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| **Committee:** | Northern A Health and Disability Ethics Committee |
| **Meeting date:** | 12 July 2016 |
| **Meeting venue:** | Novotel Ellerslie, 72-112 Greenlane Rd East, Ellerslie, Auckland |

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| **Time** | **Item of business** |
| 1.00pm | Welcome |
| 1.05pm | Confirmation of minutes of meeting of 14 June 2016. |
|  | New applications (see over for details) |
| 1.30pm | i 16/NTA/90  ii 16/NTA/89  iii 16/NTA/91  iv 16/NTA/92  v 16/NTA/94  vi 16/NTA/95  vii 16/NTA/96  viii 16/NTA/97  ix 16/NTA/98  x 16/NTA/99 |
| 6.00 | General business:   * Noting section of agenda |
| 6.15pm | Meeting ends |

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| **Member Name** | **Member Category** | **Appointed** | **Term Expires** | **Apologies?** |
| Dr Brian Fergus | Lay (consumer/community perspectives) | 11/11/2015 | 11/11/2018 | Present |
| Ms Susan Buckland | Lay (consumer/community perspectives) | 11/11/2015 | 11/11/2016 | Present |
| Dr Karen Bartholomew | Non-lay (intervention studies) | 13/05/2016 | 13/05/2019 | Present |
| Dr Christine Crooks | Non-lay (intervention studies) | 11/11/2015 | 11/11/2018 | Present |
| Ms Shamim Chagani | Non-lay (health/disability service provision) | 11/11/2015 | 11/11/2016 | Present |
| Dr Kate Parker | Non-lay (observational studies) | 11/11/2015 | 11/11/2018 | Apologies |
| Dr Charis Brown | Non-lay (intervention studies) | 11/11/2015 | 11/11/2018 | Present |
| Ms Rosemary Abbott | Lay (the law) | 15/03/2016 | 15/03/2019 | Present |

## Welcome

The Chair opened the meeting at 1.00pm and welcomed Committee members, noting that apologies had been received from Dr Kate Parker. The Chair noted Dr Karen Bartholomew would arrive at 2.00pm and that the meeting was quorate in her absence.

The Committee noted and agreed the agenda for the meeting.

The Committee discussed access to identifiable health information for a variety of secondary purposes to what it was collected for, for example research recruitment. The Committee discussed different recruitment strategies and the role of those who ordinarily had access to identifiable health information, but may use it for other purposes.

## Confirmation of previous minutes

The minutes of the meeting of 14 June 2016 were confirmed.

## New applications

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| **1** | **Ethics ref:** | **16/NTA/90** |
|  | Title: | The DIAMOND trial |
|  | Principal Investigator: | Mrs Tanith Alexander |
|  | Sponsor: | University of Auckland |
|  | Clock Start Date: | 23 June 2016 |

Mrs Tanith Alexander and Prof. Frank Bloomfield were present in person for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. The study investigates whether the nutritional approach taken a few days after birth in moderate pre term babies has long-term impacts on mental and metabolic health. The study aims to improve outcomes for babies.
2. The Researcher(s) explained that the babies are born between 32 and 36 weeks gestation, only a few weeks early. The standard of care is to try and establish breast milk feeding with the aim to have only have breast milk by the time they go home. However, it takes time for babies to start feeding on breast milk, sometimes several days though it could be up to a week or more. This is for a variety of reasons – primarily related to the immaturity of the babies. Their gut may not be developed so they can’t tolerate milk, or they have not developed sucking mechanisms that can manage swallowing and breathing, or risks of aspirating milk into their lungs. Until the babies are ready they need some form of supplementary feeding, and the method of early feeding is in equipoise among both New Zealand clinicians and international guidelines.
3. The Researcher(s) explained that some consultants use a 10% dextrose that is rubbed into the gums of babies, others use intravenous nutrition and others use breast milk or a milk formula.

Researchers explained the approach to nutritional feeding for preterm babies varied between consultants. It is not known what the optimum approach is.

