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| **Committee:** | Northern B Health and Disability Ethics Committee |
| **Meeting date:** | 04 November 2014 |
| **Meeting venue:** | Novotel Ellerslie, 72-112 Greenlane Road East, Auckland |

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| **Time** | **Item of business** |
| 12.00pm | Welcome |
| 12.05pm | Confirmation of minutes of meeting of 30 September 2014 |
| 12.30pm | New applications (see over for details) |
|  | i 14/NTB/166  ii 14/NTB/167  iii 14/NTB/169  iv 14/NTB/170  v 14/NTB/172  vi 14/NTB/175  vii 14/NTB/176  viii 14/NTB/177  ix 14/NTB/178  x 14/NTB/179  xi 14/NTB/180 |
| 6.05pm | General business:   * Noting section of agenda |
| 6.15pm | Meeting ends |

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| **Member Name** | **Member Category** | **Appointed** | **Term Expires** | **Apologies?** |
| Mrs Raewyn Sporle | Lay (the law) | 01/07/2012 | 01/07/2015 | Present |
| Mrs Maliaga Erick | Lay (consumer/community perspectives) | 01/07/2012 | 01/07/2015 | Present |
| Mrs Kate O'Connor | Non-lay (other) | 01/07/2012 | 01/07/2015 | Present |
| Mrs Stephanie Pollard | Non-lay (intervention studies) | 01/07/2012 | 01/07/2015 | Present |
| Dr Paul Tanser | Non-lay (health/disability service provision) | 01/07/2012 | 01/07/2015 | Present |
| Ms Kerin Thompson | Non-lay (intervention studies) | 01/07/2012 | 01/07/2015 | Present |
| Miss Tangihaere Macfarlane | Lay (consumer/community perspectives) | 19/05/2014 | 19/05/2017 | Present |
| Mrs Phyllis Huitema | Lay (consumer/community perspectives) | 19/05/2014 | 19/05/2017 | Present |

## Welcome

The Chair opened the meeting at 12.00pm and welcomed Committee members.

The Chair noted that the meeting was quorate.

The Committee noted and agreed the agenda for the meeting.

## Confirmation of previous minutes

The minutes of the meeting of 30 September 2014 were confirmed.

## New applications

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| **1** | **Ethics ref:** | **14/NTB/166** |
|  | Title: | Simvastatin treatment for patients with COPD and elevated CRP |
|  | Principal Investigator: | Ms Raewyn Hopkins |
|  | Sponsor: |  |
|  | Clock Start Date: | 23 October 2014 |

Ms Raewyn Hopkins and Dr Rob Young 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

* The Committee congratulated the researchers on their HRC funding.
* The Committee commended the length of the patient information sheet.

Summary of ethical issues (resolved)

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

* The Committee queried who was providing Maori consultation. The researchers confirmed Dr Helen Wihongi, Maori Advisor at Auckland and Waitemata DHB, was providing Maori consultation.
* The Committee queried if there would be interpreters available for the study. Researchers explained that Maori interpreters were available but there was not enough funding to support other language interpreters. The Committee noted that COPD was a Pasifika health issue too. The researchers acknowledged this and planned to exclude those who could not understand information enough to provide informed consent, due to the resource constraints. The Committee noted that this is entirely reasonable. The researchers confirmed that because the study is a feasibility study it will generate information on who is not eligible. By assessing how effective this study would work in the patient population it will generate data which may inform future research.
* (P.4.4) Researchers confirmed that kaupapa Maori research methodologies would be used in this study.
* The Committee requested clarification of who the co-ordinating investigator (CI) is, noting the application states Ms Hopkins however Dr Young’s CV was submitted. Researchers confirmed that Dr Young CI – insert info on amendment to change CI.
* Researcher confirmed ethnicity data would be collected using the New Zealand Census as a template.
* The Committee noted that on one of the questionnaires it stated that to be Maori you must have 3 of 4 grandparents as Maori. Researchers explained that Maori could self-identify in this study. The quoted statement was left over from another study on genetics study where this conception of ethnicity was appropriate.
* (R.3.1) The Committee noted the application states no human tissue is collected. Researchers confirmed blood samples would be used and then destroyed.
* The Committee advised clinical findings that may affect clinical care should go into patient records.
* Committee noted the potential for incidental findings was ticked no (R.4.1), yet this was not correct as blood samples were being taken. Researchers explained that the incidental findings would feedback to the healthcare team and participants, adding that while in the study the participants would be contacted by study team and any findings after the study would go to GP.

Summary of ethical issues (outstanding)

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

* The Committee asked the CI to confirm if there was a sponsor for the study. Please clarify.
* Committee suggested having an independent person on the internal DSMC who can review study data.

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

* Amend pg.1 of PIS *‘neither you nor study doctor will know’* – indicating double blind. Currently incorrect as study is single blind.
* Please increase the font size on the patient information sheet (12pt), and perhaps more white space for readability.
* Please amend ‘would’ to ‘may’ be eligible (ACC).
* Include potential telephone calls as a procedure.
* Include a statement in the CF regarding potential phone contact.
* Consider removing yes/no boxes if these are not optional.
* Consider including some of the main eligibility criteria or key exclusion (age, statin use).

