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| **Committee:** | Northern A Health and Disability Ethics Committee |
| **Meeting date:** | 08 April 2014 |
| **Meeting venue:** | Novotel Ellerslie, 72-112 Greenlane Rd East, Ellerslie, Auckland |

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| **Time** | **Item of business** |
| 1.00pm | Welcome |
| 1.05pm | Confirmation of minutes of meeting of 11 March 2014 |
|  | New applications (see over for details) |
|  | i 14/NTA/10  ii 14/NTA/31  iii 14/NTA/47  iv 14/NTA/48  v 14/NTA/49  vi 14/NTA/50  vii 14/NTA/51  viii 14/NTA/52  ix 14/NTA/53 |
| 4.40pm | General business:  Noting section of agenda |
| 5.00pm | Meeting ends |

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| **Member Name** | **Member Category** | **Appointed** | **Term Expires** | **Apologies?** |
| Dr Brian Fergus | Lay (consumer/community perspectives) | 01/07/2012 | 01/07/2015 | Present |
| Ms Susan Buckland | Lay (consumer/community perspectives) | 01/07/2012 | 01/07/2015 | Apologies |
| Ms Shamim Chagani | Non-lay (health/disability service provision) | 01/07/2012 | 01/07/2014 | Present |
| Mr Kerry Hiini | Lay (consumer/community perspectives) | 01/07/2012 | 01/07/2014 | Present |
| Dr Etuate Saafi | Non-lay (intervention studies) | 01/07/2012 | 01/07/2014 | Apologies |
| Ms Michele Stanton | Lay (the law) | 01/07/2012 | 01/07/2014 | 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 |
| Ms Raewyn Idoine | Lay (consumer/community perspectives) | 01/07/2013 | 01/07/2015 | Present |

## Welcome

The Chair opened the meeting at 1.00pm and welcomed Committee members, noting that apologies had been received from Dr Etuate Saafi and Ms Susan Buckland.

The Chair decided that it would be necessary to co-opt members of other HDECs in accordance with the SOPs.

Ms Raewyn Idoine confirmed their eligibility, and was co-opted by the Chair as members of the Committee for the duration of the meeting.

The Chair noted that the meeting was quorate.

The Committee noted and agreed the agenda for the meeting.

The Chair noted that Dr Etuate Saafi has resigned from the NTA Committee.

## Confirmation of previous minutes

The minutes of the meeting of 11 March 2014 were confirmed.

## New applications

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| **1** | **Ethics ref:** | **14/NTA/10** |  |
|  | Title: | A Study of RG1662 in Adults and Adolescents with Down syndrome (CLEMATIS) |  |
|  | Principal Investigator: | Prof Ed Mitchell |  |
|  | Sponsor: | Roche Products New Zealand Limited |  |
|  | Clock Start Date: | 30 January 2014 |  |

Prof Ed Mitchell (CI) 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 concern about the lawfulness of conducting a study involving participants who cannot consent and for whom there is no other person legally authorised to consent, in circumstances where it was not clear that the proposed research would be in the best interests of the participants.

* The Committee discussed the letter from health legal with the researcher.

 Committee noted it is a phase II study. This means the study is assessing safety of the study drug.

 The Committee noted the number of risks and side effects from study drug.

 The Committee noted concern that there was potentially no therapeutic benefit for participants on the active treatment arm, or on the placebo arm.

Decision

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

* In non-consensual studies it is the investigator’s responsibility to ensure that all applicable legal standards are met.
* Intervention studies with no therapeutic intent should be undertaken only with the prior informed consent of the competent individual, unless a legal proxy can consent for an incompetent individual. (*Ethical Guidelines for Intervention Studies* *para* *6.28)*
* New Zealand law substantially limits the powers of health practitioners to offer treatment without consent in the context of research. It also substantially limits the powers of others to consent to such treatment on behalf of any person who is not competent. (See, in particular, the New Zealand Bill of Rights Act 1990, the Protection of Personal and Property Rights Act 1988 and the Code of Health and Disability Services Consumer Rights, particularly Right 7(4).) (*Ethical Guidelines for Intervention Studies* *para 6.26).*
* According to Right 7(4) of the Code any research involving participants not able to provide consent may only be undertaken where it is in the best interests of the participants.
* The Committee considered the following factors described in the documentation and the initial presentation by Professor Mitchell to consider whether this best interests test was met:

