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| **Committee:** | Northern A Health and Disability Ethics Committee |
| **Meeting date:** | 08 July 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 10 June 2014. |
|  | New applications (see over for details) |
| 1.30pm | i 14/NTA/94  ii 14/NTA/97  iii 14/NTA/98  iv 14/NTA/99  v 14/NTA/100  vi 14/NTA/101  vii 14/NTA/102  viii 14/NTA/103  ix 14/NTA/104 |
| 4.30pm | General business:   * Noting section of agenda |
| 4.50pm | Meeting ends |

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

## Welcome

The Chair opened the meeting at 1.11pm and welcomed Committee members, noting that apologies had been received from Dr Karen Bartholomew.

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 10 June 2014 were confirmed.

## New applications

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| **1** | **Ethics ref:** | **14/NTA/94** |
|  | Title: | A randomised controlled trial to assess the effect of zopiclone on the uptake of and adherence to CPAP therapy |
|  | Principal Investigator: | Dr Andrew G Veale |
|  | Sponsor: |  |
|  | Clock Start Date: | 26 June 2014 |

Dr Andrew G Veale was present by teleconference with Mrs Carol Veale and Mrs Kareen Redulla 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 study is conducted only in New Zealand, in-house and investigator initiated study.
* The researchers explained that people who start on CPAP machine therapy often complain about the quality of sleep, often experiencing difficulty in getting sufferers to continue using the machine. There is some evidence to suggest that increasing sedation concurrent with starting CPAP therapy may increase uptake.
* Currently people who have difficulty using CPAP are prescribed the study drug, ad hoc, to ease comfort of use. The study drug, Zopiclone, is the standard practice sedative used to treat sleep problems yet it is not systematically used for people starting CPAP therapy.
* The Committee was satisfied with the response on maintenance of participant confidentiality.
* The researchers explained the AHI measure relates to the number of times a patient stops breathing, per hour, while sleeping. Mild, moderate to severe relates to the number of events. This study will only recruit mild to moderate, as providing sedatives to those with severe AHI would pose health risks.
* Potential participants will attend the respiratory clinic for an overnight stay to assess whether they should be treated with CPAP therapy; this occurs regardless of participation in this current study.
* The Committee clarified that the potential participants stay over for the first night, then will use the CPAP machine at home, in combination with the study drug.
* The researchers expect 2 years to recruit and follow up 300 participants.
* The researchers were asked what they consider are the ethical issues relating to this study. The researchers responded there is a risk of evening alcohol use impacting the strength of the study drug. There are potential risks with participants with liver problems. The researchers explained that screening will occur to mitigate these risks, and the interactions and exclusion criteria is covered with participants. The use of a placebo arm also constitutes a risk, though this is standard practice and is mitigated by the placebo arm having best standard practice as treatment (the CPAP machine).
* The researchers explained their relationship with the consultants who will inform researchers of any issues that the patients experience, or for participants who do not show up to the clinic appointments.
* The Committee confirmed Maori consultation has been received.
* The Committee requested the following changes to the Participant Information Sheet and Consent Form:
* Pg.2 at the bottom there is an \*. Please remove, it does not refer to anything.
* Include the dose of the tablet.
* In the Consent Form (CF) it mentions there are risks associated with pregnancy. Please make sure this is in the Patient Information Sheet as well as the CF. The researcher’s added that pregnancy was an exclusion criteria.
* Include information on length of data storage. The Committee suggests having a maximum length of storage, not a minimum.

Decision

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

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| **2** | **Ethics ref:** | **14/NTA/97** |
|  | Title: | KONA WAVE IV Study: Phase II Study of Subjects with Uncontrolled Hypertension |
|  | Principal Investigator: | Dr John Ormiston |
|  | Sponsor: | Kona Medical Inc |
|  | Clock Start Date: | 26 June 2014 |

