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| **Committee:** | Northern A Health and Disability Ethics Committee |
| **Meeting date:** | 14 July 2015 |
| **Meeting venue:** | Novotel Ellerslie |

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| **Time** | **Item of business** |
| 1.00pm | Welcome |
| 1.05pm | Confirmation of minutes of meeting of 09 June 2015 |
| 1.30pm | New applications (see over for details) |
|  | i 15/NTA/79  ii 15/NTA/81  iii 15/NTA/83  iv 15/NTA/84  v 15/NTA/85  vi 15/NTA/86  vii 15/NTA/87  viii 15/NTA/88  ix 15/NTA/89 |
| 5.15pm | General business:   * Noting section of agenda |
| 5.30pm | Meeting ends |

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

## Welcome

The Chair opened the meeting at 1.00pm and welcomed Committee members, noting that apologies had been received from Mr Mark Smith and Ms Michelle Stanton.

The Chair noted that it would be necessary to co-opt members of other HDECs in accordance with the SOPs. Ms Kate O’Connor confirmed her eligibility, and was co-opted by the Chair as member of the Committee for the duration of the meeting.

The Chair welcomed Ms Philippa Bascand, the HDEC manager, who was in attendance.

The Chair welcomed Ms Helen Wihongi, Māori Advisor – Research, Auckland and Waitemata DHBs, who discussed Maori and research prior to the meeting.

The Chair noted that the meeting was quorate.

The Committee noted and agreed the agenda for the meeting.

## Confirmation of previous minutes

The minutes of the meeting of 09 June 2015 were confirmed.

## New applications

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| **1** | **Ethics ref:** | **15/NTA/79** |
|  | Title: | Clinical outcomes of a cohort of patients presenting to an emergency department with sepsis: relationship to patient, staff and family/whanau understanding of disease |
|  | Principal Investigator: | Dr Paul Huggan |
|  | Sponsor: |  |
|  | Clock Start Date: | 19 June 2015 |

Dr Paul Huggan 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

* The Committee discussed observational research and right 7(4) of the Code of Rights.
* The Committee noted that the study is a hypothesis generating pilot study that aims to identify awareness of sepsis. The researchers plan to compare outcomes and pathways to hospital with the level of knowledge of sepsis.
* The Committee noted that the study is essentially a feasibility study.
* The patient group are patients presenting to emergency departments and next of kin.

Summary of ethical issues (resolved)

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

* The Committee queried whether all participants could consent for themselves, noting that no one can consent to any research on behalf of another in New Zealand. Even if a participant had an EPOA the research must meet right 7(4) of the code of rights. Dr Huggan stated that the next of kin are providing anonymous survey responses. The Committee noted that the survey information would not be anonymous. Dr Huggan accepted this point.
* The Committee requested more information on the study design, noting that the consent processes, who the participants were and how the study aims to generate knowledge on a relationship between sepsis knowledge and hospital pathways was unclear.
* The Committee requested that any mention of proxy consent is removed from the study. Dr Huggan confirmed that patients who were very unwell would not have their next of kin provide proxy consent.
* Dr Huggan clarified that the survey information that next of kin filled out was only about general knowledge and awareness of sepsis. This part of the study was not related to clinical details or linked to health information.
* Dr Huggan stated that not approaching those who were too sick to provide consent simplified the study. The Committee agreed that excluding these patients was appropriate.
* The Committee suggested looking at research on ambulatory sensitive hospitalisation (including in Waikato) for more information and guidance on researching pathways to care.
* Dr Huggans confirmed that Maori consultation had occurred and that a letter confirming this was submitted with his application to ethics.
* The Committee requested that Maori health advisor contact details are put at the back of the PIS.
* The Committee suggested that informing the GP of study participation was not necessary for this study (R.1.2). Dr Huggans agreed.
* The Committee noted that there were some inconsistencies in the application form, particularly relating to whether the survey information would be linked to NHI data or not. Please be consistent in future applications.