Summary of ethical issues (resolved)

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

1. The Committee queried if babies are assigned to arms of the study or whether consultants choose and the study data is only observed. The Researcher(s) stated randomisation occurs to avoid bias in study results.
2. The Committee queried whether there are any babies who don’t get treatment in this study. The Researcher(s) stated all babies get one of the treatments in equipoise, and if a certain type of treatment is determined to be clinically required the baby would not be randomised, but they would inevitably get one of the three types of nutrition in this study.
3. The Researcher(s) added they are also adding smell and taste to those having IV treatment feeding, as a sub study, by breast milk being added to cotton buds and wiped on the baby’s face and nose prior to feed.
4. The Researcher(s) confirmed no samples sent overseas. Samples are stool and saliva.
5. Confirmed no samples stored beyond duration of study.
6. The Committee queried the consenting process, noting the acute context. The Researcher(s) stated they will try in all cases to speak to mothers before they go into labour, adding some potential participants can give consent before labour due to pre-admission.
7. The Researcher(s) explained that there was a cohort who delivers very quickly, as they come into hospital and are directed straight to the delivery suite. The Researcher(s) felt it was not appropriate to talk to this group before delivery, however they will seek consent after their baby had been born. In these cases families are given time to discuss with family or whanau. This period is about 24 hours. The Researcher(s) then come back to the family and seek their consent. Anecdotally, this method works effectively, and balances respect for the family as well as the acute nature of feeding.
8. The Researcher(s) noted it was important not to exclude this group of women, whose babies may have particular feeding needs.
9. The Committee queried if there was a potential conflict of interest if the individual’s treating physician was also the recruiting researcher. The Researcher(s) stated often the recruiting individual was a clinical fellow or part of the research team, though acknowledged it could be an attending consultant on occasion, though past experience suggests the conflict is managed as they will not approach if there is a medical reason not to recruit, and that participation is voluntary and the arms are in equipoise.
10. The Researcher(s) explain other studies have reviewed the consenting process used in this study and none of the respondents have raised a problem with the proposed process (in particular of those who decline).
11. The Committee asked about Maori children who are preterm, in terms of prevalence. The Researcher(s) stated that Maori experience an increase of preterm babies at about 0.5 percent compared to non-Maori.
12. The Researcher(s) stated they consult with Maori research advisor at ADHB and Waitemata, as well as with Auckland University. The Researcher(s) explained that they have Maori research nurses who both help with recruitment as well as playing a big part in the follow up phase. The Researcher(s) added prior research experience in this context show no difference in recruitment rates between ethnicities.

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

1. The Committee noted that it is not very clear in participant documentation that there are 8 factor groups - maybe add a table (like the one in the protocol) or some better explanation of this for participants.
2. The Committee noted that the Health Research Council reviewers noted that maternal environment doesn't seem to have been included in measures as a confounder, and asked about the collection of health information collected. The Researcher(s) stated they are looking at these variables. The Committee requested that if health information was to be used it should be clearly stated in the Participant Information Sheet.
3. Remove non-optional yes or no statements from the consent form.
4. Needs a bit more info on the tests on the sample, where samples are kept (ie going overseas?) and how long for.

Decision

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

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| **2** | **Ethics ref:** | **16/NTA/89** |
|  | Title: | CLIP Study |
|  | Principal Investigator: | Dr Shay McGuinness |
|  | Sponsor: |  |
|  | Clock Start Date: | 30 June 2016 |

Dr Shay McGuinness 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 study investigates whether cryo-preserved blood platelets (clotting agent) works as well as fresh blood platelets.
2. The Researcher(s) explained why there is a clinical need for stored platelets, particularly in rural areas in New Zealand.
3. There are 90 participants in total, with 20 recruited from New Zealand, and the remainder in Australia.
4. The Researcher(s) explained the military clinical use from Bosnia and Afghanistan, in some 1000 civilian patients, with success. These were primarily in a younger population and in trauma contexts, adding there was a small trial with 70 participants too.
5. The Researcher(s) explained that the study was primarily driven by Australian military intensive care specialists and is funded in part by their defence force, however New Zealand Blood Service has an interest in terms of rural use of platelets.
6. The Researcher(s) explained that this is, to an extent, a pilot in pre-op patients who can provide consent. Once more efficacy for the frozen platelets is established, and safety, in patient group who can consent without time duress, a larger randomised trial in a trauma context may be conducted.