Dr John Ormiston and Ms Faye Somerville, 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 noted the study was interesting, particularly in its design involving a sham arm.
* The researchers explained that the device is non-invasive with no blood or radiation involved.
* The Committee queried if the study was first in human. The researchers explained there had been 13 participants involved in earlier phases, within New Zealand, and roughly 50 globally. The researchers added that patients in New Zealand have mostly responded well.
* The Committee requested both explanation and justification of the placebo (sham) arm. How will this be conducted and is it necessary? The researchers explained that studies have shown that all forms of renal denervation seem to reduce blood pressure. When these studies added a sham placebo arm they found that the treatment arm was no better than the sham arm. The studies identify various factors that impact blood pressure. There were cultural differences identified, as well as individual psychological mentalities that each attributed to changes in blood pressure. Another factor was the cognitive bias of the person taking the blood pressure reading – they would continue to take the measurement until they felt it was ‘normal or correct’ as if it were too high or had decreased they thought it would be a false reading. A sham placebo arm is useful in mitigating these factors, particularly with blood pressure which can vary daily, or even hourly.
* Please explain the difference in participant experience between sham and treatment arm? The researcher explained the treatment arm has more pain, but there are anaesthetics used (while patient stays awake) to mitigate any pain.
* The Committee asked for more information about the blinding. The researchers explained that the patient, the doctors, the person who is conducting the blood pressure reading and the company treatment providers who administer the intervention will not know. The Co-ordinating investigator will know but he will not conduct any measurements.
* After one year everyone is un-blinded. The participants who have had sham treatment are given the option to cross over to the treatment arm.
* The Committee asked for more information on the peer review provided, noting it was a statistician who did not have clinical experience. The researchers explained that there are no adverse events associated with the device. The committee explained that the design of the experiment had been reviewed sufficiently but the clinical side had not been reviewed. The Committee requested a peer review is provided that relates to the clinical component of the study.
* The researchers suggested asking Mark Webster to prepare a peer review with respect to the clinical side. The Committee felt this was appropriate.
* Please explain how many people in each group. Researcher responded that hopefully 10 people in the randomised group in New Zealand, with 160 worldwide over 12 sites. The researchers can offer study participation to people who have not responded well to other treatments, such as catheter treatment.
* The researchers believed the participants would be keen to participate as it is a treatment movement from invasive to non-invasive.
* The Committee and researchers confirmed all participants will give informed consent.
* Committee confirmed Maori consultation is ongoing.
* The Committee requested the following changes to the Participant Information Sheet and Consent Form:
* Please remove box for someone else to provide informed consent for a potential participant’s behalf.
* Please include information on not being able to claim ACC and include more information on RMI guideline equivalent compensation being available.
* Please remove reference to American legalisation.
* Please review for typo and grammar, in particular (pg.9).
* Please include a statement on destruction of tissue samples.

Decision

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

* Please provide evidence of peer review of the clinical components of the study (*Ethical Guidelines for Intervention Studies* Appendix 1).
* 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 submit a protocol for the study. All intervention studies should be conducted according to written protocols. The amount of detail in the written protocol and the extent of protocol review processes should be sufficient to ensure appropriate conduct of the study and to cover the level of risk the study presents to participants. (*Ethical Guidelines for Intervention Studies* *para 5.41*).

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

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| **3** | **Ethics ref:** | **14/NTA/98** |
|  | Title: | BOLSTER |
|  | Principal Investigator: | Associate Professor Andrew Holden |
|  | Sponsor: | BARD |
|  | Clock Start Date: | 26 June 2014 |

Associate Professor Andrew Holden and Miss Helen Knight 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 Committee queried how similar this device was to earlier devices that the CI had researched. The researchers explained that the BARD company will be the third company in the market to work on such a device.
* The Committee queried why develop a third stent? The researchers explained that the BARD company stent may be better, worse or the same as the earlier stents.
* The Committee requested information on the data safety monitoring in place. The researchers explained that there are two levels of monitoring. The first is on-site internal monitoring which ensures that the data being entered at a site level is correct.
* There is also independent data safety monitoring committee that monitors all trial data – this committee will assess any safety concerns and this will inform termination or any halting of the study.
* The researchers explained that first in man studies generally require the monitor to assess 100% of the data. This ensures the data is robust and is one reason the data quality is so high. This is occurring for this study.
* The Committee queried if there are any health risks related to becoming pregnant after the procedure? The researchers explained that patients are followed for up to 12 months after treatment, usually if they are not having problems by 12 months they will not experience any complications. Future follow up is clinical and ultrasound, which is within standard of care and provides no risk to pregnant participants.
* The Committee asked for more information about the peer review provided. The researchers acknowledged the difficulty in having an international sponsor who does not have to provide independent peer review for other countries ethics applications.
* The researchers explained that for every intervention that occurs within the study a multidisciplinary group is involved, and assesses the intervention against the participant’s unique circumstances. These meetings are minuted.
* The Committee noted the FDA has approved the device which involves a substantial peer review. The Committee and researcher had a useful discussion on future ways to address the issues of reviewing projects involving devices.
* The Committee requested the following changes to the Participant Information Sheet and Consent Form:
* Pg.2 please amend to Northern A Health and Disability Ethics Committee.