Summary of ethical issues (outstanding)

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

* The Committee requested that ethnicity data is collected using the Ministry of Health Ethnicity Data Protocols: <http://www.health.govt.nz/publication/ethnicity-data-protocols-health-and-disability-sector>. Using this collection method ensured national consistency and appropriate categories for a New Zealand context.
* The Committee stated that study data should not be stored in an identifiable form (R.2.4).
* The Committee queried whether there was a sponsor for the study (A.5.8). The Committee explained that the DHB might be the sponsor, adding that it was aware it was a locality. Please check with the DHB research office.
* The Committee requested a PIS/CF for the other participant groups in the study – particularly the next of kin, the control group and those patients who are well enough to participate themselves. The Committee added that for those who are well enough, you can include information on assessing outcome data and have them consent to this access, which allows the research to link data.
* The Committee stated that if the researchers wanted to gain an understanding of a sample of the general populations awareness of sepsis it would be better to conduct an anonymous survey. This option avoids the need to link health information to the control group.
* The Committee queried the role of the control group and requested a further justification of the control group. Dr Huggan stated it was intended to be age-matched patients that were in ED at same time as the patients with sepsis. It aimed to show whether sepsis knowledge impacted outcomes compared to those in ED for other reasons. The Committee noted that these patients should provide consent for their data to be accessed for research purposes.
* The Committee suggests limiting the study to sepsis patients, their own reported level of understanding and their pathway to hospital and refrain from comparing this group against a population control group
* The Committee noted that a PIS is only needed for sepsis patients if the study is limited as described and suggested by the Committee.
* The Committee explained that given that this is hypothesis-generating piece of work it would be inappropriate to compare awareness of sepsis with outcomes between the two groups as it may result in stigmatisation. This is because the research scope does not address other factors that will be relevant, such as socio-economic factors, access to primary care, quality of primary care and health literacy.
* The research may generate harmful and misleading study findings if you don’t fully understand other relevant study factors outside of awareness of sepsis.

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

* The Committee requested a general tidy up of the PIS and CF. Review for consistent font sizes and typographical errors.

Decision

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

* Provide an amended protocol, in particular taking into account the suggestions on the scope of the study and the processes for consent and participant groups made by the Committee (Ethical Guidelines for Intervention Studies para 5.4).
* Please amend the information sheet and consent form, and assent forms, taking into account the suggestions made by the Committee (Ethical Guidelines for Observation Studies para 6.11).

This following information will be reviewed, and a final decision made on the application, by Ms Kate O’Connor and Ms Susan Buckland.

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| **2** | **Ethics ref:** | **15/NTA/81** |
|  | Title: | JPBM / Monarch 3 **(CLOSED)** |
|  | Principal Investigator: | Dr Audrey Fenton |
|  | Sponsor: | Eli Lilly and Company (NZ) Limited |
|  | Clock Start Date: | 25 June 2015 |

Dr Audrey Fenton, Ms Maureen Blackmore 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.

Dr Christine Crooks declared a potential conflict of interest, and the Committee decided to have Dr Crooks stay in the room and not participate in discussion of the application.

Decision

This application was *provisionally approved* by consensus.

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| **3** | **Ethics ref:** | **15/NTA/83** |
|  | Title: | Comparison of the blood levels of two forms of isotretinoin 20 mg capsules in healthy male volunteers |
|  | Principal Investigator: | Dr Noelyn Hung |
|  | Sponsor: | Douglas Pharmaceuticals Ltd |
|  | Clock Start Date: | 25 June 2015 |

Dr Noelyn Hung 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

* The Committee asked whether this study, or a very similar one, had been submitted before. The researchers explained that new international (FDA) regulations require that the study be repeated. US regulators will not accept studies older than 3 years. This is because 3 years ago the requirements were not as stringent as they are now.
* Requirements for approval then was a typical validation process but now there are 8 different processes required.
* The researchers confirmed study is more or less identical to earlier study. In this study participants are well fed opposed to fasted.
* Both studies submitted (83 and 84) are identical except for the dose (20mg – 40mg).
* The Committee commended the peer review and PIS.
* Please amend PAYE to withholding tax.

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

* Page one - please remove the statement about alternative therapies, as this is a nontherapeutic study. State that the dose is for research purposes only.

Decision

This application was *approved* by consensus.

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| **4** | **Ethics ref:** | **15/NTA/84** |
|  | Title: | Comparison of the blood levels of two forms of isotretinoin (1 x 40 mg and 2 x 20 mg capsules) in healthy male volunteers |
|  | Principal Investigator: | Dr Noelyn Hung |
|  | Sponsor: | Douglas Pharmaceuticals Ltd |
|  | Clock Start Date: | 25 June 2015 |

Dr Noelyn Hung 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

* Note this study was reviewed in tandem with 15/NTA/83.