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) stated there are two potential risks. The first is that the frozen platelets might not work as well as a clotting agent as the fresh platelets. The Researcher(s) stated monitoring the amount of clotting and amount of bleeding after heart surgery would minimise this risk. The second risk is that they may actually work better, and may theoretically result in more clots forming than desired. Because they use platelets in actively bleeding patients this is not considered a big risk, but to minimise risk they will conduct DVT scans to make sure no undesired clots.
2. The Researcher(s) explained risk overall is minimised by only recruiting patients who already need platelets. Of all recruited participants about one third will require platelets.
3. The Researcher(s) explained that the platelets are manufactured in New Zealand by the blood bank, so the donor blood related risks are the same between arms of the study.
4. The Researcher(s) confirmed that a research nurse conducts the consent process and is not involved in clinical care, but are involved in follow-up.
5. The Researcher(s) explained why the peer review was from 2013. The issue related to capacity to have the freezers, and Australian hold ups due to the process of freezing platelets.
6. The Committee queried the blinding process. The Researcher(s) explained that participants are blinded, and the clinician is blinded as best as possible, as well as the research nurses being blinded during follow up.
7. The Researcher(s) confirmed un-blinding procedures in place.
8. The Researcher(s) confirm no half-life considerations for platelets and therefore no need for long term follow up.
9. The Researcher(s) confirm patients with high risk of DVT are excluded.
10. The Committee queried if the plan was to conduct a safety review after 50% might all New Zealand patients be recruited and treated prior to the first safety review. The Researcher(s) noted theoretically yes we could have 1/3 of the first 50%.
11. The Committee requested there is a safety review for New Zealand group, for instance 10 patients, then following 10. The Researcher(s) stated the main risk is DVT clots and these would be screened post-surgery, so we will know major risks for certain – but acknowledged importance of monitoring.

Summary of ethical issues (outstanding)

The main ethical issues considered by the Committee and require addressing:

1. The Researcher(s) noted a conversation between SCOTT and the Blood Service was ongoing. The Committee asked for an outcome from this discussion.

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

1. Explain what it means for the study to be blinded.

Decision

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

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| **3** | **Ethics ref:** | **16/NTA/91** |
|  | Title: | KEEP IT |
|  | Principal Investigator: | Dr Derisha Naicker |
|  | Sponsor: | University of Otago Christchurch |
|  | Clock Start Date: | 30 June 2016 |

Dr Derisha Naicker 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 study assesses children and their family’s experience of the end to end process of kidney transplants at Starship hospital.

Summary of ethical issues (resolved)

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

1. The Committee queried why the study involved 6 year olds. The Researcher(s) explained they have transplants at Starship from 1 year of age to 15 years. Decided not to go 1-5 year old. These patients can however have a good understanding of what is going on. They considered could ask the right questions of these are younger children as well as their family.
2. The Researcher(s) anticipated an ethical issue, as the Co-ordinating Investigator may be treating some participants. In an effort to mitigate the conflict a nurse practitioner will lead the interviews, and the CI will only be there as a support person.
3. The Researcher(s) explained transcripts are written from the interviews, and then de-identified. An investigator who is independent from the patient will always review these transcripts to further mitigate conflict. The Committee suggested the transcripts did not need to be de-identified, as it would be important to match with clinical outcomes.
4. The Committee noted the potential for an acute or stressful context of recruitment. The Researcher(s) state they are not approaching any potential participants in an ICU setting. Instead, participants will be approached a few months after the transplant. There is no urgency to consent.
5. The Researcher(s) explained they also have psychologist on study team with experience with these families. This researcher will be in interviews as a means to further mitigate potential vulnerability.
6. The Committee requested health information is stored for 10 years after each child turns 16 as per Health Information Retention regulations.
7. The Committee asked about support for Maori and Pacific Island participants. The Researcher(s) explained that Maori health workers are available for the consenting process, as well as during the interviews. Support is available from the very beginning.
8. The Researcher(s) explained the expression of interest process and the overall recruitment process.
9. The Researcher(s) confirm ethnicity collected in line with census categories.
10. The Committee noted that the researchers should be careful drawing conclusions from such a small sample size, with potentially small geographic or ethnic samples. The Committee and The Researcher(s) discussed qualitative research methods. The Committee suggested thematic analysis, critical theory.
11. The Committee queried how potential participants identified. The Researcher(s) stated all transplant patients are on a database that will be used to recruit. The Committee requested a clinician contact initially rather than researchers accessing identifiable health information.
12. The Committee note important to contextualise any experiences due to small sample size.
13. The Committee queried process for following care (referral, follow up), resulting from alerts or risks identified during interviews. The Researcher(s) explained referrals and support during the interviews.