Decision

This application was *approved* by consensus.

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| **4** | **Ethics ref:** | **14/NTA/99** |
|  | Title: | Low carb kids |
|  | Principal Investigator: | Dr Caryn Zinn |
|  | Sponsor: | AUT University |
|  | Clock Start Date: | 26 June 2014 |

Dr Caryn Zinn and Prof Grant Schofield 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.

Dr Christine Crooks declared a potential conflict. The Committee decided it was not a substantial conflict and all agreed that Dr Crooks could take part in discussion and decision of the application.

Summary of ethical issues

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

* This is a feasibility study run over 12 weeks. It is a single arm study that will provide guidance and assessment of a carbohydrate restricted diet for overweight and or obese children.
* This study aims to look at feasibility of a larger study, recruitment, existing referral pathways, cost effectiveness, and efficacy to some extent. If results are successful it will inform a larger study.
* The study offers the wider family a chance to participate too, not just children. The primary participant group is 8 to 13 year olds.
* Do you have a process in place if your study procedures identify blood test results outside of reference range? Researchers explained that the results may be outside for ‘normal’ but for their health status (being overweight) it may be ‘normal’. The issue of ‘normal range’ is somewhat controversial however as a precaution we do have GPs on board to manage and contextualise any findings.
* Confirmed AUT Māori research committee has been approached for consultation.
* The researchers acknowledged the sensitive context of referral, where the participants are identified in relation to being overweight, and have considered ways to avoid stigmatisation.
* Please explain how confidentiality will be maintained, adding that study participation inevitably involves family, as well as during the focus groups.
* The researchers explained that the family will be aware of study participation and did need to be involved.
* The researchers acknowledged that they had not considered the lack of confidentiality resulting from the need to be present in person at the focus groups. The researchers explained the existing stigmatisation the participants will have already experienced and added that this study would aim to support and help the participants rather than increase stigmatisation.
* The researchers explained their own experience in working with overweight children and the issues of stigmatisation.
* The Committee requested the potential participants be well informed of the various levels of confidentiality, such as health information and study results being confidential, yet personally being identified at the focus groups.
* Please explain what tests will occur on the blood and saliva. The researchers explained that blood tests will assess lipid profiles at weeks 0, 4 and after week 12. The saliva will assess the enzyme amylase.
* The researcher confirmed that the low-carb diet has evidence to support it works with adults.
* The researcher confirmed the blood results will not go on the NHI records unless the GP is involved and this is consented to by the participants.
* 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). In cases of studies involving minors it must be 10 years after the youngest participant turns 16.
* The Committee queried if there are any culturally specific tools that can be used to accommodate Pacific, Maori or Asian family’s dietary transition, and to assist with support and uptake. The researchers explained they are developing an online tool that can provide this kind of support.
* Please consider accessibility issues for potential participants, including web access and home phone lines are available.
* The Committee requested the following changes to the Participant Information Sheet and Consent Form:
* Please reword ‘because we think it will be good for your health’ (page 1 under heading ‘why you have been chosen’. Current wording is too positive, as it indicates there will be positive benefits. Change to reflect that it is possible but not certain.
* Remove Page 1, child PIS - heading ‘you have been chosen’… to avoid coercion to participate.
* Explain in lay language, what a ‘quick scan’ involves and or is, in the children’s PIS.
* Please provide details how much blood you are taking – for instance ‘half a tea-spoon’.
* Include information about confidentiality will be managed. Be clear about what the participants will experience, for instance seeing each other at the focus group.
* Include information on the DEXA scan under the risks section, and explain the risk factor in lay language.
* If you feel it is appropriate please make informing the GP as optional.
* Please explain that tissue samples can be returned.
* Please revise and or remove references to pregnancy.
* Explain ‘general state of inflammation’ in lay language. Pg.3 adult PIS Para 4.