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*).
* Please clarify if there is a sponsor for the study.

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

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| **2** | **Ethics ref:** | **14/NTB/167** |
|  | Title: | A Comparative Analysis: ROCHE Cobas BRAF Version 1 vs Version 2 |
|  | Principal Investigator: | Doctor Timothy Sutton |
|  | Sponsor: | Roche Diagnostics |
|  | Clock Start Date: | 23 October 2014 |

Doctor Timothy Sutton 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.

Dr Paul Tanser declared a potential conflict of interest, and the Committee decided to have Dr Tanser stay in the room but abstain from the discussion or decision of the application.

Summary of ethical issues (outstanding)

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

* The Committee requested more evidence to support the claim that all patients who have historical tissue slides are probably deceased. The Committee stated it should not be too difficult to review health information to confirm mortality and contact potential participants if they are alive, and seek consent.
* Committee noted the peer review was not sufficient as it was completed by an employee of the sponsor. Please provide independent peer review.
* (B.4.5) Will the historical samples be stored in a tissue bank for future use?
* (R.3.8) Please clarify if any human tissue is sent overseas.
* (R.4.1.1) What is the rationale behind the decision – what reasoning would be behind a decision not to go back to the participant? Please provide an example of when it would not be appropriate to inform a participant about incidental findings.
* The Committee queried how the researchers will know that the result that they get is valid if the whole point of this project is to validate the assay? Please clarify.
* (P.3.2) The Committee noted that these participants may be vulnerable. Please explain how their needs will be managed.
* (P.4.2) The Committee noted that tissue being sent overseas is a cultural issue for Maori that must be considered.
* The Committee requested that ethnicity data is collected using the same format as the New Zealand Census.
* Please explain what will happen to leftover tissue. Elaborate on plans for results and or follow up for participants – how is this managed?
* The Committee queried the statement on Pg. 2 of the PIS. Is this tissue actually ordinarily discarded? The Committee did not expect that New Zealand laboratories would discard this tissue.
* Please confirm study results summary for participants will be in a lay language
* P.4.3.2 – for future applications please use ‘will be carried out in accordance with’ rather than ‘obtained’.
* The Committee noted that if there is future unspecified research a separate PIS/CF will need to be submitted for review. Please view the 2007 guidelines for future unspecified research.

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

* Please use consistent font.
* Please explain indemnity information in lay language as this may be confusing for participants.
* Include Pg. number, footer, date
* Use HDEC suggested wording for ACC information. In particular please amend to state participants ‘may’ be eligible for ACC rather than ‘would’.
* Please review the yes or no options on the consent form – please only offer an option if the statement is optional, if the statement is mandatory for study participation it should only have the yes option.
* Explain what BRAF analysis is in lay language.
* Include more information on where leftover tissue is going.

Decision

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

* 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*).
* Please provide a separate Participant Information Sheet and Consent Form for the use of tissue for future unspecified research (*Guidelines for the Use of Human Tissue for Future Unspecified Research Purposes, para 2*).
* Please address outstanding ethical issues.

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

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| **3** | **Ethics ref:** | **14/NTB/169** |
|  | Title: | An evaluation of Puawaitahi |
|  | Principal Investigator: | Dr. Patrick Kelly |
|  | Sponsor: |  |
|  | Clock Start Date: | 23 October 2014 |

Dr Patrick Kelly, Rachel Stevenson and Professor Seymour 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

* Professor Seymour explained the study team’s qualifications and experience.
* The study aims to identify experiences of the service, to find potential improvements or find out what is working.
* Researchers explained the prior study on providers of care at Puawaitahi (staff members).

Summary of ethical issues (resolved)

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

* The Committee queried if the service (Puawaitahi) was exclusive to Maori and Pacific Islanders? The researchers stated it was not, however Maori are over-represented. The Committee suggested including the general function of the service and who it is for to make it a bit clearer.
* Committee queried if there is anywhere that lists the relevant authorities involved with the organisation – police, CYFS and the DHB health division. The researcher explained the information is referenced in the PIS, and was considered well known by the potential participants.
* Committee requested clarification on the 30 dollar voucher for children. The researchers explained how the gift acknowledges willingness to take part and is to recognise the bravery displayed in participating. It is an acknowledgement and a reimbursement. The researchers explained the voucher can be for a variety of things, and is chosen in collaboration with the parents who sign the consent form.
* The Committee asked about the measures or plans to address stress (of children) resulting from the research. The researchers explained that a great deal of care is taken during the consenting process. The first discussion is conducted by someone who knows the child. To that extent it performs a screening function. This discussion may find a particular child is not suitable to participate due to particular vulnerabilities. Furthermore those who do participate can bring support people, as well as the interviewer being sensitive. The tapes are reviewed to ensure the interviewing is appropriate.
* The researcher added there are ways to address stress, such as stopping interviews, changing subjects and responding to signs of distress. All interviewers are trained to identify and implement these strategies. Researchers are very aware of the risks and feel they have many plans in place to mitigate the risk and from their experience even though it is inherently risky it is more often than not a good experience for the children.
* The researchers confirmed the obligation to disclose information is a professional and ethical consideration rather than a legal one.
* The Committee asked for information on the safety protocols for those who are working in private homes. Researchers explained a mobile phone will be used to make calls before and after home interviews occur.
* Please note that health data derived from the study must be stored for a minimum of 10 years according to the [Health (Retention of Health Information) Regulations 1996](http://legislation.govt.nz/regulation/public/1996/0343/latest/DLM225650.html). With participants under 16 health information must be stored for 10 years after the youngest participant turns 16.
* Please explain how to mitigate the risk of future care due to giving negative reviews (by children etc). The researcher stated all interviewees are independent, Puawaitahi staff will not be aware of who has participated and will not access the interviews. The Committee requested that this information is made clear.
* Researchers confirmed parental supervision for interviews is entirely up to the participants.
* Please clarify if data is anonymous, including the audio? The researchers explained that during analysis the data is de-identified. Once transcribed the data is anonymous, and the audio will be locked away.
* Committee noted it was important to seek verbal assent of all children and written assent if age-appropriate. Researchers responded the verbal assent will be recorded via audio.
* Committee queried whether a certificate of participation in this study was appropriate for children. Researcher explained that this suggestion came from Maori consultation.