Summary of ethical issues (resolved)

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

* The Committee queried whether this dose could cause depression or mental illness, noting Medsafe drug information states .5 mg per kg per day may cause depression. If there is a 70kg person would it meet that level of dosing?
* Researcher stated this is one dose so there is no risk. The Medsafe information relates to long-term use.
* The Researchers confirmed study would be registered on a trial registry.
* Please amend PAYE to withholding tax.

Decision

This application was *approved* by consensus.

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| **5** | **Ethics ref:** | **15/NTA/85** |
|  | Title: | A study to determine the bioequivalence of two Peginterferon alfa-2a formulations |
|  | Principal Investigator: | Dr Chris Wynne |
|  | Sponsor: | Quintiles |
|  | Clock Start Date: | 25 June 2015 |

Dr Chris Wynne 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

* Bioequivalence study that assessing an alternative form of interferon that does not contain benzyl alcohol. The drug, once approved by Chinese authorities, will be marketed in China.

Summary of ethical issues (resolved)

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

* The Committee queried why this formulation doesn’t contain benzyl alcohol. Dr Wynne explained that Chinese authorities are not allowing it, adding they were not sure why as the levels used in the standard interferon formula do not pose health risks.
* The Committee asked why the research is not being conducted in China. Dr Wynne explained that it would take too long, up to 18 months to obtain ethical approval. The NZ HDEC review process is much quicker.
* The Committee asked if there is a possibility that the drug is marketed outside of China, based on the data generated in this study. Dr Wynne said yes, in theory.
* Dr Wynne confirmed a SCOTT submission has occurred.
* The Committee queried if there should be some more information on inclusion/exclusion criteria in the PIS, for instance the exclusion if someone has a cold or the flu.
* Dr Wynne explained that while not all inclusion criteria was in the PIS there was a pre-screening process via telephone and an extensive verbal process during informed consent procedures. These measures would capture what is not listed in the written documentation.
* Dr Wynne confirmed that participants would be recruited from an existing registry as well as advertising.
* Dr Wynne explained that both parents must be Chinese. Dr Wynne stated he thought it was self identification as Chinese. The secretariat noted that the protocol states there will be blood testing for confirmation of ethnic Chinese.
* The Committee requested a general review of the PIS for typographical and formatting errors. For example page 3 under HIV the sub bullet points roll onto urine sample and drug of abuse points which should be separate.
* Dr Wynne confirmed that there is one blood test at 24 hours and then discharged if they feel well enough.
* Please amend ‘samples’ to singular.
* The Committee requested clarification on whether reimbursement is a singular payment in the patient information.
* Dr Wynne confirmed that taxis were available for all participants.
* The Committee queried whether English speaking was required to participate. Dr Wynne clarified that some level of English speaking was required however written documentation would be translated into Chinese and back to English, as well as translators being available.
* Page 3 states there will be examinations of genital and rectal areas – is this necessary? Dr Wynne stated it is not standard and would not occur unless there are specific issues that might impact eligibility. Please remove this from the PIS.
* Dr Wynne confirmed that the cannula is in for first 24 hours then removed day 2 following discharge. Remaining samples are venepuncture.
* Page 14 PIS states blood samples are required to be stored by health authorities. What does this refer to? Dr Wynne explained that sometimes health authorities require extra drug and blood samples are stored so outcome and veracity of study is checked. This is for audit and quality assurance measures and not for further research.
* The Committee queried where these quality assurance samples were stored. Dr Wynne explained they were stored in the laboratory until the end of the study and will be destroyed once the Chinese authorities approve the outcome of the study.
* The Committee queried whether there would be any benefit for Maori, noting that while the population group studies in Chinese there could be a benefit relating to the drug generally. Dr Wynne stated there was no benefit and that this had been clearly stated in the application.
* Please explain the data safety monitoring arrangements. Dr Wynne explained that data is sent to contract research organization. The drug is a registered drug and the formula is minimally changed – only very low levels of preservative that is different from approved formula. Medical monitor and the CI at each site will review SE and SAE.
* The Committee reminded the researchers that sponsors should not hide behind insurance companies for commercial trials. Dr Wynne stated CCST has no history of large claims but agrees that Sponsors and their insurers must abide by New Zealand’s requirements, adding that they are stronger requirements due to ACC equivalent compensation being required.