*Risks*

* Professor Mitchell stated that his clinical assessment was that the adult participants did not have the capacity to consent.
* The overall risks, including relatively limited safety data from Phase 1 studies and uncertainty about how generalizable this is to participants with Down’s Syndrome who often have other co-morbidities.
* Professor Mitchell’s description of a potential risk of increased suicidality.
* Lengthy assessment visits

*Benefits*

* Placebo arm where participants would derive no benefit but undergo blood tests, ECGs and tissue banking
* Uncertainty of participants deriving benefit from the study medication given limited data about efficacy.
* At best, even if participants did derive benefit, it would be time limited to the duration of the study as the sponsor has not agreed to post trial access to the study medication. This raises the prospect of participants possibly deriving short term benefit which would then be withdrawn.

When weighing all these factors, the Committee did not think that the study could be said to be in the best interests of the participants.

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| **2** | **Ethics ref:** | **14/NTA/31** |  |
|  | Title: | ASPECT - A double-blind study to assess the safety and efficacy of intravenous Ceftolozane/Tazobactam with that of Meropenem in Ventilated Nosocomial Pneumonia |  |
|  | Principal Investigator: | Dr Shay McGuinness |  |
|  | Sponsor: | Cubist Pharmaceuticals, Inc. |  |
|  | Clock Start Date: | 27 February 2014 |  |

Dr McGuinness (CI) was present by teleconference and Rachael Parke 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

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

 The Committee explained the recent letter received from Health Legal.

 The Committee noted that it is the investigator’s responsibility to ensure that all applicable legal standards are met. New Zealand law substantially limits the powers of health practitioners to offer treatment without consent in the context of research. It also substantially limits the powers of others to consent to such treatment on behalf of any person who is not competent.

 The Committee stated that any non-consensual research needed to be in the ‘best interest of the participant’ (right 7.4 of the Code) to receive approval, provided all other ethical standards are met.

 The Researcher queried how the best interests of the patient is met. The Committee responded it would be assessed on a case by case basis in relation to the information provided with each application.

 The Researcher stated the difficulty of determining the right course of action on a case by case basis when there is no case law. The committee noted that the wording of the Code is clear and that an ordinary and natural interpretation of the meaning of the Code would be applied.

 The Researcher explained the inclusion and exclusion criteria always include a provision that the treating clinician (who is not involved in the study) needs to be satisfied that study involvement is best for the patient. This measure protects patients from being recruited when it is not in their best interests.

 The Researcher explained that in his experience the majority of patients are happy to be in studies, or actively want to be in studies (where consent can be sought pro-actively).

 The Researcher acknowledged that this did not mean each individual participant would consent to research but did to some extent show research was desired by patient populations.

 The Researcher explained that it is difficult to state a clear benefit as the absence of proven benefit is the reason why the research is being conducted in the first place. The Researcher added that the treatment population that is affected by the difficulty of conducting non-consensual trials was large, including sedated, unconscious, or critically ill ICU patients.

 The Researcher explained current standard practice in ICU.

 The Committee responded this is related to treatment, not research, adding that under the Code the rules for research are clear.

 The Committee requested a positive justification, not a negative one.

 The Committee queried whether, if it was up to the researcher, he would have chosen a superiority design (as opposed to the FDA non-inferiority design). The Researcher explained the reason non-inferiority trials were specifically related to antibiotics and the need to have multiple treatments for bacterial infection to avoid bacteria resistance to treatments resulting in superbugs.

 The Researcher explained non-inferiority was ‘as good as or better’ which suggests a case could be made that if the standard treatment didn’t work and the experimental treatment did it could therefore be in the best interest of the patient to participate in the research.

 The Committee noted approval related to potential extra risks relating to the experimental drug. The Researcher noted there is less clinical experience with the study drug, Although there is substantial Phase II evidence for this combination in healthy volunteers and patients unwell with other infections, the risks are therefore able to be relatively well quantified, clarifying that there were no ‘known’ extra risks.

 The Researcher explained the study drug had been used for other indications – it is not a drug that has been specifically developed for this research treatment. The knowledge about this drug was quite advanced.

 Committee noted this is a phase III study. The Committee clarified that the known risks are no worse than the risks involved for current treatment. There is some early evidence that the study drug is more effective.