Decision

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

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| **5** | **Ethics ref:** | **14/NTA/100** |
|  | Title: | M12-963 Rheumatoid Arthritis Study |
|  | Principal Investigator: | Dr Sunil Kumar |
|  | Sponsor: | AbbVie Pty Limited |
|  | Clock Start Date: | 26 June 2014 |

Dr Sunil Kumar and Miss Catherine Howie 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.

* Researchers explained this is a multi-site international phase II study to assess a study drug treating active rheumatoid arthritis (RA).
* The main site will have 3-4 participants with 9 in total over the other sites in New Zealand.
* The Committee asked about thecurrent standard of care? Currently there main treatment is methotrexate. If this does not work there are other biological and non-biological agents that are used. The study agent is a duo-agent.
* The researchers explained that RA is difficult to treat and has a variety of treatment options.
* Study will investigate dosage, safety and efficacy.
* Occurrence: 0.6 to 1 in 1000 patients have RA in NZ.
* The Committee queried the recruitment strategy, adding that participants may not receive a benefit. The researcher stated they will have short term benefit where they will receive 12 weeks of treatment. Short term treatments, while over a short period of time, may last longer than the study’s 12 week length, though this won’t necessarily happen.
* The researcher added the patients will receive regular follow up - more than standard practice.
* The researchers explained that the study drug has been tried on 28 participants with RA in earlier trials overseas.
* The Committee queried whether there was a process for participants who show no improvement on the study drug? What will they be offered? The researchers explained that participants will go to their usual standard of care, adding these participants failed treatment with methotrexate. If participants indicate they are struggling they will be offered the chance to withdraw.
* Committee queried if CI is satisfied with governance at the overseas lab. CI was satisfied but acknowledged that as a site they did not have much control over how samples were handled.
* Committee confirmed study submitted to SCOTT.
* Confirmed questionnaires are electronic.
* HDEC queried the sponsor length of storage for samples. Be clear about expectations to store and therefore be explicit in the PIS/CF.
* The Committee requested the following changes to the Participant Information Sheet and Consent Form:
* Please make it clear on pg. 5 and 14 of main PIS that the sub study is OPTIONAL.
* Pg.1 last paragraph – please consider moving this to the second sentence, as it is seems it should be in the introductory paragraph.
* Include that the study drug is not approved for use in NZ.
* Committee suggested the monkey information be removed as they believed it was irrelevant to the risks to humans.
* Better explain the risks in lay language
* Review for repetition to reduce overall length of PIS.
* The sub study samples are de-identified.
* Confirm in PIS that any results or adverse findings from sub study will not be sent back to participants.
* Include information on compensation, state clearly that participants are not eligible for ACC. pg.17 main PIS though also relates to sub study 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*).
* Clarify length of storage of tissue samples that are sent overseas. (*Guidelines for the Use of Human Tissue for Future Unspecified Research Purposes*).

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

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| **6** | **Ethics ref:** | **14/NTA/101** |
|  | Title: | Mana Moana: The Journey to Motutapu |
|  | Principal Investigator: | Dr Karlo Mila-Schaaf (Mila) |
|  | Sponsor: | University of Auckland |
|  | Clock Start Date: | 26 June 2014 |

Dr Karlo Mila-Schaaf and Prof Airini 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.