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

* The Committee noted that the NEAC guidelines for intervention studies state that sponsors should not terminate the study purely for commercial reasons. Please remove this statement from the PIS.
* Please remove legally authorised representative section – not relevant for New Zealand participants.
* Dr Wynne confirmed the pregnant partner PIS is optional. The Committee requested that this is made clear in the header.
* Please remove revocation of consent in writing. Participants can verbally withdraw.
* The Committee requested that the statement about participants not taking part in other studies specifies ‘drug’ studies.
* Page 15 – Maori health support – this not required, as all participants must be Chinese.
* Please include standard HDEC wording for ACC / insurance.
* HDEC notes that HIV is not reportable by law in New Zealand. There is enhanced surveillance in NZ for HIV but it isn’t notifiable. HDEC requests that anyone with HIV identified through this process to be followed up and appropriately managed.
* ‘Take action through courts’ – remove this statement.
* Add lay language title.

Decision

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

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| **6** | **Ethics ref:** | **15/NTA/86** |
|  | Title: | Isotretinoin in chronic sinusitis |
|  | Principal Investigator: | Associate Professor Richard Douglas |
|  | Sponsor: | University of Auckland |
|  | Clock Start Date: | 02 July 2015 |

Associate Professor Richard Douglas and Dr Ravi Jain 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

* Primary focus of study is observing healing after sinus surgery. There is a small window of opportunity to support healing. Various topical treatments have been investigated with varying success.
* This study will assess effectiveness Retinoic acid  (an active metabolite of vitamin A), which is commonly used for treatment of acne. The difficulty with vitamin A analogues used topically is that vitamin A has side effects, in particular irritation, and the nasal cavities are quite sensitive.
* Animal studies, including our own, have suggested that topical retinoid application aids healing. The researchers want to extend this research into the effect of oral preparations.

Summary of ethical issues (resolved)

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

* The Committee stated that this is essentially basic biomedical research that looks at the effect of a drug on the microbiological features and observation of healing. This is a phase I randomised trial. The trial does not constitute treatment (it is looking at some markers of potential effectiveness) and is therefore nontherapeutic. This means that the researchers cannot claim that the participants will benefit. Please amend the PIS where it presupposes benefit in several places.
* The Committee noted that the drug has well known side effects. While there have been some mitigations made by the researchers (eg excluding women of childbearing age) it was important to be upfront with participants about the status of this drug – this is an off licence use; a potential new indication.
* The Committee requested information about the operation and how it relates the study. The researchers explained that everyone involved in the study would have standard practice sinus surgery; this is an inclusion criteria. Please note this in your protocol and in the invitation statement in your PIS..
* The researchers explained that an injury would be induced in the potential participants (a small biopsy sample under local anaesthetic) in order to then determine the effect of the study drug on wound healing. This is not standard of care. .
* The Committee asked about how the repeat biopsy (the excision of the biopsy site and a small amount of surrounding tissue) altered standard care during surgery. The researchers explained that tissue is removed in standard practice sinus surgery. The location of the repeat biopsy site is often removed completely during survey, but this may not occur in all cases. If that structure is not removed in surgery, then the additional small amount planned for removal for the repeat biopsy is small. As a result they do not consider this a very substantial deviation from standard care. All other structures around the area are removed – in the greater scheme of things the biopsy is very small. The researchers added that the main difference from standard practice is the small wound made prior to surgery.
* The Committee requested that the PIS is reviewed, and asked that it is written as if the researchers were talking to a participant about the study. For instance, be clear about what you are doing, that the drug is not approved for use in this setting etc. There must be more information on the well described drug side effects such as depression/suicidality. The researchers are invited to consult colleagues on whether they should also include a pre-screening for mental health given these side effects, or to confirm that the dose and treatment course being used are unlikely to be problematic. Most importantly it must be very clear that there is no benefit for participants.
* The Committee asked for clarification on the power calculations for the study, noting that there were 32 total, 16 from each site – with 8 placebo and 8 on active treatment. The researchers confirmed that there are no quantitative endpoints, adding that the sizing was double the animal studies. The researchers confirmed that they were confident the sample size could demonstrate an observable difference, but will focus primarily on description of difference – clarifying the study is not powered to generate efficacy data, adding this is typical of pilot studies.
* The Committee queried the data safety monitoring. The researchers explained that there is a research nurse who monitors patients.
* The Committee requested that ethnicity data is collected using the Ministry of Health Ethnicity Data Protocols (census question for collection) to ensure national consistency and relevance for a New Zealand context. <http://www.health.govt.nz/publication/ethnicity-data-protocols-health-and-disability-sector>
* The researchers confirmed tissue samples are destroyed once study is finished.
* The Committee noted that there are potential cultural issues for Maori and that these should have been identified in the application (P.4). Some examples are use of tissue and that the head is Tapu. The Committee suggests seeking guidance during Maori consultation.