 The Committee explored additional monitoring procedures relating to study drug.

 Committee queried if BAL samples were best practice for diagnosis. Researcher confirmed it was international recommendation to use BAL samples to diagnose ventilator acquired pneumonia. Researcher added it is not always diagnosed this way as it requires skilled people to administer and read the test. The researcher added that participants will definitely get the gold standard for diagnosis which is a secondary benefit of being involved in clinical research.

 Committee queried if any countries had approved the study since the last HDEC meeting. The Researchers responded that it has been submitted in NZ first.

 Committee confirmed SCOTT approval has been received.

 The Researcher confirmed he would put in writing how this particular trial provides a benefit to each individual participant due to the equal risk:benefit ratio compared with standard treatment, as well as the diagnostic tools being better than standard practice.

 Committee noted the researcher previously briefed the Committee on the need to have new more effective antibiotic treatments.

 The Committee suggested that the Researcher seek formal legal advice (about the legality of non-consensual studies. para 15 Standard Operating Procedures for Ethics Committees).

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

* + Please review section 6 in the PIS. Include information about previous trials that truly reflects the anticipated experience and benefit for the patient.
  + Please re-write a PIS for a next of kin. The Researchers explained the PIS was trying to combine the assent and consent. Committee noted it is too confusing currently and should be separated.
  + The PIS is confusing with respect to the PK samples and where they go. Please clarify length of time they are stored and when they are going to be destroyed.
  + Please explain what the bio-marker studies involve.
  + The Committee queried if it was appropriate that tissue samples can be collected before consent has been sought. Researchers explained that tissue samples were not sent overseas until consent was sought – if consent was not given the samples could be destroyed before analysis.
  + The Committee stated bio-marker research is quite different to PK marking.
  + The Committee asked for a time limit before sending tissues overseas.
  + Please make it explicit that having samples sent overseas is optional.
  + Make it clear that participants can be involved in the study without sending tissue samples overseas.
  + Pg.9 ‘how can I access my information’ – Please remove the clause relating to withdrawing participants if they insist to access their health information. New Zealand participants have the right to access their health information under the Health Information Privacy Code. The Researchers explained it was likely to be a sponsor required statement.
  + Please remove reference to US laws.
  + Pg.2 ‘warning’ – please remove.
  + Pg.11 – please remove reference to being taken off study drug – Researcher acknowledged this is probably a standard statement from prior studies and can be removed.
  + Please include the pregnancy information on the consent form, not just the PIS.

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*).

 If a person is not competent to make an informed decision about participating in a therapeutic study, then the decision may be made by an individual who is legally entitled to decide on behalf of that person. If no such individual is available, and the investigator can legally undertake the study, then study participation must:

* + meet appropriate ethical standards, which include the best intervention standard (see ‘Best intervention standard’, paragraphs 5.13–5.17) and the equipoise standard (see ‘Equipoise standard’, paragraphs 5.18–5.21)
  + be consistent with the views of other suitable people who are interested in the person’s welfare and available to advise on this
  + be in accordance with a study protocol approved by an ethics committee.

 Participation in the research must be in the best interests of the patient and reasonable steps need to have been taken to ascertain the views of the consumer.

Please justify the above in relation to your study.

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

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| **3** | **Ethics ref:** | **14/NTA/47** |
|  | Title: | MK-8835-004/B1521021 |
|  | Principal Investigator: | Dr John Baker |
|  | Sponsor: | Pfizer Inc |
|  | Clock Start Date: | 27 March 2014 |

