|  |  |
| --- | --- |
| **Committee:** | Central Health and Disability Ethics Committee |
| **Meeting date:** | 24 March 2020 |
| **Meeting venue:** | Room 1S.5, Level 1, Ministry of Health, 133 Molesworth Street, Wellington |

|  |  |
| --- | --- |
| **Time** | **Item of business** |
| 12:00pm | Welcome |
| 12:05pm | Confirmation of minutes of meeting of 25 February 2020 |
| 12:30pm | New applications (see over for details) |
| 12:30 – 12:55pm  12:55 – 1:20pm  1:20 – 1:45pm  1:45 – 2:10pm  2:10 – 2:35pm  2:35 – 3:00pm | i 20/CEN/47  ii 20/CEN/50  iii 20/CEN/51  iv 20/CEN/59  v 20/CEN/61  vi 20/CEN/63 |
|  | Substantial amendments (see over for details) |
| 3:00-3:15pm | i 19/CEN/68/AM01 |
| 3:15-3:20pm | General business:  Noting section of agenda |
| 3:20pm | Meeting ends |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Member Name** | **Member Category** | **Appointed** | **Term Expires** | **Apologies?** |  |
| Mrs Helen Walker | Lay (consumer/community perspectives) | 01/07/2018 | 01/07/2021 | 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 Cordelia Thomas | Lay (the law) | 20/05/2017 | 20/05/2020 | Present |  |
| Dr Peter Gallagher | Non-lay (health/disability service provision) | 30/07/2015 | 30/07/2018 | Present |  |
| 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.

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 25 February 2020 were confirmed.

## New applications

|  |  |  |  |
| --- | --- | --- | --- |
| **1** | **Ethics ref:** | **20/CEN/47** |  |
|  | Title: | Pepi Splint Project |  |
|  | Principal Investigator: | Dr Deborah Harris |  |
|  | Sponsor: | Victoria University of Wellington |  |
|  | Clock Start Date: | 12 March 2020 |  |

Dr Deborah Harris 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. Iatrogenic skin injury in hospitalised babies is common. The majority of babies admitted to a Newborn Intensive Care Unit require a peripheral intravenous catheter (PIVC) for fluids, medication and nutrition. PIVCs (drips) are the most commonly used device in unwell babies, with many babies requiring multiple drips. PIVCs are secured to the baby’s limb using splints and adhesive dressings. Removing the adhesive dressing (elastoplast) frequently tears the fragile skin, causing pain, increasing the risk of infection and lasting skin damage.
2. Following a traumatic evident to a newborn we sought to design a product which was more situable for babies. The Pēpi Splint is made from medical silicone. It will secure the drip to the baby without the need for adhesive dressings to be applied to the baby’s skin.
3. The Researchers are proposing a proof-of-concept pilot study to determine the effectiveness and acceptability of the Pēpi Splint in 30 hospitalised newborn babies at Wellington Newborn Intensive Care Unit. If the Pēpi Splint is found to be effective, we will proceed to a randomised controlled trial. It is possible that the we will be able to considerably reduce the incidence of skin injuries in medically fragile babies.
4. The Researchers propose a step-wise investigation. The first phase is proof-of-concept pilot to determine the effectiveness and acceptability of the Pēpi Split. We will recruit 30 newborn babies > 1000g who will require a drip as part of routine treatment in the Wellington Regional Newborn Intensive Care Unit. Babies enrolled in the study will be cared for in the same way as those not in the study, with the addition of the Pēpi Splint.

Summary of resolved ethical issues

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

1. The Committee thanked the Researcher for the detailed response to the previous decision letter.

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 noted it was unclear from the information in the PIS whether the baby was the only participant or whether the parents would be participants too. The Researcher explained the baby was the primarily participant, but the parent would be asked to complete a questionnaire. The Researcher stated the primary outcome of the study is whether the splint is useful. The Committee requested a clarification to the PIS to explain this.
2. The Committee requested a revision of the PIS compensation information to refer to both the baby and parent.
3. The Committee requested information explaining who will have access to study data.
4. The Committee requested the inclusion of advocacy details ([advocacy@advocacy.org](mailto:advocacy@advocacy.org)) ) and appropriate Māori health contact to the PIS.
5. The Committee requested the inclusion of information explaining all potential risks to the PIS.
6. The Committee suggested separating the pictures into a brochure to introduce the study and keeping the PIS simple.
7. The Committee queried the statement about understanding a doctor will look at medical records. The Committee queried whether this would be the baby’s records only or the parent as well. The Researcher stated only the baby’s records would be accessed. The Committee requested this be clarified.
8. The Committee noted the wording that participants can request their baby’s data back at any time by contacting staff is quite loose. The Committee explained that parents have the right to access and correct information held about themselves and their baby. The Committee recommended the Researcher adapt the wording on the HDEC PIS template to explain this.

