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| **Committee:** | Northern B Health and Disability Ethics Committee |
| **Meeting date:** | 06 May 2014 |
| **Meeting venue:** | Novotel Tainui, 7 Alma Street, Hamilton |

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| **Time** | **Item of business** |
| 12.00pm | Welcome |
| 12.10pm | Confirmation of minutes of meeting of 01 April 2014 |
|  | New applications (see over for details) |
| 12.30pm  5.00pm | i 14/NTB/42  ii 14/NTB/43  iii 14/NTB/47  iv 14/NTB/49  v 14/NTB/52  vi 14/NTB/54  vii 14/NTB/55  viii 14/NTB/56 |
| 5.10pm | General business:   * Noting section of agenda |
| 5.30pm | 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 | 01/07/2014 | Apologies |
| 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 | 01/07/2014 | Present |
| Ms Kerin Thompson | Non-lay (intervention studies) | 01/07/2012 | 01/07/2015 | Present |
| Ms Sandy Gill | Lay (consumer/community perspectives) | 01/07/2012 | 01/07/2015 | Present |

## Welcome

The Chair opened the meeting at 12.10pm and welcomed Committee members, noting that apologies had been received from Mrs Mali Erik.

The Chair noted that fewer than five appointed members of the Committee were present, and that it would be necessary to co-opt members of other HDECs in accordance with the SOPs. Ms Sandy Gill confirmed her eligibility, and was co-opted by the Chair as a member 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.

## Confirmation of previous minutes

The minutes of the meeting of 1 April 2014 were confirmed.

## New applications

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| **1** | **Ethics ref:** | **14/NTB/42** |
|  | Title: | FLT3510 |
|  | Principal Investigator: | Dr Dean Richard Quinn |
|  | Sponsor: | Mundipharma Research Ltd |
|  | Clock Start Date: | 24 April 2014 |

Dr Dean Richard Quinn 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 the application was clear and well put together.
* The Committee noted the study had not been registered on a WHO approved registry. Dr Quinn confirmed the study would be registered before recruitment started.
* The Committee queried if there was any level of independence on either of the monitoring committees. Dr Quinn stated the internal monitoring was not independent and was not sure about the other monitoring mechanism.
* Committee stated some level of independent monitoring would be appropriate.
* The Committee noted the potential conflict of interest if the treating physician was recruiting participants. Please explain management of potential conflict.
* Dr Quinn explained that the CI will not be the treating physician for this study. Dr Quinn explained that potential participants are referred from the treating physician to the CI who will conduct the consent process. The Committee confirmed the treating physicians will only refer.
* (P.3.2.1) Dr Quinn confirmed translators could be sought for participants with English as a second language. Committee queried how the diary complement would be managed if English is a second language. The Committee queried if a proxy would be appropriate for filling out the diary. Dr Quinn explained the diary is about consistency and it is not very difficult to fill out, adding that if someone were to help the person with the diary the responses may be more consistent.
* The Committee queried if family members would be used or independent translators. The Committee felt it was problematic to have a family member be a translator particularly when being involved in the consent process.
* The Committee felt there was a risk of family members translating to suit the family or not fully represent the participant’s preferences. The Committee requests independent interpreters.
* The Committee noted that if it was unlikely an interpreter would be provided please make that clear on the PIS/CF.
* The Committee queried if the ethnicity data collection was based on the NZ Census to ensure the data is relevant to a New Zealand context. Dr Quinn confirmed this was possible.
* Committee queried if informing GP is an option or if it is mandatory. Dr Quinn clarified that they will require the GP to be informed of study involvement. Please make this explicit to participants.
* Committee queried if the questionnaires are sent directly to the sponsor or if they entered into an electronic format and then sent. Committee noted that currently it asks participants to enter their name. Please confirm this data will be de-identified. Dr Quinn confirmed no identifying information would be sent to sponsor.
* Please explain the sponsor restrictions on publication and or data. Dr Quinn confirmed he would submit the CTRA to ethics.
* Committee clarified that future ethics approval would be required for any future use on additional samples. Dr Quinn clarified it would need ethics approval but it would not be in New Zealand.
* Dr Quinn confirmed SCOTT had been submitted but there was no outcome at time of meeting.
* Committee confirmed study results would be provided to participants in lay language.
* (F.1.2) The Committee noted that the question is not answered correctly, adding there was detailed statistics earlier on in the application relating for Maori and Pacific participants that could have been used here to provide a more meaningful response.
* The Committee requested the following changes to the Participant Information Sheet and Consent Form:
* Please run a New Zealand spell check – currently has Americanised spelling.
* Committee asked if the yes/no answers are truly optional. Please consider reviewing the options and remove any of the options that would preclude study involvement. Dr Quinn confirmed they would discuss this with the sponsor.
* Please make it clear that the study drug will not be made available to participants once the study concludes.
* Please include restrictions that are discussed in the protocol – for instance no smoking, eating large meals (in relation to spirometry).
* Please review statement ‘research would go ahead if the research was properly approved’ on Pg.4 optional genetic consent form and detail what this approval would be.

