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| **Committee:** | Northern A Health and Disability Ethics Committee |
| **Meeting date:** | 07 October 2014 |
| **Meeting venue:** | Novotel Ellerslie, 72-112 Greenlane Rd East, Ellerslie, Auckland |

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| **Time** | **Item of business** |
| 1.00pm | Welcome |
| 1.10pm | Confirmation of minutes of meeting of 09 September 2014 |
| 1.30pm | New applications (see over for details) |
|  | i 14/NTA/153  ii 14/NTA/154  iii 14/NTA/148  iv 14/NTA/157  v 14/NTA/162  vi 14/NTA/159  vii 14/NTA/160  viii 14/NTA/161  ix 14/NTA/162 |
| 5.25pm | General business:   * Noting section of agenda |
| 5.45pm | 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 | Apologies |
| Ms Susan Buckland | Lay (consumer/community perspectives) | 01/07/2012 | 01/07/2015 | Apologies |
| 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 | Present |
| 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 |
| Dr Mark Smith | Non-lay (intervention studies) | 01/09/2014 | 01/09/2015 | Present |

## Welcome

The Chair opened the meeting at 1.12pm and welcomed Committee members, noting that apologies had been received from Dr Brian Fergus and Ms Susan Buckland.

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 9 September 2014 were confirmed.

## New applications

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| **1** | **Ethics ref:** | **14/NTA/148** |
|  | Title: | Randomised Controlled Trial of patient satisfaction with uncemented Oxford Unicompartmental Knee Arthroplasty and Total Knee Arthroplasty |
|  | Principal Investigator: | Dr Jonathan Manson |
|  | Sponsor: |  |
|  | Clock Start Date: | 25 September 2014 |

No researchers 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 ethical issues

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

* The Committee raised a number concerns with the application.
* The Committee asked for clarification on the sample size as this differs in the application and protocol.
* The Committee asked for clarification on the length of the study.
* The Committee were concerned about the possibility of conflict of interest (R.5.4) and asked for a detailed description of how this would be managed, including during the recruitment process. They asked for clarification on how the researchers will recruit participants and keep their role as the treating doctor and researcher separate.
* The Committee noted that it is not clear whether participants will have enough time to go away and discuss the study (P.2.1). As there may not be a research nurse, there may be the risk of coercion and the Committee asked how this risk would be managed.
* The Committee noted that Northland DHB will fund the study. As there is no obvious support from the DHB Research Office, the Committee asked that the GM of Surgical Services provides a letter of support confirming that they are happy for this research to take place.
* The Committee advised that they were not comfortable with an internal data safety monitoring committee (R.1.4).
* The Committee asked that an external peer review be provided from outside the DHB. They noted that it would be useful to have peer review from the authors of the international study on which this study is based.
* The Committee asked for the results of the Māori research review to be submitted.
* The Committee recommended collecting ethnicity information.
* The Committee were concerned that the researchers had not clearly understood privacy issues in relation to having access to information as a clinician vs having access to information as a researcher.
* The Committee advised that clinical notes are not an appropriate place for study records to be stored (R.2.1.1), a Clinical Research Form (CRF) or similar would be expected.
* The Committee noted that data needs to be kept for 10 years after the end of the study as per the Health Information Retention Regulations.
* The Committee asked how the researchers planned to collect follow up data as the only end point described are revision rates from the New Zealand Joint Registry. They said that the researcher needs to be clear on the end points and include how these will be collected in the PIS.
* The Committee noted that the PIS needs a lot of work. The Committee recommended referring to the participant information sheet and consent form template available on the HDEC website. The PIS should include:
  + a clear explanation on why this study is being undertaken and how this is different from standard care,
  + a statement outlining that taking part in the study is voluntary and that a decision not to participate will have no impact on their care,
  + a full set of patient rights,
  + contact details, including for patient advocate services and Māori Health,
  + ACC statement,
  + selection process ,
  + nature and length of follow up.
  + the separate role of the researcher and treating doctor,
  + length of blinding

Decision

This application was *declined* by consensus, as the Committee did not consider that the study would meet the ethical standards relating to conflict of interest, study design, locality and informed consent.