* A feasibility study. Overall the development and thinking about the project, its design and questionnaires and interventions goes back close to 4 years.
* Researchers discussed how earlier PhD work had focused on how cultural capital is expressed in different cultural contexts. In New Zealand born populations the dominant form of culture to access is western. This is a way to introduce Pacific culture that was accessible. Particularly for teens and or youth.
* The goal is to have participants being proud about their culture, which should lead to better mental health and wellbeing outcomes.
* How serious is the suicide risk for this patient population? In terms of suicidal attempts and ideations the pacific group has a higher proportion than the general population, with an observable spike in suicide recently.
* Researchers explained how current practice to address these problems is not good enough, and this is what the study aims to address.
* As a safety point of view, is it safe for two adults to supervise up to 50 children? The researcher clarified the groups will be made up of 6 to 10 children, and the journey is to a virtual aspirational place not a physical place, Motutapu means ‘sacred island’.
* What data safety monitoring do you have in place? Faculty of Education and Faculty of Health Science will be involved, facilitated by the existing relationships with Dr Karlo Mila-Schaaf and Dr Terry Flemming, who is the research expert. They will monitor data resulting from the study.
* The Committee confirmed the PIS are accessible to the patient group, and confirmed it was the product of a rigorous form of consultation.
* The Committee queried if there was a plan in place to mitigate cases where advising family members of a young person’s problems may not be appropriate, noting the family could be the cause of the issue and it may make things worse. The researcher acknowledged this point.
* The Committee suggested making the referral information in the PIS more general, for instance including information on referral to someone who can help rather than strictly reporting to parents.
* Please describe the scientific design or the framework of analysis? The study will use purpose built validated measures, however the main feature is the content of the study – the experience and the support.
* How will you know whether your programme worked? The researchers described the satisfaction survey that has been designed, as well as a whole host of questionnaires. Uptake and completion rates will assist in knowing how successful the study was, as well as individual focus groups which provide feedback.
* A new measure is being developed and validated that looks at Pacific wellbeing and mana, and has been uploaded for this application. There are also World Health Organization templates used.
* Who are the recruiters? Youthline will be running this programme in schools, Kia Aroha College and Wesley College, with the assistance of guidance counsellors.
* What process is in place if the study identifies someone who is seriously at risk? All study researchers will be well trained but there is no formal process. The Committee strongly suggests formalising the referral process and including this information in PIS across all sites and recruiters.This protects both the participants and the researchers.
* The researchers added if something comes up during supervision they will have regular meetings.
* What would you like to see for the participants as far as outcomes go? The researchers explained a sound sense of purposes, legacy, feeling resilient, knowing where they have come from and a sense of where they are going and having the skills to get there.
* The Committee requested the following changes to the Participant Information Sheet and Consent Form:
* Please include standard ACC information.
* Include standardised pathways for referral information.
* 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). In cases of studies involving minors it must be 10 years after the youngest participant turns 16.

Decision

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

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| **7** | **Ethics ref:** | **14/NTA/102** |
|  | Title: | The COMPLEMENT Study |
|  | Principal Investigator: | Dr Mark Webster |
|  | Sponsor: | Metavention Inc. |
|  | Clock Start Date: | 26 June 2014 |

Dr Mark Webster and Ms Jan Burd and Miss Nicole Somerville 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.

* Diabetes is an epidemic. If such a simple procedure can help it will make a big difference.
* Researchers explained that there a range of evidence which indicates that if the sympathetic nerves near the liver undergo denervation it may help regulate blood glucose.
* The aim of this study is to scan the hepatic artery with a catheter. A First-in-Human study with up to 30 patients, primary end point – can the procedure be done safely, second end point - can this be done with a participant group who are at the end stage of oral treatment.
* This treatment may prove better than insulin or oral treatments which have their own associated issues.
* The researchers explained that the study is a feasibility safety study and acknowledges the low participant size. This study will provide a safety signal with some element of an efficacy signal.
* The committee discussed the review board for the study, the researcher explained it was independent review, though it was American based.
* The Committee discussed whether it would be appropriate to include a hepatologist on the data safety monitoring board as recommended by peer review The researchers agreed this is a reasonable request and stated they would consult with the sponsor.
* Is there a chance to find unexpected results from the blood? The researchers explained that participants would be informed of any findings in relation to the main study.
* Referral of unexpected results is not a component for the optional elements of the study (future unspecified research and or bio banking).
* Committee was satisfied with the peer review document, but requested the researchers action one of the outstanding peer review comments.
* Committee confirmed recruitment was through diabetes service.
* The Committee requested the following changes to the Participant Information Sheet and Consent Form:
* Pg.8 please start this sentence with ‘if your injury was caused by the investigator’. This makes it clear that it only relates to medical injury at the fault outside of study or by not following the outlined research procedures.

Decision

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

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

This following information will be reviewed, and a final decision made on the application, by Mrs Susan Buckland, Dr Christine Crooks and Dr Brian Fergus.

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| **8** | **Ethics ref:** | **14/NTA/103** |
|  | Title: | Development of a personalised predictive model of clozapine response for people with treatment-resistant schizophrenia |
|  | Principal Investigator: | Dr Bruce Russell |
|  | Sponsor: | The University of Auckland |
|  | Clock Start Date: | 26 June 2014 |

Dr Bruce Russell and Ms Carolyn Mcnab 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.