Summary of ethical issues (outstanding)

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

* Please explain how you are receiving the study drug – is this commercially sponsored trial? The Committee noted this would have implications for ACC eligibility.
* Please confirm that Medsafe approval is not required for off label use of the study drug.

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

* Please be clear that you are doing with study data – either consent is given for future use or you will seek re-consent (page 4).
* Please clarify where tissue is stored during analysis.
* Review for jargon – either explain or change to lay language.

Decision

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

* Clarify how the drug is being supplied and whether the study is commercially sponsored – who will benefit from this study if the study drug proves to be beneficial? (Ethical Guidelines for Intervention Studies para 4.20 In intervention studies, potential for conflict of interest may arise when the investigator: is remunerated for participant recruitment (eg, with per capita payments) or has a commercial interest in the intervention or financial links to the study sponsor).
* 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*).
* Confirm further regulatory approval is not required to use the study drug off label.

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

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| **7** | **Ethics ref:** | **15/NTA/87** |
|  | Title: | PQB 4 FP II |
|  | Principal Investigator: | Dr Andrew Holden |
|  | Sponsor: | PQ Bypass, inc. |
|  | Clock Start Date: | 02 July 2015 |

Ms Helen Knight 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

* This study will support the data collection process for a CE mark.
* This study relates to a prior study submitted to HDEC, a first in man study. This study recruited 4 patients. Ms Knight referred to the cover letter submitted with the ethics application. The Committee noted that the situation was clearly described.
* The prior study was able to indicate a proof of concept for the delivery system and was effective when paired with commercially available devices.
* Surgical bypass is gold standard for these patients but it has requirements to be effective, in particular it needs a good vein. Other option is synthetic graft but these have a higher rate of infection. We hope PBQ can be a viable alternative treatment option for this patient population. PBQ can be administered under local anaesthetic. This means it is potentially much easier for people to recover from PQB.
* This study will study recruit participants in Latvia, Poland and Chile.
* The Committee noted the study is very similar in design to the prior approved study, but uses improved technology. The delivery system remains the same but the device is modified to be more in line with commercially available models. The exclusion criteria have also been altered for safety purposes.
* Study will recruit up to 15 participants from New Zealand.

Summary of ethical issues (resolved)

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

* The Committee asked about the DSMC arrangements. Ms Knight explained that at this point in time there were internal procedures to review safety. All AE and SAE were also reported to the sponsor and medical monitor. As of September 2015 there should be a DSMC to look at events across all sites.
* The Committee asked how recruitment for this study works. Ms Knight explained that there were multidisciplinary meetings that discussed and referred potential participants. The CI talks with the potential participants about treatment options and this research is but one option available.
* The Committee asked whether the researchers would disclose the experiences of the 4 prior participants in earlier study. Would such information be included in the PIS? Ms Knight explained that verbally they would discuss the context of the treatment, its status and its involvement in prior research. The Committee requested that information is included in the PIS about how the delivery system and an earlier version of the device was used in a prior study with mixed results and that this study has an improved device that should address the problems experienced in the prior study.

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

* Please add lay language title.

Decision

This application was *approved* by consensus.

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| **8** | **Ethics ref:** | **15/NTA/88** |
|  | Title: | Gastrointestinal motility study |
|  | Principal Investigator: | Dr Susanna Every-Palmer |
|  | Sponsor: |  |
|  | Clock Start Date: | 25 June 2015 |

Dr Susanna Every-Palmer was not present for discussion of this application.

Potential conflicts of interest

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

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

Summary of ethical issues (outstanding)