Decision

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

* Please update the participant information sheet and consent form, taking into account feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17).*

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.

|  |  |  |  |
| --- | --- | --- | --- |
| **2** | **Ethics ref:** | **20/CEN/50** |  |
|  | Title: | COG AALL1732 HR-B-ALL |  |
|  | Principal Investigator: | Dr Siobhan Cross |  |
|  | Sponsor: | Children's Oncology Group (COG) |  |
|  | Clock Start Date: | 12 March 2020 |  |

Ms Sara Parkin 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. AALL1732 is a Children’s Oncology Group (COG) group-wide, Phase 3 study for patients between the ages of 1 -25 years with newly diagnosed High-Risk B-lymphoblastic leukaemia (HR-B-ALL), mixed phenotype acute leukaemia (MPAL) or disseminated (Murphy stage III or IV) B-lymphoblastic leukaemia (B-LLy). Patients in this study with HR B-ALL will be stratified into HR favourable B-ALL (HR-fav) or HR B-ALL and this study will assess whether the incorporation of two blocks of inotuzumab ozogamacin (InO) into a modified Berlin-Frankfurt-Munster (mBFM) chemotherapy backbone will improve the disease-free survival (DFS) for patients with HR B-ALL.
2. There will be no randomisation for other patient groups (HR-Fav, MPAL, and B-LLy) who will receive mBFM chemotherapy with one (HR-Fav or two (MPAL and B-LLy)
3. Interim Maintenance (IM-phases) and will have DFS and event-free survival (EFS) described.

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 was an investigational drug. The Researcher stated it was a new drug that had recently been registered in New Zealand. The Researcher explained this is the time it will be used in a paediatric population.
2. The Committee queried the identifiability of samples being sent overseas. The Researcher stated that samples intended for treatment required some identifiers as a safety mechanism. The Committee requested information to the PIS explaining that some identified samples would go to the United States. The Researcher confirmed any samples not intended for direct treatment would have identifiers removed.
3. The Committee noted the application had indicated adults with intellectual disabilities could be included and queried whether incompetent adults would be recruited. The Researcher confirmed they would not and this was likely an error. The Committee explained that in New Zealand an adult cannot legally provide proxy consent for another adult.

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

1. The Committee noted the cultural statement was in some of the information sheets but not all. The Committee requested the insertion of the cultural statement into all sheets
2. The Committee requested the removal of the phrase ‘high risk’ from the induction and consolidation section of the PIS.

Decision

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

* Please update the participant information sheet and consent form, taking into account feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17).*
* Please provide written confirmation that incompetent adult participants unable to provide consent will NOT be recruited.

|  |  |  |  |
| --- | --- | --- | --- |
| **3** | **Ethics ref:** | **20/CEN/51** |  |
|  | Title: | SQUEEZE |  |
|  | Principal Investigator: | Dr Andrew Wilson |  |
|  | Sponsor: | Auckland District Health Board |  |
|  | Clock Start Date: | 12 March 2020 |  |

Dr Andrew Wilson 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. Postoperative hypotension is a common occurrence following major non-cardiac surgery, how this is treated varies nationally and internationally. The commonest treatment is intravenous fluids but occasionally an infusion of medication is required – typically the medication is from a class of drugs called vasopressors, that increase blood pressure. The receipt of postoperative vasopressor infusions has never been described and that is the focus of this study.

Summary of resolved ethical issues

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

1. The Committee noted the study was akin to a prospective audit and did not believe the Code of Health and Disability Services Consumers’ Rights would apply as the research did not involve treatment being offered.
2. The Committee queried at what stage the data would be anonymised. The Researcher stated each patient will be assigned with a study ID code and so the data would be anonymised upon entry into the database.
3. The Committee queried whether any statistics on prevalence in Māori were available. The Researcher stated this was currently unknown but as Auckland hospital has a large population of Māori, Pasifika and elderly people the study would hopefully generate information about this.

Decision

This application was *approved* by consensus.

|  |  |  |  |
| --- | --- | --- | --- |
| **4** | **Ethics ref:** | **20/CEN/59** |  |
|  | Title: | TIPS |  |
|  | Principal Investigator: | Associate Professor Peter H Sykes |  |
|  | Sponsor: | University of Sydney |  |
|  | Clock Start Date: | 12 March 2020 |  |

Associate Professor Peter H Sykes was present by teleconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. The purpose of the TIPS study is to compare the effectiveness of two different interventions given before surgery to see if they improve the time needed to recover after surgery. The two interventions being tested are a ‘carboloading’drink and pain medication called pregabalin (Lyrica ®). The study aim is to reduce the time needed to recover after surgery. The interventions are being tested in women who will undergo an operation for ovarian cancer.