* *Conflict of interest may also arise when the investigator is a participant’s usual health or disability service provider. This may cause a conflict between the investigator’s role and the clinician role. In some circumstances this dual role will be appropriate. However, this possible conflict should always be disclosed and discussed with any potential participants (Ethical Guidelines for Intervention Studies, para 4.22).*
* *Every effort should be made to ensure complete follow-up for all study participants. Incomplete follow-up means there is data missing from the study. This will be for non-random reasons and has the potential to compromise the reliability of the study findings (Ethical Guidelines for Intervention Studies, para 5.10).*
* *Investigators should ensure that they comply with internal organisation requirements when conducting intervention studies. The appropriate approach will vary from organisation to organisation; as such, organisations might also specify their own processes regarding notification or approval (Ethical Guidelines for Intervention Studies, para 5.45).*
* *Informed consent is essentially a matter of good communication between people. Information should be provided to potential participants in a form and in a way that assists their informed decision making (Ethical Guidelines for Intervention Studies, para 6.22).*

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| **2** | **Ethics ref:** | **14/NTA/151** |
|  | Title: | NEAT |
|  | Principal Investigator: | Associate Professor Andrew Holden |
|  | Sponsor: | TVA Medical, Inc. |
|  | Clock Start Date: | 24 September 2014 |

Associate Professor Andrew Holden, Mr Andrew Hill and Ms Anna Zhou 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 ethical issues

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

* The researchers explained that this is a study of an alternative, less invasive vascular procedure (the FLEX System) to create a fistula for haemodialysis. There has been a first in man study in South America, with around 24 participants and a limited number of procedures (around 30) in Canada.
* A/Professor Holden explained that this study is not changing the dialysis in any way but it is a different way of creating a fistula. This procedure is less invasive as it can be done under a local anaesthetic, but evidence is needed to demonstrate the safety of this procedure and to show that this method produces an effective fistula.
* Mr Hill advised that dialysis cannot be given until the fistula has matured, which is normally around six weeks. The limited advice available says that the FLEX System is about the same in terms of the fistula maturing.
* The Committee asked if the primary aim of the study is to monitor safety issues through to six months. Mr Hill explained that most of the study outcomes relate to dialysis adequacy, such as blood flow, pressure and standardised measures. He thought that six months would be long enough as the failure rate is nearly always due to the fistula failing to achieve maturation.
* The Committee asked what the key safety issues of this study were. Mr Hill advised that these were around procedure, for example, injury to arteries or vein, blockages, inability to get a sufficient vein to use and treatment site complications.
* Mr Hill explained that the vascular team is responsible for creating and maintaining fistulas but the renal medical team look after dialysis patients. He said that the renal team been consulted about this study and the renal nurse has been in contact with the study team in Canada.
* The Committee asked how this study varies to standard care. Mr Hill explained that the standard technique creates a communication between a superficial artery and a superficial vein. The FLEX System creates a communication between two deeper blood vessels. It is a different site, level and depth.
* Ms Zhou confirmed that the DSMB is based in Toronto and is independent.
* Mr Hill advised that participants will be recruited from Auckland DHB with the possibility of extending this to Waitemata DHB. These will be from an existing list of patients who are likely to need dialysis in the next six months. The research coordinator will send potential participants information on the study and consent will be obtained at the surgical visit before the procedure. This study will probably require one additional visit before the procedure.
* The Committee asked if the researchers would look at quality of life. Ms Zhou advised that there is a vascular questionnaire and another that looks at general quality of life. She said that she did not anticipate any issues with people completing the long surveys as the research coordinator would sit down with participants to ensure that they understood it.
* The Committee asked if there would be any issues if all participants had the same ethnic background. Mr Hill advised that this was a possibility but would not be an issue. He noted that there were some differences in the population in the Canadian group but said that there would be some scientific merit in assessing a bigger group. A/Professor Holden explained that one of the criticisms of the South American study was that participants’ BMIs were low. He said that the sponsor is looking to get more “real world patients” as 40% of New Zealand dialysis patients have a BMI of over 30.
* Ms Zhou confirmed that the certificate of insurance will be renewed.
* The Committee requested the following changes to the PIS and consent form:
  + Please remove reference to being able to go home on the same day (page 3 of the PIS)
  + Please clarify what images will be sent to TVA Medical, Inc. (page 9 of the PIS).