Ms Catherine Howie and Dr John Baker (CI) 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 study is a non-inferiority study to compare study drug verses placebo.
* Study is trying to examine whether there are reduced cardiovascular outcomes for the type II diabetic population using the new medication.
* Researchers explained the FDA requirement for all new compounds have to demonstrate there are no additional cardiovascular risks.
* The Committee noted study is seeking SCOTT and Maori consultation in tandem with HDEC application.
* Committee clarified the sample size.
* Committee noted DSMC is appropriate.
* Committee asked about current standard treatment. The researcher clarified participants remain on their own standard diabetes medication.
* The Researcher added that their treatment management can be adjusted if their blood sugar spikes or any other adverse effects are identified.
* Committee queried the use of such old data in relation to the potential benefits for Maori (P.4.2). In future please use updated data
* Please explain where samples will be stored and or analysed. Researcher explained samples go from Singapore and then the US for specialised analysis.
* Committee queried need to bio-bank.
* Committee queried where Maori beliefs statements came from on PIS pg.12. Researchers responded they were from Middlemore Hospital via previous presentations to the Counties Manukau Māori Research Review Committee.
* The Committee requested the following changes to the Participant Information Sheet and Consent Form:
* Pg.10 – please amend ‘rugs’ to ‘drugs’.
* Please include information about study involvement being at least 6 years at the beginning of PIS.
* In order to assist participant understanding please start the PIS saying ‘you have been invited because you have diabetes…’
* Please amend paragraph 3 on page 15 – in New Zealand legislation compensation is not ‘dependent on the likelihood of adverse reactions’.
* Pg.21 – wording around the time of consent being given. Please give the participants the opportunity to take the PIS home, given it is 23 pages.
* Pg.22 – it is not appropriate for someone to simply read the PIS to someone who can’t read i.e is illiterate. Please delete the words ‘who cannot read’ from p22 of PIS
* Pg.3 of optional PIS –‘If I have an adverse (bad) effect, who will pay the doctor and hospital bills?’ Please revise as this statement is not in line with RMI guidelines.
* Please amend the optional PIS to make it an OPT IN not an OPT out.
* Include where tissue samples are being stored and for how long.
* Please review PIS and reduce repetition.
* Pg.19 – on data access. General and health information is able to be accessed by participants in line with the Privacy Act and Health Information Privacy Code. Please revise wording.
* Please be clear about what participants are opting into and what they have the chance to opt out of.
* As a general guide to future PIS, consider the use of more concise language and make use of a better layout including bullet points as for example. All this assists readiability.

Decision

This application was *approved* with non-standard conditions by consensus. Please submit non-standard conditions to [HDECS@moh.govt.nz](mailto:HDECS@moh.govt.nz) for completeness.

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| **4** | **Ethics ref:** | **14/NTA/48** |
|  | Title: | A trial of one stage vs two stage procedure for BBAVF |
|  | Principal Investigator: | Dr JK Wicks |
|  | Sponsor: | Capital and Coast DHB |
|  | Clock Start Date: | 27 March 2014 |

Dr JK Wicks (CI), Dr Alice McLachlan and Ms Marina Dzhelali 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 the study aims to identify which of the equally poised standard practice measures is better and or more efficient.
* Committee queried if Maori consultation had been received. Researcher confirmed it had been provisionally approved. Please send letter once received.
* The Committee queried if NHI number would be linked to study data. Researcher explained that only Wellington Hospital will remain potentially identifiable, as they are their patients. Other DHB sites will be assigned a study number.
* Committee queried mitigation of coercion by being asked to participate by their surgeon (R.5.4.1). The Committee requested a further explanation of mitigation of coercion.
* The Committee requested the following changes to the Participant Information Sheet and Consent Form:
* Please include what is standard care and how this may be different if enrolled in the study.
* Explain reason of study – to figure out which treatment is best. Explain how this would be chosen outside of the study i.e. the surgeon would usually decide.
* Include patient is randomized (by chance) and assigned to one of two procedures.
* Be clear about the additional follow up.
* Amend reference to CEN HDEC to NTA HDEC.
* Make it clear that refusing to participate will not affect standard of care.
* Remove the word ‘always’ from some surgeons.
* Please amend to Accident Compensation Act 2001.
* 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). Include this information for participants.

Decision

This application was *approved* with non-standard conditions by consensus. Please submit non-standard conditions to [HDECS@moh.govt.nz](mailto:HDECS@moh.govt.nz) for completeness.

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| **5** | **Ethics ref:** | **14/NTA/49** |
|  | Title: | A Dose-Ranging Study to investigate NVR 3-778 in Healthy Volunteers and Patients with Chronic Hepatitis B |
|  | Principal Investigator: | Prof Edward Gane |
|  | Sponsor: | Clinical Network Services (CNS) Pty Ltd |
|  | Clock Start Date: | 27 March 2014 |

