assessing the efficacy of hyperbaric oxygen therapy used in combination with high dose oral corticosteroids against treatment with high dose corticosteroids alone (the usual treatment) for acute idiopathic sensorineural hearing loss (ISSHL).
2. ISSHL is a condition with an incidence estimated at 5-20 per 100,000, whilst the exact mechanism is unknown it is postulated to have either a vascular, traumatic or viral aetiology. The former two causing ischaemic injury to the cochlear (hearing) nerve.
3. Current management of this condition includes an initial audiogram to confirm the diagnosis and a short course of high dose oral corticosteroids. Patients are reviewed after a week in our acute otolaryngology clinic at Christchurch Public Hospital (a tertiary centre in the South Island of New Zealand) with repeat audiometry. If there is little response and a moderate-severe hearing loss then high dose intra-tympanic dexamethasone is considered.
4. ISSHL has a mixed prognosis and many patients are left with permanent hearing loss in the affected ear.
5. There is emerging evidence that hyperbaric oxygen treatment may play a role in improving the prognosis in ASHL.
6. The study question is ‘can hyperbaric oxygen therapy in combination high dose corticosteroids (the standard treatment) improve the outcomes following ISSHL?’
7. We will recruit patients who have been referred to our department with ISSHL confirmed on pure tone audiometry. Participants will be randomised to receive either a course of hyperbaric oxygen treatment in addition to standard steroid treatment or the steroid treatment alone.
8. Researchers will measure both audiology outcomes at periods post treatment.
9. The study aims to demonstrate hyperbaric oxygen treatment to be a useful treatment for a condition which carries significant morbidity benefiting participants in the study and future patients presenting with ISSHL.

Summary of outstanding ethical issues

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

1. The Committee stated that the Researcher must confirm whether any of the data or samples being collected will also be used for Future Unspecified Research (FUR). If so, a separate PIS must be used for this, and it must be declared whether the samples and/or tissue being used for FUR are also being sent overseas.
2. The Committee stated that consultation with Māori must be completed.
3. The Committee requested more information in the PIS regarding who has access to data collected for this study, and how long that data will be accessible for.
4. The Committee stated that peer review must include greater detail in the comments from the reviewer, and that the reviewer must declare whether they are independent from the study or not.

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

1. The Committee stated that the PIS needs to be amended to include page numbers
2. The Committee stated that the PIS needs to be amended to include footers with date version number
3. The Committee stated that the PIS needs to be amended to include Māori contact numbers
4. The Committee stated that the PIS needs to be amended under the section regarding participants choosing to withdraw from the study, to state what happens with information that has been collected up until they withdraw from the study, and whether that information will still be included in the data analysis.
5. The Committee stated that the PIS should be amended to clarify whether or not the study is joining up with an Australian study.
6. The Committee stated that consent to data and tissue being sent overseas must be stated in both the PIS and the Consent Form.
7. The Committee stated that the PIS should be amended to include the participant’s right to request corrections to personal health information.
8. The Committee stated that consent to inform the participant’s GP of participation, pregnancy, or significant findings should be consistent across both the PIS and Consent Form.
9. The Committee stated that the PIS should be amended to include greater detail about what entering the hyperbaric chamber involves for participants, including, if possible, an image of the chamber.
10. The Committee stated that the PIS must be amended to include the latest ACC statement in accordance with the HDEC PIS/CF template.
11. The Committee stated that the Consent Form should be amended so that tick boxes are only present for optional parts of the study.

Decision

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

* Please confirm whether any of the data or samples being collected will also be used for Future Unspecified Research (FUR). If so, a separate PIS must be created for this, and it must be declared whether the samples and/or tissue being used for FUR are also being sent overseas.
* Please provide evidence of consultation with Māori.
* Please provide more information regarding who has access to data collected for this study, and how long that data will be accessible for.
* Please provide scientific peer review that includes greater detail in the comments from the reviewer, and declaration from the reviewer as to whether they are independent from the study or not.
* Please refer to the requested changes to the Participant Information Sheets and Consent Forms listed above.
* The Committee strongly encourages the Researcher to contact the Secretariat with any questions or queries for guidance.

After receipt of the information requested by the Committee, a final decision on the application will be made by Mrs Helen Walker and Dr Peter Gallagher.

|  |  |  |
| --- | --- | --- |
| **11** | **Ethics ref:** | **19/CEN/118** ***(Provisional Approval Response)*** |
|  | Title: | Pilot study for determining the prevalence of drug use in trauma patients in the Emergency Department |
|  | Principal Investigator: | Professor Ian D Civil |
|  | Sponsor: |  |
|  | Clock Start Date: | 11 July 2019 |

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 this study

1. When people come into hospital in the situation of a trauma call, they go through a standardised process that includes having a range of bloods taken with a single draw that is used for a range of tests. The proposal in this version of the protocol is that there is an additional sample taken for the secondary purpose of this research. The previous protocol proposed use of left over routinely collected sample at the lab but the Researchers were concerned that increased the risk of an individual being identified as samples are labelled. The idea with this protocol is that the sample would be placed in a tube without any patient identifiers before being sent to the lab.
2. The reason for this prevalence study is that nothing is known about the prevalence of the illicit substances in traumatic events as the police sampling process and existing hospital sampling process is selective and does not test for the types of drugs or levels apart from the fact that someone may have had some exposure to an illicit substance.
3. Patients will not be competent to consent at the time that this additional sample is taken for the intended use in this research.

Summary of resolved ethical issues

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

1. The Committee discussed the legal advice provided by the Researcher, and were satisfied that the advice was sound and that the proposed study is not in breach of current laws.

Decision

This application was *approved* by consensus.

## Substantial amendments

## Review of approved studies

## 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:** | 24 September 2019, 12:00 PM |
| **Meeting venue:** | Room GN.7, Ground Floor, Ministry of Health, 133 Molesworth Street, Wellington, 6011 |

The following members tendered apologies for this meeting.

* Mrs Helen Walker

1. **Problem with Last Minutes**

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

1. **Matters Arising**
2. **Other business**
3. **Other business for information**
4. **Any other business**

The meeting closed at 5:00pm.