Decision

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

* Please amend the participant information and consent form, taking into account the suggestions 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 Christine Crooks and Dr Mark Smith.

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| **3** | **Ethics ref:** | **14/NTA/153** |
|  | Title: | DS5565-A-E311 |
|  | Principal Investigator: | Dr Sunil Kumar |
|  | Sponsor: | Daiichi Sankyo India Pharma Pvt. Ltd. |
|  | Clock Start Date: | 25 September 2014 |

Dr Sunil Kumar and Mrs Catherine Howie 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 ethical issues

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

* Dr Kumar explained that this is a randomised, double-blind, placebo and active controlled study of DS-5565 in subjects with pain associated with fibromyalgia. He advised that this affects around 1.1% of the Caucasian population and around 1.5% of the Māori population. There are currently several medications available but these are not good at controlling the symptoms.
* The Committee noted that the PIS was comprehensive.
* The Committee asked for clarification on the recruitment strategy. Dr Kumar explained that rheumatologists in the rheumatology clinic will be advised of the study and asked to refer patients. There is also a database of patients in the rheumatology clinic and the study coordinator will identify and call potential participants, advise them of the study and send them information if they are interested in the study. There will also advertisements in GP newsletters and local papers. Mrs Howie advised that the study coordinator will make contact with potential participants which will mitigate potential conflicts of interest.
* The Committee asked for clarification on the DSMB given that this is a new drug. Dr Kumar explained that any major adverse reactions will be reported to the investigators and participants will have the option of stopping treatment. He said that if there are any liver enzyme abnormalities these will be reported to the Hepatic Adjudication Committee and participants will stop taking the study drug.
* The Committee were concerned about the study drug causing increases in depression and suicidality and noted that identifying suicidality was difficult, particularly using a screening tool. Dr Kumar advised that any patients identified as at risk of depression will be excluded during the screening period. He said that around 30% of fibromyalgia patients have depression and they will try to pick this up in the screening to ensure that they are not at risk. Dr Kumar explained that if participants answer yes to questions 3, 4 and 5 on suicide ideation or yes to any questions on suicidal behaviour in the questionnaires, they will stop taking part.
* The Committee noted that there were two suicides in previous studies and neither participant had scores that were picked up in the suicide questionnaires. Dr Kumar thought that the two people who had committed suicide may have had underlying depression.
* The Committee asked if all sites had sufficient psychiatric or mental health expertise within the study team. Dr Kumar advised that they do not have anybody trained in their study team but they do have access to mental health services and the crisis health team at Middlemore Hospital. Mrs Howie noted that some of the sites are not affiliated with a hospital and they will need to ask them what actions are in place to manage this risk. The Committee asked that a clear protocol on suicide risk, including a management plan be provided. Study team should include someone with expertise in mental health.
* Dr Kumar explained that fibromyalgia is very rare in those over 60 and that they expect most participants to be between 30 and 60.
* Dr Kumar advised that this drug had not been used in any previous fibromyalgia studies but in previous arthritis studies, there was a 15% drop out rate.
* The Committee asked that the Māori Research Review be forwarded to the Committee.
* The Committee asked for clarification on what information would be collected from hospital records and GPs. Mrs Howie advised that the researchers will seek consent from the participants for the study coordinator to access their medical records for any information on their condition which will be helpful for the researchers in taking care of the patient. Please include this information in the PIS.
* The Committee noted that the peer review had raised a number of concerns that did not appear to have been fully addressed. These included the MMRM approach for data analysis, withdrawal rates, the requirement for a Phase II dose ranging study and the three big risks of potential for abuse, suicidality and hepatic concerns. Mrs Howie agreed to check this with the sponsor.
* The Committee noted that all of the patient letters called the study Alday but there is no mention of this in the PIS.
* The Committee asked if the researchers anticipated any problems with participants complying with study procedures for 12 months. Dr Kumar did not think there would be any issues.
* The Committee were concerned that there seems to be a heavy emphasis on determining the safety of the drug for a Phase III study and asked why there had not been a Phase II study for fibromyalgia. Dr Kumar advised that he thought that the first part of the study should be Phase II study and the second a Phase III study. The researchers agreed to clarify this with the sponsor.
* The Committee requested the following changes to the PIS and consent form:
  + Please remove the reference to the study doctor being paid by the sponsor (page 2 of the PIS).
  + Please reference New Zealand data protection legislation (page 15 of the PIS).
  + Please remove American references.
  + Please insert “if any additional testing is identified at a later time” to the beginning of the sentence “you will be asked to consent to them being carried out…” (page 5 of the PIS).
  + Please include how long samples will stored in the PIS.
  + Please clarify that the study records that may not be available until after the study is finished refers to blinding (page 16 of the PIS).
  + Please include the study schedule as an appendix to reduce the volume of information for the participant.