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

1. Add when researchers will approach participants post-transplant.
2. The Committee queried the process for including children from the far north, in terms of facilitating their participation. The Researcher(s) stated they would try work around clinic visits to reduce burden of participation. The Committee requested this is included in Participant Information Sheet.
3. Perceptions and experiences of kidney transplant etc. Could some of these be identified in the Participant Information Sheet to give participants an idea of what to expect?  
    The Researcher(s) confirmed they would add some examples.
4. Add pictures for assent documents.
5. The Committee noted the application involves access to patient notes. The Committee stated this data could be sought from the participants, and the general information about health information was not very clear in Participant Information Sheet. The Committee noted it should be clear in the Participant Information Sheet about what data, what it is used for, storage etc.
6. The Committee requested the researchers both have a guidance or information on Participant Information Sheet in event of referral or support, and also suggested the researchers formalise the process with a protocol.

Decision

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

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| **4** | **Ethics ref:** | **16/NTA/92** |
|  | Title: | Safety and Efficacy of suvorexant (MK4305)for the treatment of insomnia in AD subjects |
|  | Principal Investigator: | Dr Nigel Gilchrist |
|  | Sponsor: | Merck Sharpe and Dohme Austtralia |
|  | Clock Start Date: | 30 June 2016 |

Dr Nigel Gilchrist and a sponsor representative 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 Chairperson asked the Co-ordinating Investigator whether the meeting needed to be closed, as requested in the ethics application. The Researcher(s) stated that they were happy for the meeting to remain open.

Summary of ethical issues (resolved)

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

1. The Committee queried if all participants can consent for themselves. The Researcher(s) stated yes, most have mild Alzheimer’s disease (AD). If an individual cannot consent they are not recruited.
2. The Committee noted increased sleep time reported from prior trials, but noted the increased sleep time seemed low. The Researcher(s) stated that 3 overnight sleep studies should be able to more accurately look at the increased time sleep.
3. The Committee queried the questionnaires noting that they are alarming, for example the questions about suicidal ideations. The Researcher(s) explained that such questions are part of all questionnaires undertaken by those taking dementia and Alzheimer’s drugs. This is because such questions are a measure of progression of Alzheimer’s.
4. The Committee queried if this drug is only option, or if there are alternatives. The Researcher(s) stated there are other medical options for increased sleep, but AD patients often have side effects from medications, which makes their choices limited.
5. The Committee noted it was important to keep AD patients off sedatives but get them sleep. The Researcher(s) confirmed this is a goal for treating AD patients, and stated this treatment method supports this goal.
6. The Committee noted in Participant Information Sheet does not contain much information about previous trials. The Researcher(s) stated there is not much data from prior trials.
7. The Committee queried whether this drug been tested enough on healthy participants, before testing on AD patients. The Researcher(s) noted it has been available for use in United States and Japan. However in AD patients the evidence is lacking, which is what this study aims to address.
8. Please review for overuse of interchanging references (trial partner and participant).
9. The Committee ask if SCOTT review received. The Researcher(s) have submitted it but not received approval yet.
10. The Researcher(s) explained when the questionnaires are administered.
11. The Researcher(s) confirmed that if an individual can’t continue to provide valid consent, they would be withdrawn. This relates to any concurrent condition or AD.
12. The Committee ask if there are cognitive tests to check ongoing eligibility. The Researcher(s) sated there are a number of memory and functional tests throughout the study. Participant and caregiver complete these tests, and they give a very good measurement about whether patient is getting better or worse.
13. The Researcher(s) stated samples stored in a lab in Singapore and are only used by the sponsor at that lab. The samples are not sent elsewhere.

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

1. The Researcher(s) stated that for future unspecified research Participant Information Sheet the gene testing is actually restricted to Alzheimer’s disease. The Committee noted this needs to be clearly specified.
2. The Committee queried why caregiver consents for use of their health data. Why does trial partner need to provide access to his or her own health data? The Researcher(s) confirmed they are not doing any health research on the partner; it is just the opinions of the partner on the partners sleep. The Committee request this statement is amended.
3. Clarify where samples are going overseas.
4. Main Participant Information Sheet has no standard length of time for storage of tissue; add length and place of storage, and ensure the future unspecified research Participant Information Sheet and main Participant Information Sheet are consistent.

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*).

This following information will be reviewed, and a final decision made on the application, by the Secretariat.