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 noted the peer review and requested a copy of the reviewer’s comments along with any responses.
2. The Committee requested a clarification to the statement that the study doctor will explain a participant’s own results ‘where relevant’ to specify what results and why they may or may not be relevant.
3. The Committee noted the response to P.4.2. in the application was inadequate. The Committee advised that there are cultural considerations to be aware of when undertaking research involving human tissue, information is a taonga and there is likely to be participants with feelings of whakamā. The Committee requested the Researcher be mindful of this during the study and for future applications.
4. The Committee queried whether only women with ovarian cancer would be included or if the study was open to women with similar cancers. The Researcher explained the participant population was women having major surgery for ovarian cancer but a small number of women are operated on with suspected ovarian cancer who do not in fact have it, although this is a rare occurrence. The Committee noted the application referenced cancers of the Fallopian tubes and peritoneum. The Researcher stated from a practical point the diseases are the same and it is difficult to determine the primary origin. The Researcher explained the cancer process and treatment are the same from a clinician’s perspective. The Committee suggested including an explanation of this in the PIS.
5. The Committee queried the likelihood of a participant becoming pregnant. The Researcher stated it would be very unlikely. The Committee recommended the removal of the statement instructing participants not to become pregnant. The Researcher agreed it was a potentially upsetting statement and agreed to remove it.
6. The Committee noted there was no safety protocol to manage a participant expressing severe anxiety or depression. The Researcher stated this would be managed as per standard clinical practice and this support was important for ovarian cancer patients. The Committee was satisfied the Researcher had a support plan in place. The Committee requested the addition of a paragraph advising that if the study team is concerned about responses from the questionnaires, they will enact a safety plan and what this entails.

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

1. The Committee noted there was no consent related to samples being sent to Australia. The Committee requested information in the PIS explaining this along with a clause in the consent form for participants to agree to this.
2. The Committee requested the first page be sorted in chronological order.
3. The Committee requested the phrase ‘one or more’ on page 3 of the PIS be clarified to specify exactly how many questionnaires participants would be asked to complete.
4. The Committee requested the inclusion of a cultural tissue statement to the PIS. The Committee recommended the following statement:

“You may hold beliefs about a sacred and shared value of all or any tissue samples removed. The cultural issues associated with sending your samples overseas and/or storing your tissue should be discussed with your family/ whānau as appropriate.

There are a range of views held by Māori around these issues; some iwi disagree with storage of samples citing whakapapa and advise their people to consult before participating in research where this occurs. However, it is acknowledged that individuals have the right to choose.”

Decision

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

* Please update the participant information sheet and consent form, taking into account feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17).*

|  |  |  |  |
| --- | --- | --- | --- |
| **5** | **Ethics ref:** | **20/CEN/61** |  |
|  | Title: | IMG-7289-CTP-201 Phase 2 Essential Thrombocythemia study |  |
|  | Principal Investigator: | Dr James Liang |  |
|  | Sponsor: | INC Research Australia Pty Ltd (Syneos Health NZ L |  |
|  | Clock Start Date: | 12 March 2020 |  |

Dr James Liang and Mrs Catherine Howie were present for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. Essential thrombocythaemia (ET) is slow paced haematological cancer characterised by over production of platelets in the blood stream (the main cell in blood that forms blood clot), which leads to increase in blood clots and bleeding, resulting in premature development of strokes, heart disease and related disorder. There is 1% per year risk of transformation to myelofibrosis and acute myeloid leukaemia (respectively). The main comorbidity from ET is the blood clotting and bleeding risk from the excessive platelet production from megakaryocytes.
2. IMG -7289, a new oral agent, acts on cancer cells to make them mature into normal cells. By inhibiting LSD1, IMG- 7289 may decrease platelet number and lower cytokine (inflammatory proteins) levels. About 40 ET patients requiring platelet control that have

failed at least one standard therapy will be treated.

1. The study aims to learn the following about IMG-7289 in patients with ET:

• Its effectiveness, including changes in blood counts and disease-related symptoms

• Its safety and tolerability

• How to dose adjust IMG-7289 to have the best impact on each patient’s disease

1. This is a multi-centre, open-label study with two treatment periods that will run for 2 years:

The Initial Treatment Period is up to 24 weeks of treatment, with an Additional Treatment Period that allows qualifying patients to continue dosing for repeating 24 week treatment periods. All patients commence treatment at 0.6 mg/kg/d with up and down titrations contingent on blood counts.

1. AE's will be monitored via clinical signs/symptoms and safety labs, and pharmacodynamic (PD) effects by hematology assessments and bone marrow aspirates/biopsies. Symptom burden and quality of life will be assessed using validated instruments, the PGIC and MPN-SAF. A Safety Advisory Board meets at least quarterly.