Decision

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

* Please amend the participant information and consent form, taking into account the suggestions by the Committee *(Ethical Guidelines for Intervention Studies, para 6.22).*
* Please provide a protocol on suicide risk, including a management plan, with particular reference to those sites not affiliated with a hospital *(Ethical Guidelines for Intervention Studies, para 6.62). Note recommendation from the Committee for the inclusion of someone on study team with expertise in mental health issues.*
* Please confirm why this study is not a Phase II trial *(Ethical Guidelines for Intervention Studies, para 5.4).*

This following information will be reviewed, and a final decision made on the application, by the Committee at their next meeting.

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| **4** | **Ethics ref:** | **14/NTA/154** |
|  | Title: | DS5565-A-E312 |
|  | Principal Investigator: | Dr Sunil Kumar |
|  | Sponsor: | Daiichi Sankyo India Pharma Pvt. Ltd. |
|  | Clock Start Date: | 25 September 2014 |

Dr Sunil Kumar and Mrs Catherine Howie 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 ethical issues

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

* The Committee noted this is an open label extension, with the same methodology and patients as 14/NTA/153 and that the same issues applied.
* The Committee asked if the researchers were expecting any de novo participants or if this would only be if the dropout numbers from DS5565-A-E312 are high. Dr Kumar advised that they are only expecting de novo participants if they do not have adequate numbers from the previous study.
* Mrs Howie confirmed that there is no PK testing on the maintenance phase.
* The Committee requested the following changes to the PIS and consent form:
  + Please remove the reference to the study doctor being paid by the sponsor (page 2 of the PIS).
  + Please reference New Zealand data protection legislation (page 13 of the PIS).
  + Please remove American references.
  + Please include how long samples will stored in the PIS.
  + Please clarify that the study records that may not be available until after the study is finished refers to blinding (page 14 of the PIS).
  + Please include the study schedule as an appendix to reduce the volume of information for the participant.

Decision

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

* Please amend the participant information and consent form, taking into account the suggestions by the Committee *(Ethical Guidelines for Intervention Studies, para 6.22).*
* Please provide a protocol on suicide risk, including a management plan, with particular reference to those sites not affiliated with a hospital *(Ethical Guidelines for Intervention Studies, para 6.62). Note recommendation from the Committee for the inclusion of someone on study team with expertise in mental health issues.*

This following information will be reviewed, and a final decision made on the application, by the Committee at their next meeting.

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| **5** | **Ethics ref:** | **14/NTA/157** |
|  | Title: | Mothers and infants admitted together to a mother-baby unit. Does it help? |
|  | Principal Investigator: | Dr Tanya Wright |
|  | Sponsor: | The University of Auckland |
|  | Clock Start Date: | 25 September 2014 |

Dr Trecia Wouldes was present by teleconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of ethical issues