Summary of ethical issues (outstanding)

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

* Please make it clear that a co-investigator (Rachel) is a student and health information from the study will be used to gain a qualification.

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

* Committee stated that another PIS was required for the very young children, suggesting that cartoon pictures are used.
* Remove 3 years in relation to HDEC approval.
* Review use of ‘you’ rather than ‘your child’. Also include info on seeking assent from children.
* Include space for name, signature and date of person taking consent on the consent form.
* Please re-consider the statement ‘we will not ask you about the abuse’.

Decision

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

* 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*).
* Please provide an assent form for non-consenting participants to sign (*Ethical Guidelines for Observation Studies 6.21)*

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

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| **4** | **Ethics ref:** | **14/NTB/170** |
|  | Title: | Performance Evaluation of Adjustable External Splint for Distal Radius Fracture |
|  | Principal Investigator: | Dr Sarmad Iwaz |
|  | Sponsor: |  |
|  | Clock Start Date: | 23 October 2014 |

Dr Kumar 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 ethical issues (resolved)

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

* Please explain the relationship between the peer reviewer and study team. Dr Kumar explained the reviewer was independent from the study. Dr Kumar confirmed the peer reviewer did not have any involvement in the study and is not within the same organisation.
* The Committee confirmed that Zero-cast is paying for the manufacturing of the device.
* The Committee queried whether Zero-cast has access to the database during the study. Dr Kumar confirmed they did.
* The Committee queried whether the company could terminate the trial? Dr Kumar stated it was not possible for them to terminate the study.
* Please explain if the study is for equivalence or superiority. The Committee noted the application suggests the new device is superior. Does this study have power to prove superiority? Dr Kumar explained that standard plaster cast has been standard practice for a long time, though there is actually little data to provide its efficacy. There may be a way to determine movement of fracture as a measure, or the complications as side effects due to the encasement of standard practice casts. The lack of a comparator made the study difficult to power.
* The Committee queried if there are any risks involved in the experimental splint and what measures are in place to mitigate them. Dr Kumar explained that the clinician will be reviewing the splint / fracture and can change treatment course to stabilise the fracture if required.
* Please explain why follow up schedules are not standardised between groups? Dr Kumar stated different hospitals function differently but confirmed that both groups will have the same procedures at same timelines for follow up.
* Dr Kumar confirmed there is no additional radiation for study involvement.
* Dr Kumar confirmed randomisation occurs before splinting.

Summary of ethical issues (outstanding)

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

* Please explain if there is a sponsor for the study. Dr Kumar explained that Ministry of Business, Innovation, and Employment were providing funding, as well as funding support from the company Zero-cast. The clinical aspect of the study would be funded by the DHBs who are participating. Please clarify if Zero-cast is the sponsor.
* The Committee queried how data is managed. Dr Kumar explained that the data is openly available and accessable to the clinicians to review.
* Dr Kumar explained that the team of clinicians will meet at scheduled dates and assess data together. Six clinicians at multiple DHBs will participate. Dr Kumar stated the manufacturer will not have any governance over the study. Please provide a formal explanation about the oversight committee including a terms of reference, composition and what they will be analysing.
* The Committee noted that committee oversight may need independence as without this there is a chance for bias.
* The Committee queried if this study is principally for the benefit for the manufacturer? Dr Kumar stated the aim was to create a better treatment of the patient compared to standard practice. Please provide more information on how the study is not primarily for the benefit of the manufacturer, and if it is not what safeguards are in place to stop the company from being involved in the conduct and management of the study, noting that the company provides the device as well as accesses the data during the study.
* Please provide information on the methodology of the study including end points, data points. Please consider having a biostatistician review the study to ensure it is well designed. The Committee noted the researchers should consider a feasibility study to generate some data which will make this comparative study easier.
* How will this study create new knowledge? Dr Kumar explained that data will provide information about new device. (P.1.3) please readdress this question explaining what generalisable scientific knowledge is generated by the study.
* The Committee queried if there was any consideration of what kind of fracture the participants present with, or age, or handedness? Are variables taken into account in relation to analysing the study data? Dr Kumar stated they would gauge the level of functionality of the arm prior to injury. The Committee noted that the biostatistician would be useful to make sense of these variant features.
* (R.2.3) please explain what the CI confidentiality agreement is? Dr Kumar explained that data from the database will be accessed by the CI. The Committee requested that data confidentiality of the oversight committee is elaborated on, adding it should be formally written up.
* The Committee asked if there was any official data safety monitoring committee? Dr Kumar stated there was not.
* Please note that health data derived from the study must be stored for a minimum of 10 years according to the [Health (Retention of Health Information) Regulations 1996](http://legislation.govt.nz/regulation/public/1996/0343/latest/DLM225650.html).
* The Committee noted that Maori cultural considerations had not been adequately addressed.
* Please submit further information about the consent process will work. i.e. who will talk to patients, how long they have to consider the study, assent processes – practicalities of consent processes.