* Researcher explained this application builds upon findings from an earlier study. This application aims to investigate if some patients are better responders to clozapine, and whether a predictive model can be used to know prior to treatment.
* This would avoid treating people with clozapine unnecessarily. This is important as clozapine has substantial side effects.
* The Committee queried how common schizophrenia is in the population. Researchers explained that 1% of the population have schizophrenia. 1/3 of people with schizophrenia don’t respond to standard treatment. After a substantial period of time they are put on Clozapine. The study drug is effective yet it has some very negative side effects.
* The Committee asked about the financial cost of clozapine. The drug itself is not expensive but the monitoring process was, requiring frequent monitoring.
* Recruiting 80 people, 20 healthy participants. The 20 participants will not take clozapine, just undergo observations.
* 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 confirmed the researchers will feedback to GPs and psychiatrists.
* The Committee confirmed Maori consultation is ongoing.
* The Committee confirmed there is no DSMC because it is an observational study. Existing standard practice monitoring occurs regardless of study participation.
* The Committee clarified that blood is taken at the baseline visit for genetic testing.
* The Committee noted that all participants will all be able to give informed consent to participate.
* The Committee requested the following changes to the Participant Information Sheet and Consent Form:
* Please provide a separate Participant Information Sheet and Consent Form for the use of tissue for future unspecified research. For more information please see <http://www.health.govt.nz/publication/guidelines-use-human-tissue-future-unspecified-research-purposes-0>
* There is a template future unspecified research PIS at <http://ethics.health.govt.nz/home> under ‘quick links’.

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*).

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

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| **9** | **Ethics ref:** | **14/NTA/104** |
|  | Title: | An Open Label Study of Oral Regimes in Patients with Chronic HCV |
|  | Principal Investigator: | Professor Edward/EJG Gane |
|  | Sponsor: | Gilead Sciences, Inc. |
|  | Clock Start Date: | 26 June 2014 |

Professor Edward/EJG Gane and Ms Vithika Suri 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 researchers explained the study is conducted only in New Zealand, with 125 participants.
* The study will investigate tolerability and toxicity.
* The researchers explained standard treatment has failed with these participants.. The participants have indicated a desire to have treatment with study drug and are recruited through existing referral pathways.
* Confirmed no payments for participation but reasonable transport costs are reimbursed.
* The Committee requested information on the screening process, noting the need to screen genotype? Yes, genetic screening is part of eligibility. The researchers explained that the genotype of participants has implications for the type and duration of treatment, adding some new medicines are only funded for certain genotypes.
* Is it a specific gene type or a panel that you test for? Researchers confirmed it is a specific, virus related, gene type.
* Committee confirmed that course of treatment is usually 12 weeks. The researcher explained that they would not administer longer treatment periods. This would not be appropriate as this form of treatment will either work after 12 weeks or fail. Those who do not respond within 12 weeks will be offered an alternative treatment.
* The Committee requested the following changes to the Participant Information Sheet and Consent Form:
* Committee commended the font and structure of PIS.
* Pg. 4 and 5 language is heavy handed ‘you must’ ‘you will’ and ‘needle stick’. Please soften language.
* Pg.2 bottom paragraph ‘open label study’ please change to lay language.
* Where are bloods going? Please be specific. Please include on the optional PIS.
* ACC Act changed its name in 2010, please amend references to the Act to the Accident Compensation Act 2001
* Change the HDEC to NTA.
* Please be clear about options available to participants who are not cured by end of the study – alternative treatments that will be available post study.

Decision

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

## General business

1. The Committee noted the content of the “noting section” of the agenda.
2. Secretariat to send information on commercial insurance claims update to members to discuss wording for PIS/CF. In addition, increased scrutiny of insurance company wording in policies, will be initiated for the major drug studies
3. The Chair reminded the Committee of the date and time of its next scheduled meeting, namely:

|  |  |
| --- | --- |
| **Meeting date:** | 12 August 2014, 01:00 PM |
| **Meeting venue:** | Novotel Ellerslie, 72-112 Greenlane Rd East, Ellerslie, Auckland |

1. **Problem with Last Minutes**

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

The meeting closed at 4.40pm