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

* The Committee noted that there was some confusion in the PIS about what is research and what is standard care. Dr Wouldes explained that the mother and baby unit is a new service which will look at the characteristics of mothers who are referred to the service and follow them through the service at different time points. The study aims to establish if this care is appropriate and effective, however a set of diagnostic and clinical tools for standard care has not yet been established for the new unit. Currently only the HONOS tool is standard of care at a similar unit in Christchurch. Some, perhaps most, of the data collected from the clinical tools (questionnaires and video) planned for this study are likely to be standard of care in the new unit however this may evolve over time.
* Dr Wouldes noted that the researchers were particularly concerned about the consent issues in this proposed study, as consenting mothers as they are likely to be mentally unwell. She said that the PIS is meant to give the mothers an idea that a study is taking place in the unit but they will not be a part of the study until they are well enough to give consent.
* The Committee noted that there was some confusion with Dr Wright’s role as a clinician working in the unit vs her role as a PhD candidate. Dr Wouldes advised that Dr Wright will not consent the participants and she will have a research assistant to ensure that the clinician and research roles are kept separate.
* The Committee asked for information on the consent process for infants. Dr Wouldes explained that this would be dependent on who had custody, for example the mother, father or CYFS and that consent would come from the child’s legal guardian. The consent will only be given by the mother when it is determined by the clinical staff that she is aware of what the study will involve for her child. If a mother does not give consent then the child will not be involved in the study.
* The Committee asked if the same tools would be used if a mother was not competent to give consent under the Mental Health Act i.e was not able to be part of the Study. Dr Wouldes confirmed that other than the follow up, all of the same tools would be used (videos and questionnaires) for clinical purposes only. The research data is seeking permission to use the already collected clinical information, plus significant additional demographic data at discharge, independent coding of clinical videos, and then a three month follow up visit which also involved collection of questionnaire, consumer satisfaction, video and observational data. The Committee believed that advising mothers when they first entered the unit that there ‘is a study going on’ may confuse them, particularly given that their participation makes no difference to their clinical care. To avoid confusion, they recommended asking mothers for their permission to access their records to evaluate the service and gain consent to do a follow up at or near to time of discharge when they are able to make an informed decision regarding consent.
* The Committee asked if the framing as a service evaluation plus follow up would work as a PhD project. Dr Wouldes advised that the aim of the research is to find the demographic information of people being referred, whether there is any change in the mother and in the baby over time and to determine the effectiveness of the unit. The collection of demographic information at discharge and consumer satisfaction follow up after three months will help answer these aims.
* The Committee asked for clarification on the videos. Dr Wouldes explained that this is a standard assessment of observing a mother and baby’s interaction which may be useful in determining a mother’s ability to care for her infant. The videos will be sent to an independent third party for analysis for research purposes but this will not be done until it is consented.
* The Committee noted that records should be kept for 10 years after infants turn 16.
* The Committee noted that there were no comments in the peer review. They asked that a peer review be provided that comments on the study design and issues around the vulnerability of participants. The Committee recommended asking colleagues who the researchers had had discussions with for their comments.
* The Committee asked that more detail be included in the protocol on a process if concerning signs are picked up at the three month follow up as this could potentially include indications that a child was at risk of harm.
* The Committee noted that the researchers should consider what would happen if participants ask to see their study information and include this in the protocol and PIS.
* The Committee requested the following changes to the PIS and consent form:
  + Please identify in first line of PIS that this is a PhD project making it clear that Dr Wright is the student but is also a clinician in the unit.
  + Please be clear in the PIS that the study is looking at a service that mothers have just used and whether it works for mothers and babies.
  + Please advise participants that they can choose whether or not to answer sensitive demographic questions.
  + Please use Statistics New Zealand Ethnicity Level 1 code to collect ethnicity data.
  + Please add ACC clause to the PIS. Suggested text is available on the PIS and consent form template on http://ethics.health.govt.nz/
  + Please include and seek consent in the PIS that participants’ GPs/referring clinician will be informed that they are taking part in this study if that is the case.
  + Please include contact details for any queries related to study generally.
  + Please clearly label the PIS for guardians and look at the use of pronouns as not all of them are currently appropriate.
  + Please provide information on how the video will be stored, whether it will be destroyed after review and confidentiality.
  + Please remove italics on PIS.

Decision

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

* Please amend the participant information and consent form, taking into account the suggestions by the Committee *(Ethical Guidelines for Observational Studies, para 6.10).*
* Please provide independent peer review *(Ethical Guidelines for Observational Studies, para 5.8).*

This following information will be reviewed, and a final decision made on the application, by Ms Michele Stanton, Dr Mark Smith and Dr Karen Bartholomew.