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

* Currently reads very ‘pro splint’ as if it is a marketing document.
* The Committee requested a full re-write of the PIS/CF. Please refer to the HDEC template at <http://ethics.health.govt.nz/>
* Need two information sheets (one for each participant group), as well as an additional PIS for any children who may participate. This must be written in age appropriate language.

Decision

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

* The Committee is unclear about the study design and therefore is unable to judge whether the protocol and information provided best answers the study question. (Ethical Guidelines for Intervention Studies para 5.4, page 11).
* The Committee has insufficient information on the consent processes for the study. Investigators are responsible for designing and conducting studies to maximise the validity and quality of participants’ informed consent. Ethics committees are responsible for checking that proposed study information sheets and consent forms enhance informed consent of this nature. (Ethical Guidelines for Intervention Studies para 6.13, page 21).
* The Committee believed that the consent documentation was overly biased towards the experimental product and did not cover features of robust informed consent (Ethical Guidelines for Observation Studies para 6.11).
* The Committee was unsure whether the study was commercially sponsored or not.

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| **5** | **Ethics ref:** | **14/NTB/172** |
|  | Title: | Veliparib plus chemotherapy in Non-Squamous Non small cell lung cancer |
|  | Principal Investigator: | Dr David Gibbs |
|  | Sponsor: | AbbVie Pty Ltd |
|  | Clock Start Date: | 23 October 2014 |

Dr David Gibbs 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 as follows.

* Committee noted it is preferable for someone to attend the meeting either in person or via teleconference.
* The Committee noted that future unspecified research must be separate from the main PIS and cannot be mandatory for study participation. Please provide a separate consent for future research.
* (R.1.1) The Committee noted that this is an open label study not a placebo study.
* (R.1.2) The Committee noted that the researchers will seek consent to contact the GP but this is not outlined in patient information sheet. Please include the intention to contact the GP.
* (R.1.4) Provide a charter of DSMC and clarify if independent.
* (P.3.2) Please acknowledge that these patients are vulnerable and explain how the researchers will manage this vulnerability.
* The Committee notes the patient’s illness but requests a confirmation of any additional radiation risk from participation.
* (R.2.4) The Committee noted the data is potentially identifiable, rather than de-identified. Please review the NEAC Guidelines for Intervention Studies for information on identifiably of data.
* (R.4.1) The Committee noted that the study may identify unexpected findings. Please explain how researchers will handle incidental findings.
* (R.5.4) Clarify that treating researchers are not the clinical care providers, and if they are the same – how will this conflict of interest be managed.
* Please confirm that ethnicity information will be collected using the same options as the New Zealand Census.
* (B.4.5.1) Please explain what sampling is part of the study and which is optional.
* (R.3.7) Please elaborate on confidentiality measures.
* Please include a patient alert card and confirm the contact number is accessible 24/7.
* (P.4.2) For future applications please delete the first sentence.
* (F.1.1) The Committee noted this should be no.
* The Committee does not accept that some participants who are consented and screened will not become participants if enrolment is filled during screening.
* Please clarify if participants can be involved in any other kinds of research or does this only mean clinical trials. Amend PIS to clarify.
* Is separate authorisation to access medical records required in New Zealand? Please clarify this statement in the PIS.
* Please explain records that are withheld from participants during study? Why is this?
* The Committee noted that participants can withdraw verbally, written withdrawal is not required.

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

* Please clarify for participants what an ‘anti-cancer supplement’ is.
* Change investigator to study doctor.
* Remove flip of coin to explain randomisation.
* Please explain timeframes in lay language.
* Please explain study procedures in lay language – needs elaboration.
* Please explain how study doctors will determine which family member will be called.
* Please review for American spelling – US law, terminology – ‘comfort care’.
* Please include severity, duration and management options for side effects / risks.
* Pg.12 – please explain archived tissue to participants.
* ‘to avoid problems at a later stage’ – please reword this (pg.12) – make it an open invitation.
* Pg.13 – destroying samples – in event of not being able to be destroyed? When would this occur? Please address this point.
* Pg.13 – remove ‘required by U.S. law’.
* Please use ACC statement from HDEC template.
* Refer to HDEC NTB on pg.15
* Please include short lay language title (PIS/CF).
* Please review language relating to death of participants. Is insensitive.
* No need to withdraw in writing – verbally is sufficient
* Pg.10 – please explain what a local label is for participants.
* Genetic sub study pg.3 – insert Maori support contact details

Decision

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

* Please provide a separate Participant Information Sheet and Consent Form for the use of tissue for future unspecified research (*Guidelines for the Use of Human Tissue for Future Unspecified Research Purposes, para 2*).
* 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*).
* Provide details of the Data Safety Monitoring Committee’s composition and monitoring plan *(Ethical Guidelines for Intervention Studies para 6.50).*
* Address outstanding ethical issues in a cover letter.