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| **5** | **Ethics ref:** | **16/NTA/94** |
|  | Title: | Comparison of the blood levels of two forms of alitretinoin 30 mg capsule in healthy male volunteers under fed conditions |
|  | Principal Investigator: | Dr Noelyn Hung |
|  | Sponsor: | Douglas Pharmaceuticals America Ltd |
|  | Clock Start Date: | 30 June 2016 |

Dr Noelyn Hung, Ms Linda Folland and Dr Tak Hung 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. A bioequivalence study on a drug, one in the standard branded form, the second a non-branded version.
2. Single dose, washout 1 week between the two treatments
3. 30 healthy volunteers
4. Peer review in order

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

1. The Committee asked why participants needed to inform insurance company of HIV test (Page 7). The Researchers stated it was a prior ethics requirement. The Committee were unsure why HDEC would ask this. Please email the HDEC Secretariat information about this request at [hdecs@moh.govt.nz](mailto:hdecs@moh.govt.nz)
2. Add side effects details, and make sure they are clear, for example in a table. Page 6 of 12.

Decision

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

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| **6** | **Ethics ref:** | **16/NTA/95** |
|  | Title: | Comparison of the blood levels of two forms of phentermine 40 mg in healthy male and female volunteers under fed conditions |
|  | Principal Investigator: | Dr Noelyn Hung |
|  | Sponsor: | Juno PC Holdings Pty Ltd |
|  | Clock Start Date: | 30 June 2016 |

Dr Noelyn Hung, Ms Linda Folland and Dr Tak Hung 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 is being conducted to determine whether the same amount of the drug is absorbed into the bloodstream from each of the two dosage forms
2. Peer Review in order

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

1. The Committee asked why participants needed to inform insurance company of HIV test (Page 7). The Researchers stated it was a prior ethics requirement. The Committee were unsure why HDEC would ask this. Please email the HDEC Secretariat information about this request at [hdecs@moh.govt.nz](mailto:hdecs@moh.govt.nz)
2. The Committee noted the comparator drug contains lactose and queried whether this be a problem for some participants. The Researcher(s) state we ask if they are intolerant, but even so, at such a small dose probably no risk.
3. The Committee noted phentermine is stated to reduce body weight – it is more accurate to call it an appetite suppressant.
4. The Committee asked whether a one off dose would return a positive result in drug test. The Researcher(s) noted it would. The Committee requested this is clearly stated.

Decision

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

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| **7** | **Ethics ref:** | **16/NTA/96** |
|  | Title: | The Chocolate Touch Study |
|  | Principal Investigator: | Associate Professor Dr Andrew Holden |
|  | Sponsor: | TriReme Medical LLC |
|  | Clock Start Date: | 30 June 2016 |

Associate Professor Dr Andrew Holden 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. Phase III study of a new stent design.
2. The Researcher(s) explained the design history of the Chocolate stent.
3. The design is the same as earlier phase II study, but randomising with a commercially available (in United States) drug coated balloon. This is designed as a non-inferiority study looking at safety and efficacy. The trial designed so that statistically it could show superiority if desired.
4. This is a 5-year trial. Follow-ups are standard – ultrasound up to 3 years and then phone calls.
5. The Committee commended the Participant Information Sheet.

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

1. The Researcher(s) confirmed comparator is available for use in New Zealand but not the standard of care at Auckland.
2. The Committee noted there is no need for the actual questionnaire names.
3. The Committee noted risks section on page 5 contains jargon. Please review, use lay language, or explain what the terms mean.
4. The Committee commended boxes, but adverse events and serious adverse events need explanations.
5. Add the imaging information to Participant Information Sheet.
6. Suggest practical explanation on confidentiality – what this means for Participant Information Sheet; ‘what are standards’ or applicable laws.

Decision

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

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| **8** | **Ethics ref:** | **16/NTA/97** |
|  | Title: | BIOSOLVE-IV |
|  | Principal Investigator: | Prof Mark Webster |
|  | Sponsor: | BIOTRONIK Australia Pty, Ltd |
|  | Clock Start Date: | 30 June 2016 |

Miss Nicole Sommerville 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 study will involve post market surveillance of a dissolvable stent.
2. The stent is not experimental however it is also currently not offered or available to patients outside of the study. Therefore participation in the study involves receiving the stent, as well as involvement on long-term follow up registry.
3. The Researcher(s) explained this is effectively a phase IV study as this stent has a CE mark, adding the stent is available in New Zealand (or will be very soon).