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| **6** | **Ethics ref:** | **14/NTA/159** |
|  | Title: | Ibuprofen bioequivalence study conducted under fasting conditions |
|  | Principal Investigator: | Dr Noelyn Hung |
|  | Sponsor: | Generic Partners Pty Ltd |
|  | Clock Start Date: | 25 September 2014 |

Dr Tak Hung and Mrs Linda Folland 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 ethical issues

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

* Mrs Folland explained that this is one of three Ibuprofren 800mg sustained release bioequivalence studies. These three studies are required as they are being submitted to the EU regulatory authority
* The Committee asked for clarification on digital monitoring equipment (page 8 of the PIS). Dr Hung explained that some sponsors insists on watching the dosing as there have been instances in the past where studies have been fictitious.
* The Committee asked if there is any independent evaluation of the results. Mrs Folland explained that the sponsor will appoint a local monitor who will be on site for the dosing. If the sponsor cannot send a monitor, they may look at the dosing through the digital monitoring equipment.
* The Committee noted that it is not necessary for participants to initial every page of the PIS.
* The Committee asked how the researchers would prevent students from feeling pressured into agreeing to the trial after the information reading. Mrs Folland explained that some people sign up on the same day, while others go home to think about it.
* The Committee asked if interpreters were provided to accommodate people with English as a second language. Mrs Folland advised that the study doctor and investigator assess participants’ understanding at the medical examination and one of the criteria is that the participant must understand the study.
* Mrs Folland noted that participants’ photos are checked at regular intervals during the study to ensure that the photo matches the participant.
* The Committee asked why study data is retained for 25 years. Dr Hung advised that this helps with EU and FDA auditing and because pharmaceutical companies often want information from old studies.
* The Committee asked if the base material of the study drug is similar to the patented drug. Dr Hung confirmed that it is not the same but still needs to be approved by the regulators.
* The Committee asked for clarification on the recruitment process. Mrs Folland explained that they have a large database of people who have generally registered through the Zenith website. When they are about to recruit to a study, Zenith will send an email to eligible people and invite them to come to an information evening. There are also advertisements on the Zenith office window. At the information evening, information is read to potential participants and questions are answered. The Committee have asked for copies of the advertisements for all three of these studies (14/NTA/159, 160 and 161).
* The Committee asked why there was no independent DSMB. Dr Hung advised that this is not necessary for generic bioequivalence studies as the drugs are already used extensively worldwide and these studies only involve two doses.
* The Committee requested the following changes to the PIS and consent form:
  + Please explain in the first paragraph how each of the three studies is different as this is not always clear from the title.
  + Please include more information on page 1 of the purpose of the study as this is currently on page 4.
  + Please change ethanol to alcohol (page 2 of the PIS).
  + Please include that participants must abstain from drinking caffeine for 48 hours before and 36 hours after receiving each dose (page 2 of the PIS)
  + Please include that participants can drink water in the 10 hours before dosing (page 6 of the PIS)
  + Please define blank plasma (page 8 of the PIS).
  + Please include in the PIS that participants’ data will be deidentified (page 8 of the PIS).
  + Please make references to Zenith consistent (pages 8 and 9 of the PIS).
  + Please include rehabilitation as a compensation type (comprised of treatment, social and vocational) (page 10 of the PIS).
  + Please remove words “to the extent that they are found liable” (page 10 of the PIS).
  + Please include travel insurance with references to health insurance as a number of participants will be international students.
  + Please move paragraph on local Runaka to under Māori cultural support contact details (page 10 of the PIS)
  + Please clarify what reasonable costs will be covered for obtaining advice, for example phone calls, going to a GP, legal advice (page 11 of the PIS).
  + Please use the Statistics New Zealand Ethnicity Level 1 code to collect ethnicity data.
  + Please amend Clause 7 to Clause 8 (page 1 of the consent form).

Decision

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

* Please amend the participant information and consent form, taking into account the suggestions by the Committee *(Ethical Guidelines for Intervention Studies, para 6.22).*
* Please provide a copy of the recruitment advertisement for this study *(Ethical Guidelines for Intervention Studies, para 6.2).*

This following information will be reviewed, and a final decision made on the application, by Ms Michele Stanton and Dr Christine Crooks.