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

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| **6** | **Ethics ref:** | **14/NTB/175** |
|  | Title: | A trial of MHAA4549A in the treatment of severe Influenza A infection, GV29216 |
|  | Principal Investigator: | Dr Alan David Pithie |
|  | Sponsor: | Covance New Zealand Limited |
|  | Clock Start Date: | 23 October 2014 |

Dr Alan David Pithie 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.

Dr Paul Tanser declared a potential conflict of interest, and the Committee decided to have Dr Tanser remain in the room, but abstain from the discussion or decision of the application.

Summary of ethical issues

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

* The Committee queried what timeframe was available in relation to the consent process (R.5.4.1). Dr Pithie acknowledged that the consent processes was generally time limited with treatment usually occurring within 48 hours of admission. The tests to confirm infection must occur quickly. Patients will be recruited after they are diagnosed with influenza.
* The Committee queried if there is time to discuss with an independent person, or their GP, due to patient sickness and the urgency for treatment. Dr Pithie explained this was not possible.
* Committee queried why there was an area for the ‘legally authorised representative’ (LAR) to sign on PIS? Dr Pithie stated patients may be under mechanical ventilation and would be unable to sign.
* The Committee requires a strong justification of why the vulnerable participants are recruited into this study. Dr Pithie stated that the patients on mechanical ventilation often have the most potential benefit for this study. The Committee requested evidence to suggest a clear benefit in the interest of these participants.
* Risks proportional to benefits (R.8.1 in application) – please address this question again as it has not been answered.
* Court appointed LARs appointed under the Protection of Personal and Property Rights 1988 cannot consent to the protected person participating in research unless it is to save the person’s life. The Committee noted that right 7(4) of the HDC code of rights states that a participant who cannot give consent can only be recruited where it can be shown that their participation is in their best interests (as opposed to the best interests of that category of participant). The research would need to offer therapeutic benefit for the participant that is as good as or better than standard treatment and pose risk that is no greater than the normal level of risk incidental to standard treatment. Given that this is a phase 2 trial it is difficult to advance the proposition that the study medication would categorically offer benefit to the individual participant in the trial. For these reasons, the Committee restricts recruitment to those participants capable of giving consent.
* The Committee acknowledges that these participants will be very unwell and recommends that the researcher develop an additional abbreviated PIS/CF that can be used to assist informed consent, bearing in mind that an ill patient may struggle to absorb a 20 page PIS/CF whilst acutely unwell.
* The Committee asked Dr Pithie to explain what monitoring arrangements are in place for the study (R.1.5). Dr Pithie explained that the sponsor had established a scientific oversight committee which may be what is referred to in the application. The Committee requested terms of reference and information on the composition and function of this committee, noting that there is a need for an independent data safety monitoring committee for phase IIb studies involving life threatening diseases.
* The Committee queried if the patient alert card’s contact phone number was available 24 hours a day 7 days a week. Dr Pithie confirmed it was.
* The Committee suggested including the patient ID on the card. Currently it only has initials.
* The Committee requested further information on the management of incidental findings in relation to communicating findings and subsequent referral processes. Dr Pithie explained that while the tests and procedures are standard practice, the repeated tests and procedures are not. Study staff will feedback to participants regularly, as is the case with clinical practice. In the event that an incidental finding occurs the study staff will refer the participant to either their GP or a specialist if required.
* The Committee noted that the recruiter would be the treatment provider, and due to how sick the participants are it created a conflict of interest. Please explain how the conflict of interest would be addressed. Dr Pithie explained that even with the time critical nature the study team tried to give the patient the PIS/CF and have an hour to consider participating. Dr Pithie added that a research nurse would often approach the patient rather than the doctor which mitigates the conflict to some extent.
* Dr Pithie stated there was a co-investigator who worked in ICU.
* (P.2.9) the Committee noted a publication may not be the best way to communicate study results to participants. Please offer a lay language summary to participants.
* (R.1.7) The Committee noted that treatment will be given by a registered health professional. This means questions have dropped out (in relation to sponsor insurance requirements). The Committee sought assurances that the sponsor agrees to provide compensation which is equivalent to the scope of ACC coverage

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

* Please replace the word ‘pint’.
* Please remove references to ‘as required by US law’.
* The Committee noted there is no obligation to sign a form to state that they (participants) will not participate.
* Review for formatting, please try to increase readability.
* Please remove yes/no option for GP being informed.
* The Committee noted that the sponsor should not terminate the study for commercial reasons as per National Ethics Advisory Committee Guidelines for Intervention Studies.
* Please review for consistent use of study doctor / local investigator.
* Please use the New Zealand Census as a template for collecting ethnicity information