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) noted the angiographic inclusion exclusion criteria.
2. The Researcher(s) explained that the European sponsor not collecting any ethnicity (at all).
3. The Committee do not accept cancelling any study purely due to commercial interests, as per National Ethics Advisory Committee Guidelines for Intervention Studies.

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

1. Add more information on the study purpose, to make it clear that this is a post market review that the stent is currently not available for clinical use in New Zealand but it is also not experimental.
2. The Committee noted the importance to differentiate between about the register / database and the stent and procedure.
3. Review jargon. Either replace with lay language or provide explanations.
4. The Committee noted that the angiogram goes overseas if something goes wrong, this is not standard. Add more information on this process, and add that the study sponsor is overseas.
5. Compensation page 5 – require remove statements that limit sponsor liability. New Zealand ethical standards require ACC equivalent compensation for commercially sponsored intervention studies.
6. The Researcher(s) confirmed the blood test is discarded. The Committee requested that information about tissue and destruction added to Participant Information Sheet.

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*).

This following information will be reviewed, and a final decision made on the application, by Secretariat.

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| **9** | **Ethics ref:** | **16/NTA/98** |
|  | Title: | A two-arm, randomised, parallel group study to evaluate the effect of fluticasone/formoterol breath actuated inhaler (BAI) or Relvar® Ellipta® DPI on ventilation heterogeneity in asthma |
|  | Principal Investigator: | Dr Andrew Veale |
|  | Sponsor: | Pharmaceutical Solutions |
|  | Clock Start Date: | 30 June 2016 |

Dr Carole Veale 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 study aims to investigate the benefit of fluticasone/formoterol taken via a breath actuated inhaler (BAI) on patients with partially, or poorly controlled asthma. It also aims to compare its efficacy against another inhaler, Relvar® Ellipta® DPI.

Summary of ethical issues (resolved)

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

1. The Researcher confirmed that ethics approval has been received overseas.
2. The Researcher explained the differences between inhalers, including the benefits and issues with available treatments.
3. This study involves a combination of products that are available internationally but not in New Zealand.
4. The Researcher(s) discussed measures to maintain the blind.
5. The Researcher explained the Maori consultation plan.

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 further information on the sponsor. Please provide an overview of the sponsor.
2. Provide more information on termination of the study. The Committee noted that National Ethics Advisory Committee guidelines prohibited termination of research for purely commercial reasons.

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

1. The Committee noted the very lengthy Participant Information Sheet. Please simplify and reduce length of the document. Use tables where possible and review for lay language.
2. The Researcher explained what the future unspecified research involves. The Committee noted that if the area of research limited please state so and if not then be clear about it.
3. Reduce length and complexity of the confidentiality and compensation sections. The Committee noted that the National Ethics Advisory Committee ethical guidelines required ACC equivalent compensation for participants in commercially sponsored clinical trials. Therefore no limiting statements should be present in the participant information.
4. Specify location of storage of tissue overseas (Germany).
5. Add a title on the optional PIS to make it clear what the document is for.
6. Make the fact that the future unspecified research is optional very clear.
7. Include the following statement(s):

You may hold beliefs about a sacred and shared value of all or any tissue samples removed. The cultural issues associated with sending your samples overseas and/or storing your tissue should be discussed with your family/whanau as appropriate. There are a range of views held by Maori around these issues; some iwi disagree with storage of samples citing whakapapa and advise their people to consult prior to participation in research where this occurs. However it is acknowledged that individuals have the right to choose.

Or when GENETIC analysis is being done use the following:

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, storing your tissue samples and or undertaking genetic analysis on them should be discussed with your family/whanau as appropriate. There are a range of views held by Maori around these issues; some iwi disagree with storage of samples and genetic testing citing whakapapa and advise their people to consult prior to participation in research where this occurs. However it is acknowledged that individuals have the right to choose.

Decision

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

* Please provide criteria for study termination. (*Ethical Guidelines for Intervention Studies* *para 6.64*).
* 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 Dr Charis Brown and Ms Rosemary Abbott.

|  |  |  |
| --- | --- | --- |
| **10** | **Ethics ref:** | **16/NTA/99** |
|  | Title: | (duplicate) Study to Improve Adherence to Type 2 Diabetes Oral Medications Through Personalised Multi-Channel Interventions |
|  | Principal Investigator: | Dr Jodie Main |
|  | Sponsor: | PHARMAC |
|  | Clock Start Date: | 30 June 2016 |

Dr Jodie Main and Mr Andrew Beszant 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 Committee noted the prior decline from the Northern B HDEC and noted the responses to the conditions outlined in the letter.
2. The Committee noted the importance of medication adherence.