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| **7** | **Ethics ref:** | **14/NTA/160** |
|  | Title: | Ibuprofen bioequivalence study conducted under fed conditions |
|  | Principal Investigator: | Dr Noelyn Hung |
|  | Sponsor: | Generic Partners Pty Ltd |
|  | Clock Start Date: | 25 September 2014 |

Dr Tak Hung and Mrs Linda Folland 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 ethical issues

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

* The Committee noted that this was a similar study to 14/NTA/159 and the same issues applied.
* Mrs Folland confirmed that this will be a different cohort to the study conducted under fasting conditions.
* The Committee requested the following changes to the PIS and consent form:
  + Please explain in the first paragraph how each of the three studies is different as this is not always clear from the title.
  + Please include more information on page 1 of the purpose of the study as this is currently on page 4.
  + Please include that participants must abstain from drinking caffeine for 48 hours before and 36 hours after receiving each dose (page 2 of the PIS)
  + Please include that participants can drink water in the 9.5 hours before dosing (page 6 of the PIS)
  + Please define blank plasma (page 8 of the PIS).
  + Please include in the PIS that participants’ data will be deidentified (page 9 of the PIS).
  + Please make references to Zenith consistent (pages 8 and 9 of the PIS).
  + Please include rehabilitation as a compensation type (comprised of treatment, social and vocational) (page 10 of the PIS).
  + Please remove words “to the extent that they are found liable” (page 10 of the PIS).
  + Please include travel insurance with references to health insurance as a number of participants will be international students.
  + Please move paragraph on local Runaka to under Māori cultural support contact details (page 11 of the PIS)
  + Please clarify what reasonable costs will be covered for obtaining advice, for example phone calls, going to a GP, legal advice (page 11 of the PIS).
  + Please use the Statistics New Zealand Ethnicity Level 1 code to collect ethnicity data.
  + Please amend Clause 7 to Clause 8 (page 1 of the consent form).

Decision

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

* Please amend the participant information and consent form, taking into account the suggestions by the Committee *(Ethical Guidelines for Intervention Studies, para 6.22).*
* Please provide a copy of the recruitment advertisement for this study *(Ethical Guidelines for Intervention Studies, para 6.2).*

This following information will be reviewed, and a final decision made on the application, by Mr Kerry Hiini and Ms Shamim Chagani.

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| **8** | **Ethics ref:** | **14/NTA/161** |
|  | Title: | Ibuprofen bioequivalence study conducted under fasting conditions and at steady state |
|  | Principal Investigator: | Dr Noelyn Hung |
|  | Sponsor: | Generic Partners Pty Ltd |
|  | Clock Start Date: | 25 September 2014 |

Dr Tak Hung and Mrs Linda Folland 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 ethical issues

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

* The Committee noted that this was a similar study to 14/NTA/159 and 14/NTA/160 and the same issues applied.
* The Committee asked if there was anybody else who could do peer review other than Dr Paul Glue. Dr Hung explained that it was difficult to find somebody who had experience in bioequivalence studies. Dr Hung agreed to look for an alternative reviewer in Dunedin.
* Mrs Folland confirmed that the three studies had been peer reviewed and that the reference to quetiapine was a typo.
* The Committee requested the following changes to the PIS and consent form:
  + Please explain in the first paragraph how each of the three studies is different as this is not always clear from the title.
  + Please include more information on page 1 of the purpose of the study as this is currently on page 4.
  + Please include that participants must abstain from drinking caffeine for 48 hours before and 36 hours after receiving each dose (page 2 of the PIS)
  + Please include that participants can drink water in the 10 hours before dosing (page 6 of the PIS)
  + Please define blank plasma (page 8 of the PIS).
  + Please include in the PIS that participants’ data will be deidentified (page 9 of the PIS).
  + Please make references to Zenith consistent (pages 8 and 9 of the PIS).
  + Please include rehabilitation as a compensation type (comprised of treatment, social and vocational) (page 10 of the PIS).
  + Please remove words “to the extent that they are found liable” (page 10 of the PIS).
  + Please include travel insurance with references to health insurance as a number of participants will be international students.
  + Please move paragraph on local Runaka to under Māori cultural support contact details (page 11 of the PIS)
  + Please clarify what reasonable costs will be covered for obtaining advice, for example phone calls, going to a GP, legal advice (page 12 of the PIS).
  + Please use the Statistics New Zealand Ethnicity Level 1 code to collect ethnicity data.
  + Please amend Clause 7 to Clause 8 (page 1 of the consent form).