Decision

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

* The Committee limits review and comments to those who can provide consent. A full justification is required for any participants who will not be able to give informed consent, which is not currently adequate to meet conditions of right 7(4) *(Ethical Guidelines for Intervention Studies para 5.28*)
* 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*).
* Please address outstanding ethical issues raised during the meeting.
* Please clarify if ACC equivalent insurance is available *(Ethical Guidelines for Intervention Studies para 8.4).*

This following information will be reviewed, and a final decision made on the application, by Ms Keirn Thompson

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| **7** | **Ethics ref:** | **14/NTB/176** |
|  | Title: | Flucloxacillin and probenecid for uncomplicated skin infections |
|  | Principal Investigator: | Dr Richard Everts |
|  | Sponsor: |  |
|  | Clock Start Date: | 23 October 2014 |

Dr Richard Everts 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.

Summary of ethical issues (resolved)

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

* The Committee queried if a biostatistician had been consulted to assist with study design? Dr Everts stated no, explaining that it was partly due to this being a pilot study. This study will indicate how many participants are feasible. This study is not powered to publish. The study is only to find failure rates, rate of recruitment, protocol working in these areas but not others.
* Please clarify publication intentions, noting that the protocol states no but application states yes. Dr Everts explained that 50-100 patients is not big enough to show any useful results (i.e. bioequivalence). Information will be presented and used but no intention for a freestanding publication of the pilot.
* Dr Everts confirmed Maori consultation is underway and has resulted in further consultation with local Maori health providers.
* Please explain the safety protocols in place due to the risks to researchers when visiting private homes. Dr Everts explained that two people will go to the interviews, with one being a large male. The Committee requested a phone call is made to the CI before and after every interview.
* Dr Everts added that there is a health risk too, due to the infectious diseases – this was mitigated by sanitizer use.

Summary of ethical issues (outstanding)

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

* Committee requested that participants are given a participant card in case the participants present to after-hours or ED clinics. This should have study drug and contact information on it.
* The Committee queried if there was any safety monitoring or reporting. Dr Everts explained there is some data safety review but was not to a clinician. The committee requested a clinician with expertise in antibiotics.
* Please amend inclusion criteria to include 16 year olds if there is no reason to exclude younger participants, as 16 year olds can consent for themselves.

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

* Include information on risks if breastfeeding.
* Amend HDEC to NTB
* Use standard ACC wording from HDEC template at http://ethics.health.govt.nz/home (please also change ‘would’ be eligible to ‘may’).
* Add contact information for HDEC
* Add information for health and disability commission advocates.

Decision

This application was *approved* by consensus.

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| **8** | **Ethics ref:** | **14/NTB/177** |
|  | Title: | A study assessing the safety and tolerability of IV ALD403 in patients with Chronic Migraine |
|  | Principal Investigator: | Dr Rosamund Hill |
|  | Sponsor: | Alder BioPharmaceuticals, Inc. |
|  | Clock Start Date: | 23 October 2014 |

Dr Rosamund Hill 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 (resolved)

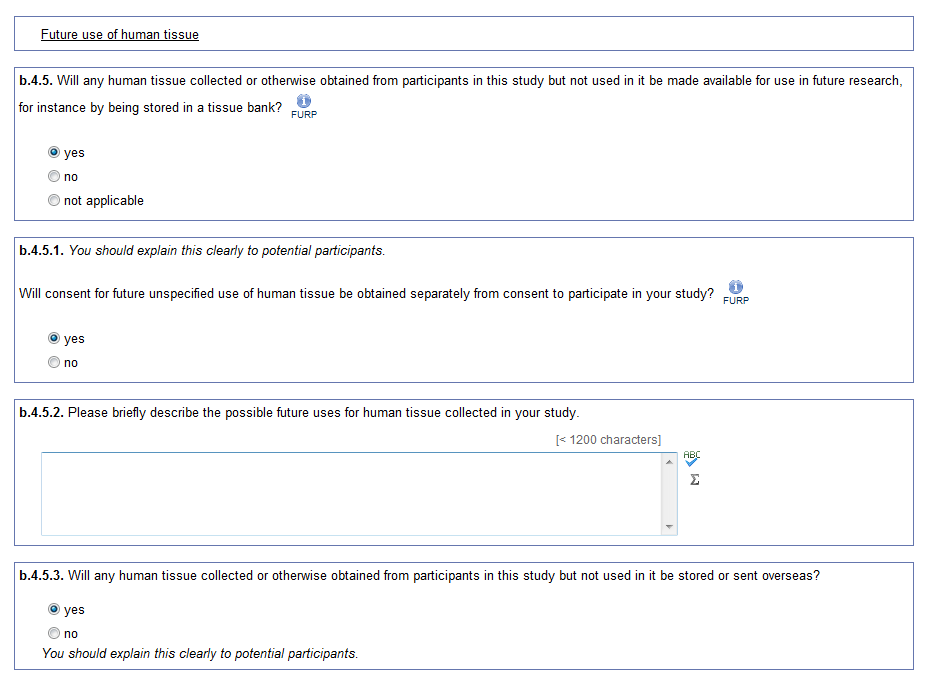
The main ethical issues considered by the Committee and addressed by the Researcher as follows.