Summary of outstanding ethical issues

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

1. The Committee queried what reimbursement would be offered to participants. The Researcher stated about $20 per visit for carparking at Middlemore Hospital. The Committee requested this be explained in the PIS.
2. The Committee requested a statement in the PIS explaining to participants they have the right to access and correct information held about them.
3. The Committee queried the likelihood of a participant becoming pregnant. The Researcher stated it was unlikely as most would have already received chemotherapy, although it was possible. The Committee stated if the study would want to follow-up a pregnant participant this would need an additional PIS. Alternatively, if the probability is very low an amendment for a pregnancy PIS could be submitted once the study has begun should a participant become pregnant.
4. The Committee requested an option on the consent form for participants to receive a lay summary of the study results when available.
5. The Committee advised the researcher that the taking of bloods had cultural implications and requested the Researcher be mindful of this for future applications. The Committee thanked the Researcher for their response to question P.4.1. in the application and for providing helpful information.

Decision

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

* Please update the participant information sheet and consent form, taking into account feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17).*

|  |  |  |  |
| --- | --- | --- | --- |
| **6** | **Ethics ref:** | **20/CEN/63** |  |
|  | Title: | Genetics of Stuttering Study |  |
|  | Principal Investigator: | Professor Lynette Sadleir |  |
|  | Sponsor: |  |  |
|  | Clock Start Date: | 12 March 2020 |  |

Professor Lynette Sadleir was present by teleconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. The present study aims to build a large sample of individuals who stutter to contribute towards a genome-wide association study (GWAS). A GWAS is the most effective way to study complex traits, like stuttering, in the general population.
2. The primary objective of the study is to perform a GWAS in individuals who stutter to identify genetic loci that are associated with stuttering.
3. A secondary aim is to gather information that delineates characteristics and impacts of stuttering (both QOL and financial) in a large population-based cohort.

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 the assent form be split into two age-appropriate versions, one for 7 – 10 year olds and the other for 11 – 15 year olds.
2. The Committee advised that any participants under 16 will need to be re-consented into the study upon turning 16 years old to comply with New Zealand law. The Committee explained this also included any samples stored for future research and participants would need to be contacted upon turning 16 years old to re-consent to this.
3. The Committee requested the inclusion of a cultural tissue statement to the PIS. The Committee recommended the following statement:

“You may hold beliefs about a sacred and shared value of all or any tissue samples removed. The cultural issues associated with sending your samples overseas and/or storing your tissue should be discussed with your family/ whānau as appropriate.

There are a range of views held by Māori around these issues; some iwi disagree with storage of samples citing whakapapa and advise their people to consult before participating in research where this occurs. However, it is acknowledged that individuals have the right to choose.”

1. The Committee noted there was no safety protocol to manage a participant expressing severe anxiety or depression. The Researcher stated they would contact the participant and ask if they would like to be referred to a psychologist in their local area. The Committee queried the scenario of if a young person wanted this, but the parents refused. The Researcher stated they would have to defer to the parent as they have no power to override them.
2. The Committee requested the addition of a paragraph advising that if the study team is concerned about responses from the questionnaires, they will enact a safety plan and what this entails.
3. The Committee requested information in the PIS explaining where samples would be sent and what would be done to them (e.g. saliva to Brisbane for DNA extraction, DNA to the Netherlands for sequencing and then storage in Melbourne).

Decision

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

* Please split the assent form into two age appropriate versions.
* Please adapt the main PIS to create a version for participants to consent to upon reaching 16 years of age.
* Please supply details of a safety protocol for managing participant distress.
* Please update the participant information sheet and consent form, taking into account feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17).*

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

## Substantial amendments

|  |  |  |  |
| --- | --- | --- | --- |
| **1** | **Ethics ref:** | **19/CEN/68/AM01** |  |
|  | Title: | whataboutme? |  |
|  | Principal Investigator: | Dr Deborah McLeod |  |
|  | Sponsor: | Mr Simon McPherson |  |
|  | Clock Start Date: | 16 March 2020 |  |

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

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

1. The Committee noted the focus group contained useful information but considered it may not be a representative sample as a hand-picked focus group may not give insight into a vulnerable population (e.g. students from decile 10 schools will likely answer differently to those from a decile 1 school). The Committee noted some participants may have had difficulty imagining the situations of those less fortunate.
2. The Committee considered the focus group also may not provide an accurate depiction of a ‘live test’ as participants were instructed that they did not have to give true answers.
3. The Committee requested the Researchers undertake the main study in older children **as instructed in the approval letter** and provide the safety data once available. The Committee stated that safety data from older children combined with the focus group could reassure it and allow it to approve the inclusion of younger participants.

Decision

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

* Please undertake the main study in older children to ensure participant safety before expanding the study to include younger participants. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 6.20).*

## 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:** | 28 April 2020, 12:00 PM |
| **Meeting venue:** | Room GN.7, Ground Floor, Ministry of Health, 133 Molesworth Street, Wellington, 6011 |

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 3:15pm.