Ms Kerry Walker and Dr Schwabe in person 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 application is for a first in human treatment for chronic hepatitis B in healthy individuals.
* Study is dose ranging. Once safety data comes back the dose will become multiple ascending doses.
* Also includes in phase 2 a proof of concept study to show a decline in infection.
* In future please demonstrate peer review or process in place. The Committee notes SCOTT is being sought but the application stated no review.
* The researchers confirmed peer review had been undertaken internally, over the last 9 months. It would be useful if the researcher could provide a brief outline of the peer review process, project design and who was involved
* Committee and researcher discussed the stopping mechanisms for the study, for individual participants as well as the entire cohorts.
* The Committee discussed the mechanism of moving from phase 1 to phase 2.
* Please submit an amendment once phase 1 is complete, with updated PIS relating to new safety data if it arises or new side effect data.
* Please clarify when and if the PK samples are destroyed. If they are destroyed please include the length of storage in the PIS.
* The Committee requested the following changes to the Participant Information Sheet and Consent Form:
* Please review formatting, such as bullet points or including more white space.
* Reduce dense text blocks.
* Include ‘OPTIONAL’ for bio-banking.
* Please introduce the study i.e. reason why we are doing the study and why participants are approached to take part.

Decision

This application was *approved* by consensus.

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| **6** | **Ethics ref:** | **14/NTA/50** |
|  | Title: | Zilver PTX Thumbwheel Delivery System |
|  | Principal Investigator: | Associate Professor Andrew Holden |
|  | Sponsor: | Cook Medical |
|  | Clock Start Date: | 27 March 2014 |

Donna Katae 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

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

* Researcher introduced the study
* The study is assessing a delivery system device.
* Researcher explained that other companies had developed a thumbwheel. The sponsor has now developed their version.
* Committee confirmed the one hand delivery system was easier for the clinician
* How are potential participants selected for these trials? Researcher explained primarily through consultation with outpatient clinics. The researcher added that at regular vascular meeting and radiology meetings clinicians discuss the patients who might benefit from these technologies and treatments.
* Will this device be standard of care? Researcher confirmed that was the goal.
* Maori research is pending on locality approval scheduled for 14 April 2014.
* The Committee requested the following changes to the Participant Information Sheet and Consent Form:
* Committee queried if a picture was able to be used to help describe device to participants.
* Please reformat for more white space, break up paragraphs, use bullet points etc.
* Please make it clear what standard practice is.
* Please note that angiograms will be sent to America. It is in the consent form but must be in the information sheet too.

Decision

This application was *approved* by consensus.

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| **7** | **Ethics ref:** | **14/NTA/51** |
|  | Title: | The LIFEGARDS Study |
|  | Principal Investigator: | Dr Shay McGuinness |
|  | Sponsor: |  |
|  | Clock Start Date: | 27 March 2014 |

Dr McGuinness (CI) was present by teleconference and Rachael Parke 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

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

* Study involves secondary use of clinical data.
* Committee noted study is not entirely retrospective.
* Committee queried how patients will be selected. Researcher explained inclusion and exclusion criteria would be assessed and then they would be recruited.

Decision

This application was *approved* by consensus.

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| **8** | **Ethics ref:** | **14/NTA/52** |
|  | Title: | Mesa Rail |
|  | Principal Investigator: | Mr John A I Ferguson |
|  | Sponsor: | K2M Inc |
|  | Clock Start Date: | 27 March 2014 |

Crista Yarrell 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

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

* The Committee confirmed Mesa Rail treatment is standard of care.
* The study will look at the Mesa Rail verses historical data.
* The study is observational – collecting data on the performance of the Mesa Rail system in the real world clinical setting, as well as data on quality of life outcomes associated with the Mesa Rail.
* The Committee requested the following changes to the Participant Information Sheet and Consent Form:
* Please reduce complexity.
* Please reduce repeated referral to signing.
* Patients do not need to initial every page.
* Please remove mention of IRB
* Pg.8 update Maori health section – new contact information.
* Please remove reference to federal regulations
* Pg.6 – please remove sentence about not being able to review own patient data and health information. Patients are entitled to view their own information under the Health Information Privacy Code.
* Pg.7 – please delete the statement referring to lack of confidentiality “If you give permission to give your identifiable health information to a person or business, the information may no longer be protected.”
* Pg.7 - Please delete ‘will not stop automatically’.
* Reduce length of headings
* Please remove need to withdraw in writing.
* Make it clear that involvement in the study requires additional procedures and information collected compared to non-participation.
* Explain that x-rays are going overseas.
* Include ACC wording - If you were injured in this study, which is unlikely, you would be eligible for compensation from ACC just as you would be if you were injured in an accident at work or at home. You will have to lodge a claim with ACC, which may take some time to assess. If your claim is accepted, you will receive funding to assist in your recovery. If you have private health or life insurance, you may wish to check with your insurer that taking part in this study won’t affect your cover.
* Please note that health data derived from the study must be stored for a minimum of 10 years, after the last participant turns 16, according to the [Health (Retention of Health Information) Regulations 1996](http://legislation.govt.nz/regulation/public/1996/0343/latest/DLM225650.html).