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

* The Committee queried the need to give reasons why participants were not participating (on consent form). Please explain why this was included and remove it.
* The Committee asked if there is another patient population that is taking clozapine that is less vulnerable than the proposed study group.
* The Committee noted that vulnerable populations can only be involved in research when there is both a need to research that particular population and also that there are not less vulnerable patient groups that could be studied to achieve the same result.
* The Committee noted the power dynamics and potential for coercion involved with this patient population increase their vulnerability.
* Please explain whether a 20 dollar warehouse voucher is appropriate for this patient population, due to the invasiveness of the study and the time involved, and the ability to use the voucher.
* How will consent be sought from these patients? Explain the consent process in detail.
* Committee noted participants are to be recruited from inpatients in a forensic long-term facility. Please explain whether you are returning to the 50 earlier participants and selecting 20? Please clarify where the 20 patients are coming from. Please comment on the level of research that these participants have already been involved in.
* The Committee expressed a concern of oversampling of captive population. Please mitigate this concern.
* Committee queried the withholding of laxatives – how will any injury be managed noting that these participants are captive, and while able to take laxatives at any time, may not do so to continue participation due to pressure to comply.
* Committee noted peer review. No issues identified by the reviewer.
* Committee required a thorough explanation of potential participant identification. How will capacity for consent be judged?
* Patient safety requires a thorough justification including management of external device e.g. potential risk of strangulation.
* Please clarify whether it is any antipsychotic or clozapine specifically. The title of the PIS should reflect this is a study of the effects of clozapine on gut motility
* Add ACC information from HDEC template to PIS.
* The Committee queried risks involved with wearing the monitor device.
* Please explain the consenting process in the prior study and any issues experienced.
* Add role of PHD student in PIS
* Should the GP be notified of study participation?
* Change cited ethics committee to the NTA HDEC

Decision

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

Address concerns outlined above.

This following information will be reviewed, and a final decision made on the application, by full electronic sub-committee.

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| **9** | **Ethics ref:** | **15/NTA/89** |
|  | Title: | A randomised double blinded placebo controlled study investigating MyriCell for the improvement of skin health in subjects with eczema. |
|  | Principal Investigator: | Dr Simon Carson |
|  | Sponsor: | Decima Health Ltd |
|  | Clock Start Date: | 02 July 2015 |

Dr Iona Weir 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

* The researchers explained that this is the second clinical trial with the experimental cream. The purpose of the trial is for regulatory proof to make label claims. The cream is not a pharmaceutical product but is an over the counter product. This does not require FDA review.
* Southern Clinical Trials will be conducting the study.

Summary of ethical issues (resolved)

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

* The Committee noted that the PIS should not use the word treatment because the product is not therapeutic.
* The researchers confirmed Maori cultural support is available.
* The researchers confirmed there are no blood tests or use of tissue.
* The Committee asked about the placebo control. The researchers explained that it is a formulation put together and reviewed by the US group who provide regulatory advice. The placebo has a therapeutic benefit due to its barrier function.
* The Committee queried how the benefit of the study cream would be identified. The researchers explained it would primarily be monitoring the legions, looking for them to either completely vanish or reduce in size. Self reported measures were also used, such as reduction in itchiness and reduction in redness. The end points are clinical features.
* The Committee noted that Aqueous cream is standard treatment for eczema.
* The Committee requested a letter from Medsafe confirming status of this study cream, in particular that no further registrations are required. Please also comment on the legal status of therapeutic claims for such creams.
* The Committee stated that this study cream is not a drug nor a treatment.
* The Committee noted the peer review was not independent but accepted it in this instance due to the low risk of the study.
* The Committee asked how participants are recruited. Researchers explained that Southern Clinical Trials have a registry, as well as recruitment via advertising.
* The Committee asked about monitoring, noting that sponsor is involved. The researchers stated that an independent party is being contacted to monitor safety data. The Committee requests that any updates on safety monitoring are sent to HDEC for review.

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

* Page 6 – confidentiality agreement. First paragraph seems unusually restrictive – please explain this clause. The researchers stated it was copy pasted from first trial, adding that they have competitors in New Zealand and wanted to keep the trial as private as possible. The Committee noted that because this was a trial the researchers must register it on a public registry. Please remove this information from the PIS.
* The Committee noted the PIS header should have the host institution not the sponsor.
* The Committee noted that the compensation clause usually states that the study is for the benefit of the sponsor.
* The Committee noted that jargon was used in the PIS – please either explain or remove jargon.
* Add Maori support numbers and investigator support numbers.
* Remove ‘for the treatment of’ ...with sufferers of eczema. Remove mention of word ‘drug’ and replace with product. Change to – appearance of skin on eczema sufferers.

Decision

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

## General business

1. The Committee noted the content of the “noting section” of the agenda.
2. The committee discussed the secondary use of health information gathered in an ICU setting when verbal consent is given but written consent has not been sought.
3. The Chair reminded the Committee of the date and time of its next scheduled meeting, namely:

|  |  |
| --- | --- |
| **Meeting date:** | 11 August 2015, 08:00 AM |
| **Meeting venue:** | Novotel Ellerslie, 72-112 Greenlane Rd East, Ellerslie, Auckland |

The following members tendered apologies for this meeting.

* Dr Brian Fergus will be away in September.
* Ms Susan Buckland will be away for September and October.

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 4.45pm