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 new consenting process.
2. A list of possible participants is compiled within the GP practice
3. The list of patient information contact details is then sent to Atlantis to make contact.
4. A nurse will then make contact with the individual, just to seek whether they would be interested to participate (not a consent process).
5. If the patient is interested the researchers sent out Participant Information Sheet. If not there will be no further contact. The Researchers give patients time to consider participation, including up to a week with the written information.
6. Then, there will be a follow up call from registered nurse who will go through the programme and offer enrolment. The potential participant can then verbally consent or decline participation.
7. The Committee noted the new consenting process, and stated it largely met the requirements set out in the prior decline.
8. The Committee noted that the protocol had not been updated, and would need to be updated with tracked changes in order for approval to be given. Please provide an updated protocol. The Committee noted that the researchers did not need to update their ethics application, as this is locked, but did need to provide the new protocol.
9. The Committee accepted that the prior participants could be re-consented, provided they were fully informed about what had occurred so far with respect to the lack of ethics review and the changes in consenting. The Committee noted participants had been enrolled without a proper consent model , which is serious, and should be clear to participants.
10. The Committee asked about the control arm, who are these participants? The Researchers explained that the Ministry of Health are matching data for us, and they will not disclose any identifiable health information to us.
11. The Researcher(s) confirmed they hold identifiable information in a New Zealand database.

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 the changes to the consent process, but asked for further information about how participants were identified, and who made the initial contact.
2. The Researcher(s) noted GP practices are involved. Once the GP agrees to be involved they will go through process of producing list of people on oral medications on diabetes who would be eligible for the study.
3. The identification also uses the electronic prescribing service. An extract from the EPS is matched with eligibility criteria. The practice will screen the list of patients and remove any that they believe should not be recruited.
4. The Committee ask how sending GP data to Atlantis is supposed to work, as this information is collected for clinical purposes, not research recruitment. The Researcher(s) stated that a PHO can send data to other parties if it is in the individual’s best interest.
5. The Researcher(s) made case for use of data disclosure without consent by citing the impracticality of asking the PHO to make the initial contact, stating that the programme could not be rolled out nationwide if the PHO had to make first contact. They added that flyer advertising would not an effective recruitment method for this study.
6. The Committee noted that disclosure of health information without consent requires a justification to be made, and should only occur if there are no alternative means to recruit. The Committee requested evidence of the method described above to be the only option to recruit, and if this is so, a case should be made with regards to the following considerations (in line with the Health Information Privacy Code and the National Ethics Advisory Committee Guidelines):

Identifiable health information can be considered for release without individual authorisation provided conditions are met by the health information privacy code:

(1) A health agency that holds health information must not disclose the information unless the agency believes, on reasonable grounds, that—

(c) the information—

(i) is to be used in a form in which the individual concerned is not identified;

or

(ii) is to be used for statistical purposes and will not be published in a form that could reasonably be expected to identify the individual concerned;

or

**(iii) is to be used for research purposes (for which approval by an ethics committee, if required, has been given) and will not be published in a form that could reasonably be expected to identify the individual concerned;**

**(c)(iii) Disclosure for research purposes**

When an agency is approached by a researcher seeking the disclosure of health information, it first needs to satisfy itself that ethical approval has been obtained (if required) and that the information will not be published in a form that could identify any individual. The agency being asked to disclose information will probably also want to be satisfied as to security safeguards and the manner of approach to the individual (if any). These issues should be anticipated by the researcher and addressed expressly within the protocol, with the ethics committee and in the approach to the agency. A researcher should also anticipate any disclosures inherent in a research proposal and address those in the protocol for the ethics committee’s consideration. The committee may wish to place conditions on the use or disclosure of the information.

(h) the disclosure of the information is required—

(i) for the purpose of a professionally recognised accreditation of a health or disability service; or

(ii) for a professionally recognised external quality assurance programme; or

(iii) for risk management assessment and the disclosure is solely to a person engaged by the agency for the purpose of assessing the agency’s risk.

If a case is to be made, below is the justification required:

The use of health records for research without the authorization of the individual concerned should only be undertaken subject to certain extra condition(s) - though I note you don't need to meet all of them.