* Dr Hill confirmed the study has been submitted to SCOTT.
* The Committee noted that the sponsor should not terminate the study for commercial reasons, as per the paragraph 6.55 of the NEAC Ethical Guidelines for Intervention Studies.
* Please explain how any identified suicidal ideations will be managed. Dr Hill responded that patients’ best interests will be the primary motivation behind management – the patient can be removed from the study if this is found to be in their best interests, the GP may need to be informed and a crisis team could be notified.
* Please ensure ethnicity information is collected using the same format as the New Zealand Census.
* Please explain what occurs if a participant decides they need to use a medicine or treatment that is banned during study participation. Dr Hill explained that participants are enrolled when they are on preventative drugs and only patients that have had stable medication for 3 months are able to enrol. There is some flexibility to change dose ranges of existing drug treatments while on study drug. If there was a reason to make a clinical call to change treatment the sponsor would be notified and would make a judgement as to whether the participant can stay in the study. If the participant wants to change their treatment they can withdraw from the study.
* The committee suggests including this information in the PIS. It should include some further inclusion criteria; i.e. you have been on a stable treatment for 3 months.
* (F.1.2) Please explain health disparity between Maori and non-Maori. Dr Hill confirmed that there is no known difference between Maori and Non Maori. Committee noted this study does not address reducing inequalities.

Summary of ethical issues (outstanding)

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

* (R.1.4) Please clarify what data safety monitoring committee arrangements are in place.
* (B.4.7) Please register the study with a World Health Organization registry.
* Please confirm that the patient card has contact information that is contactable 24/7.
* (B.4.5) The Committee noted the application does involve future unspecified research. Please address the following questions:



* The Committee queried if GPs will be informed of all study results including screening? Dr Hill stated she was uncertain, adding that if any results were abnormal they GP might be informed. The Committee noted it was important for participants to be informed about incidental findings. Please provide the system in place what process will be followed in the case of incidental findings.

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

* Pg.13 review ‘prolongation’ and explain.
* Please include lay language study title.
* Please review for US references
* Remove duplication
* Pg.16 states study could be terminated for ‘business reasons’ – please remove.
* Pg. 14 billed to insurance company – remove as not relevant for NZ context.
* Include info on action taken by study team if the questionnaire suggested suicidal ideation.
* Add information on where human tissue samples are stored, how they will be destroyed.
* Add information on prohibited treatments for duration of trial in same section as botox information.
* Include information on incidental findings on PIS/CF.
* (optional genetic PIS) – requires more information on tissue handling, storage and disposal – please review the guidelines for future unspecified research on human tissue (2007) for required information to facilitate informed consent.

Decision

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

* Please provide a separate Participant Information Sheet and Consent Form for the use of tissue for future unspecified research (*Guidelines for the Use of Human Tissue for Future Unspecified Research Purposes, para 2*).
* 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*).
* Provide details of the Data Safety Monitoring Committee’s composition and monitoring plan *(Ethical Guidelines for Intervention Studies para 6.50).*
* Please register the study on a clinical trials registry *(Ethical Guidelines for Intervention Studies para 5.42)*
* Please respond to outstanding ethical issues via a cover letter.

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

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| **9** | **Ethics ref:** | **14/NTB/178** |
|  | Title: | CP Hip Outcomes Project – Multi-Centre Study |
|  | Principal Investigator: | Professor Susan Stott |
|  | Sponsor: | University of Auckland |
|  | Clock Start Date: | 23 October 2014 |

Professor Susan Stott 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.

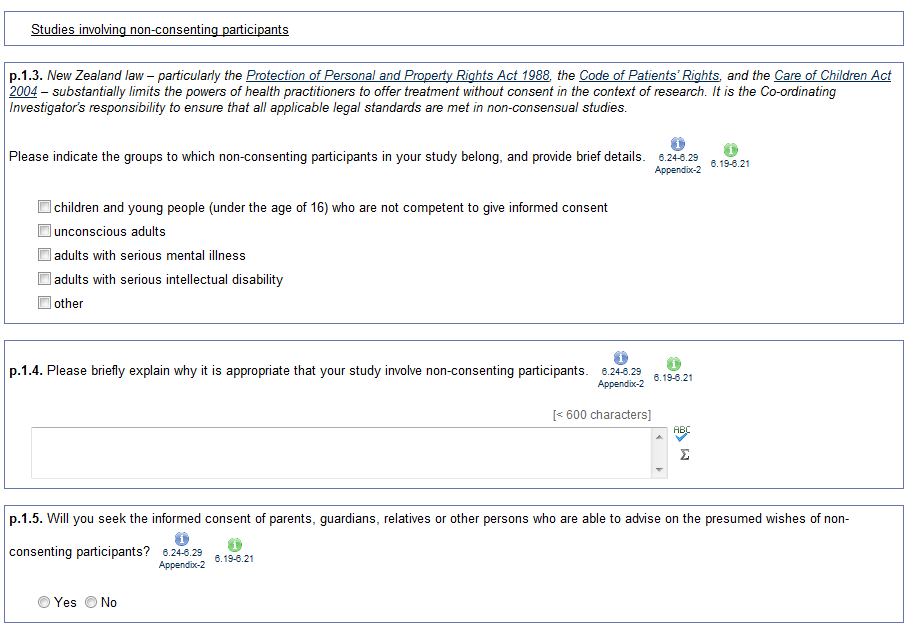
Study summary

* Study will assess children with severe CP to determine quality of life impacts from hip surgery, looking at choices of interventions and their effectiveness.
* Study is observational – outcome analysis.
* Committee appreciated the simplicity of the PIS/CF.