Decision

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

* Please amend the participant information and consent form, taking into account the suggestions by the Committee *(Ethical Guidelines for Intervention Studies, para 6.22).*
* Please provide a copy of the recruitment advertisement for this study *(Ethical Guidelines for Intervention Studies, para 6.2).*

This following information will be reviewed, and a final decision made on the application, by Dr Christine Crooks and Dr Mark Smith.

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| **9** | **Ethics ref:** | **14/NTA/162** |
|  | Title: | Behavioural assessment and treatment to transition children from tube feeding to oral nutrition |
|  | Principal Investigator: | Ms Sarah Leadley |
|  | Sponsor: |  |
|  | Clock Start Date: | 25 September 2014 |

Ms Sarah Leadley and Dr. Javier Virues-Ortega 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 ethical issues

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

* Ms Leadley explained that the study will use behavioural assessment to transition children from tube feeding to oral nutrition. She said that this is a set of evidence based, tailored set of interventions.
* The Committee asked what is standard care for this population. Ms Leadley explained that children will have a health team consisting of a speech and language therapist, a dietician and a paediatrician. This health team usually meets with children for an hour in an outpatient clinic, monthly or at six weekly intervals. The set of interventions for this study is more intensive and involved more than usual care.
* The Committee noted that information should be kept for 10 years from the when the youngest participant turns 16 (R.2.3 and R.2.5).
* The Committee asked if a universal trial number had been obtained for the study (B.4.6). Ms Leadley advised that she had started the process but the study did not appear to fit the criteria. The Committee advised that as an intervention study it should be registered.
* The Committee noted that while there was a low risk of allergic reaction or choking there needs to be a mitigation plan in the protocol to manage this risk.
* The Committee asked if the child’s dietician will be consulted when they are switched to oral nutrition. Ms Leadley said that she will liaise with clinical staff but that they will not be reducing any tube feeding unless the health team makes that decision.
* The Committee noted that peer review had discussed the large age range for participants and asked if this would be an issue. Ms Leadley explained that she had discussed recruitment with a paediatrician and she was keeping the age range wide as there were not a large number of families to recruit from. She said that behavioural literature studies tend to have a wide age range and this does not have an impact on results.
* The Committee asked for clarification on the recruitment strategy. Ms Leadley advised that she will post information on notice boards at localities and will also pass this on to the health teams.
* Ms Leadley agreed to provide the Māori consultation letter when it is received
* Ms Leadley advised that she would generally individualise child assent forms depending on the child’s age. She agreed to provide more examples of assent forms for the various age ranges both developmental and chronological.
* The Committee asked for clarification on the process for behavioural problems. Ms Leadley advised that there are general and individualised termination criteria. These include if the child is at immediate risk of physical harm. If less severe behaviour goes on for more than 10 minutes and it is not an immediate risk, then they will not present food until the behaviour stops.
* The Committee asked if enough data will be obtained on the technique given the small sample size. Ms Leadley explained that as the work is so intensive, it would be hard to manage the time commitment required for a larger sample size. She said that behavioural analysis is based on small subject design.
* The Committee requested the following changes to the PIS and consent form:
  + Please be clear in the PIS what extra things this study is asking the parent and child to do.
  + Please include more information on the procedures.
  + Please include that participants will be videoed under the “what would my participation involve” section.
  + Please make it clear in the procedures that there will be training time for parents and that they will be involved in the delivery of the intervention.
  + Please include earlier in the PIS that participation will be for 12 months.
  + Please include in the PIS that data will be coded or deidentified.
  + Please remove yes / no options in the consent form if the statements are not truly optional.
  + Please be clear whether information will be included if participants withdraw.
  + Please include that the process will be discussed with the child’s health team.
  + Please include that the video will be securely stored with the data and that separate consent will be obtained if it is going to be used further.

Decision

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

* Please amend the participant information and consent form, taking into account the suggestions 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 Karen Bartholomew and Ms Shamim Chagani.

## 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:** | 11 November 2014, 01:00 PM |
| **Meeting venue:** | Novotel Ellerslie, 72-112 Greenlane Rd East, Ellerslie, Auckland |

No members tendered apologies for this meeting.

The meeting closed at 4.58pm.