**Justification –scientific**

The reasons for not seeking consent should be justified to the ethics committee. These reasons may be scientific, practical or ethical.

The main scientific reason for not seeking consent to use health records for research is that failing to locate individuals to seek their consent may lead to less complete ascertainment of cases for study, and therefore possibly a biased (and hence incorrect) result. This is because the people who are hard to locate may differ in their health problems or the outcome of their treatment from those who are easy to locate.

**Justification - practicality**

Another reason for not seeking consent is practical. Sometimes access to records is required in order to determine who will be potential participants in a study. The researcher must identify the names of individuals with a certain condition prior to approaching the individuals to seek their consent to take part in the study.

It is usually impracticable for the individual’s own doctor to seek his or her patient’s consent for the release of the name to the researcher, because the records will not usually be held by the individual’s own doctor, but will be held by hospitals or disease registries. Other practical difficulties occur when there are very large numbers of records and many of the individuals may be untraceable or deceased.

**Justification – undue anxiety**

In some situations the process of seeking consent may cause undue anxiety or distress to individuals. This might arise where researchers were investigating a tentative link between an exposure and a serious disease.

An example is a study in New Zealand of the use of an asthma drug as a possible cause of sudden deaths from asthma. This study compared the medical records of individuals who had died from asthma with records of asthmatics who had been admitted to hospital but had not died. It would have been wrong to have sought the consent of the group who had not died, because informing these people of an untested hypothesis might have frightened and distressed them without good cause.

**If a justification has been made there must also be benefit:**

The potential benefits of the research must be described to the ethics committee, which must weigh up these potential benefits against the loss of privacy.

The potential benefits of the research may include a contribution to the identification, prevention, or treatment of illness or injury, scientific understanding relating to health, the protection of the health of individuals or communities, or the improved delivery of health services. The loss of privacy may be regarded as more important for very sensitive information, for instance termination of pregnancy, or genetic information that might have implications for other individuals.

**NEAC Guidelines state that use without consent is justifiable when:**

a) the procedures required to obtain consent are likely to cause unnecessary anxiety for those whose consent would be sought; or the requirement for consent would prejudice the scientific value of the study; or it is impossible in practice to obtain consent due to the quantity or age of the records; **and**

b) there would be no disadvantage to the participants or their relatives or to any collectivities involved; **and**

c) the public interest in the study outweighs the public interest in privacy.

Please make a case considering the above advice.

1. Earlier this year the committee reached a decision on a process used in another application by another researcher. Namely, the GP practice developed the list. The GP practice then sent a text message to the possible participant asking their permission to send their name and contact details to a third party who would contact them regarding participation in a trial – and asking the recipient to say Yes or No. If Yes, then the third party contacts the participant and starts the information sharing and enrolment and consenting process. Please consider this alternative route and provide justification for your decision on the route you have chosen as per the discussion in 19 above and the points below. This process maintains the confidentiality of patient info until they have given consent.

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

1. Please add more information on health information, and similarly confidentiality of information. Some suggestions include where data is held (Australia). Clarify what is meant by all in line with New Zealand law. The Committee suggest refer to HIPC.
2. The Committee noted the use of blood results and the plan to ask GPs to consent for this optional test. The Committee stated that participants must consent to this themselves. Please add to Participant Information Sheet. If optional, state it and allow the ability to opt out.

Decision

The decision is in two parts.

1. The Committee is generally satisfied the researchers have attempted to present new information because of the prior decline. Hence, the Committee approves the re-contact with those already enrolled in the study to obtain their re-consent.
2. With regard to the recruitment of new participants, 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*).
* Make a case for use of health information for study recruitment purposes (secondary use) without individual authorisation, or an alternative means of recruitment. Please email this to [hdecs@moh.govt.nz](mailto:hdecs@moh.govt.nz) for checking prior to formal submission through online forms.
* Once a process has been agreed to by the Committee, update the Protocol and resubmit formally.

This following information will be reviewed, and a final decision made on the application, by Ms Susan Buckland and Dr Karen Bartholomew and Dr Brian Fergus.

## 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:

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| --- | --- |
| **Meeting date:** | 09 August 2016, 01:00 PM |
| **Meeting venue:** | Novotel Ellerslie, 72-112 Greenlane Rd East, Ellerslie, Auckland |

1. **Problem with Last Minutes**

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

The meeting closed at 6.30pm