Summary of ethical issues (resolved)

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

* Committee noted children 16-17 can sign their own consent form. Please create a PIS for these participants.
* P.1.2 note that the following questions were missed:



* The researcher confirmed verbal assent is sought from children who are capable of understanding the study.
* The researcher confirmed Maori consultation is underway and confirmed they would collect ethnicity data.

Summary of ethical issues (outstanding)

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

* Please submit letter of invitation to be sent out. This can be sent via email to [hdecs@moh.govt.nz](mailto:hdecs@moh.govt.nz)

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

* Please change to HDEC to NTB.
* Include information on reimbursement for travel costs.

Decision

This application was *approved* by consensus.

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| **10** | **Ethics ref:** | **14/NTB/179** (CLOSED) |
|  | Title: | MK-3475-045 Bladder Cancer study |
|  | Principal Investigator: | Dr David Gibbs |
|  | Sponsor: | Pharmaceutical Company |
|  | Clock Start Date: |  |

Dr David Gibbs 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.

Ms Kerin Thompson declared a potential conflict of interest, and the Committee decided to have Ms Thompson stay in the room but abstain from the discussion or decision of the application.

Decision

This application was *provisionally approved* by consensus.

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| **11** | **Ethics ref:** | **14/NTB/180** |
|  | Title: | A study of Ombitasvir, ABT450/r and sofosbuvir with or without RBV in patients with chronic Genotype 3 HCV |
|  | Principal Investigator: | Prof Edward Gane |
|  | Sponsor: | AbbVie Ltd |
|  | Clock Start Date: | 23 October 2014 |

Ms Vithika Suri 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.

Study summary

* Study drug has recently been approved in NZ but is not currently funded by PHARMAC.
* Study will recruit participants who are untreated or prior treatment has failed to clear the virus.

Summary of ethical issues (resolved)

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

* The Committee noted access to study drug is not offered post study. Ms Suri explained this study protocol is intended for one treatment regimen after which it will have either cleared the virus or failed. Future treatment would be different in dose or regimen.
* Ms Suri confirmed karakia can be performed before the tissue leaves New Zealand.
* Ms Suri confirmed ethnicity data will be collected in the same format as New Zealand Census.
* (P.4.3.1) Ms Suri confirmed Maori review is by Dr Helen Wihongi
* (F.3.1) How will no access to treatment when the study finishes be explained clearly to participants? Ms Suri stated this study is a short duration, which is more about the right regime and duration opposed to continued treatment. This information is also covered during the consenting process.
* Ms Suri explained the degree of verbal information that is given along with the PIS/CF to help with the length and explanation.

Summary of ethical issues (outstanding)

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

* Include where human tissue is going for storage or analysis (Singapore).
* (P.4.2) – please include transportation
* Committee noted the insurance information was not relevant for the proposed study – please amend and resubmit.
* The Committee noted participants can withdraw verbally and it should not be required in writing.
* Ms Suri confirmed there is follow up for those who withdraw from the study. There is also a secondary option of referring back to their initial clinic for treatment, adding there is no risk of being lost out of the system. The Committee requested more information on follow up is included in PIS.
* Please explain DSMC arrangements. Ms Suri explained the study is small, no specific DSMC as drugs have been used extensively through other trials. The regular blood tests and safety information is routinely collected and the sponsor believes they can internally review this.
* Committee requested an independent DMSC to give study safety and integrity.

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

* Committee suggested making the PIS as simple as possible by removing duplication in the study visit procedures, noting generally the PIS was highly complex.
* Remove references to US law.
* Please make it clear that any future testing is **optional** pg.19 main PIS.
* Include short lay study title
* Amend to HDEC from HREC.
* Explain FSH.

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*).
* Provide details of the Data Safety Monitoring Committee’s composition and monitoring plan *(Ethical Guidelines for Intervention Studies para 6.50).*
* Please submit evidence of sponsor insurance. *(Ethical Guidelines for Intervention Studies para 8.4).*

This following information will be reviewed, and a final decision made on the application, by Mrs Stephanie Pollard

## General business

1. The Committee noted the content of the “noting section” of the agenda.
2. The Committee discussed a protocol deviation where a participant had participated in a trial twice. The error could have been avoided by ensuring the GP records are assessed before enrolling. The study team did request the GP records but had enrolled the participant before they were received. The Committee noted that phase one trials must contact GPs before participants are enrolled and that this should be an issue that is raised for future phase one studies.
3. The Chair reminded the Committee of the date and time of its next scheduled meeting, namely:

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| --- | --- |
| **Meeting date:** | 02 December 2014, 12:00 PM |
| **Meeting venue:** | Novotel Ellerslie, 72-112 Greenlane Road East, Auckland |

The following members tendered apologies for this meeting.

* Kate O Connor

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 5.15pm