Decision

This application was *approved* with non-standard conditions byconsensus. Please submit the response to [HDECS@moh.govt.nz](mailto:HDECS@moh.govt.nz) for final sign off, as requested by researcher.

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| **9** | **Ethics ref:** | **14/NTA/53** |
|  | Title: | Rheumatic Fever Risk Factors Study |
|  | Principal Investigator: | Professor Michael Baker |
|  | Sponsor: |  |
|  | Clock Start Date: | 27 March 2014 |

Professor Michael Baker (CI) by teleconference, Professor Diana Lennon and Dr Jason Gurney in person 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 researcher explained this is a national case control study funded by the HRC. The study will compare 200 cases with 400-600 control cases over 2 years. The study will look at environmental factors such as housing conditions.
* Please retain health information for 10 years after the youngest participant turns 16.
* The Committee queried why the consent form was nearly as long as the patient information sheet.
* Please make it explicit what is optional and what is not optional on the consent form.
* Make it explicit what options are mandatory for study involvement.
* Some of the options on the consent form are absent or not very clear on the information sheet. I.e. getting results for house hold members swabs.
* Include more information on biomarkers and DNA testing.
* The Committee strongly suggests revising the PIS after viewing the HDEC template, found at <http://ethics.health.govt.nz/home> to see how to structure the tick boxes.
* Committee commended the area for younger participants to sign on the PIS / CF.
* The Committee asked for clarification on the governance of Māori and or Pacific samples. The researchers explained that any future research first needs to go to the Māori or Pacific steering group and then again to ethics for approval to use.
* The steering group has a tracking system, down to the freezer level storage, for return of samples.
* The Committee queried if the Researchers have any concerns about the samples and future use. The researchers were satisfied with the steering group and HDEC as a protection mechanism, and that future use was limited to rheumatic fever related purposes as detailed in the protocol.
* The Committee noted that the CF refers to the protocol about potential future use of samples, but the participants won’t see the protocol – please include some information in the PIS about the future use of tissue.
* The Committee queried if there had been measures in place for stigmatisation or findings that may reduce mana. The Researchers were in consultation with the steering group to ensure the appropriate publication and understanding of study results.
* The Committee queried if recruitment for the 200 cases would be an issue. Researchers stated no.
* The control will be taken from a sample of participants in the New Zealand Health Survey who indicated they would be happy to participate in future research – around 5 thousand children. Committee queried if any children in the control group may have had RF. Researchers responded that if any children will be asked about RF and asked to declare it, but that the study will not diagnose RF
* P.4.2 – referral results are in place. Please make it explicit that any results go back to the GP and this is made explicit in the PIS.
* The Committee requested the following additional changes to the Participant Information Sheet and Consent Form:
* Pg.4 under ‘your rights’ – please make it clear that health information can be accessed at any time.

Decision

This application was *approved* by consensus.

## General business

1. The Committee noted the content of the “noting section” of the agenda.
2. The Committee discussed non-consensual trials and the advice received from health legal.
3. The Committee noted that the researcher must provide compelling justification to the Committee that there is a benefit for individual participants. Without an adequate justification of ‘interest to the consumer’ the HDEC is unable to approve an ethics application involving non-consensual participants. Please see ‘Non-consensual’ Research in the NEAC guidelines for Interventional Research for more information.
4. The Chair reminded the Committee of the date and time of its next scheduled meeting, namely:

|  |  |
| --- | --- |
| **Meeting date:** | 13 May 2014, 01:00 PM |
| **Meeting venue:** | Novotel Ellerslie, 72-112 Greenlane Rd East, Ellerslie, Auckland |

The following members tendered apologies for this meeting.

* Dr Karen Bartholomew

1. **Problem with Last Minutes**

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

The meeting closed at 5pm.