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*).

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

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| **2** | **Ethics ref:** | **14/NTB/43** |
|  | Title: | A study to investigate safety and efficacy of Sofosbuvir + Ribavirin in adolescents and children with GT2 or GT3 chronic HCV |
|  | Principal Investigator: | Dr Helen Evans |
|  | Sponsor: | Gilead Sciences New Zealand |
|  | Clock Start Date: | 24 April 2014 |

Dr Helen Evans and Ms Kerry Walker were present by teleconference for discussion of this application.

Potential conflicts of interest

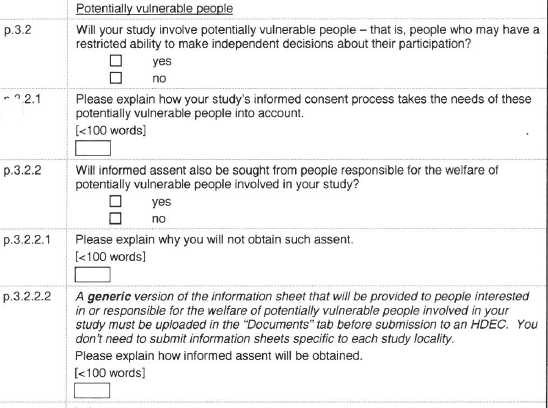
The Chair asked members to declare any potential conflicts of interest related to this application.

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 queried if this study was the Co-ordinating Investigator’s (CI) first study as the CI. Researchers explained that a prior study where the CI was leading the investigation got as far as screening patients, so will be first where the trial runs to completion. The researchers explained how the CI had been a co-investigator in other trials similar to this trial.
* The Committee queried what support the CI had. The researchers explained that Dr Ed Gane, who has a great deal of clinical research experience, was a co-investigator. The researcher added the wider research team, as well as the Auckland Clinical Study team, had a lot of support mechanisms in place. Geographically the amount of support and people with relevant knowledge is in close proximity. The Committee was satisfied with this response.
* (P.1.6) Committee queried what would happen if a child refused to provide assent. The Researchers explained that if the child did not provide assent they would not go ahead with that participant. The researchers explained that while parents could give consent on their behalf it would not be appropriate to continue without assent. The Researchers explained there may be cases when the child was so young that they could not understand any of the study participation information and would be enrolled by their parents.
* (P.3.1) Committee queried the response and the researchers confirmed this information was left over from a prior ethics application.
* (P.3.2) Committee noted the answer should be yes (regarding vulnerable participants). Committee noted that this resulted in questions being skipped. Questions included below:



* (P.3.3.1) Committee queried compensation payments. The Researchers explained there will not be a payment for study involvement but will be reimbursement.
* (P.4.3.1) Committee asked how the Maori consultation was progressing. The Researchers explained that a letter of support had been received, requesting minor changes. The Researchers added that the Maori advisor (Helen Wihongi) was happy to be a point of contact listed on the PIS, particularly in regards to genetic research and or bio-banking.
* (P.4.6) Committee queried if the study will use the NZ Census as the ethnicity information standard? The Researchers explained that the sponsor had their own CRFs for ethnicity data. The Committee suggested using the NZ Census as a template for the New Zealand collection of ethnicity data to ensure data collected and study findings are relevant to a New Zealand context.
* Committee queried if SCOTT had been received. Researchers confirmed no outcome.
* (P.4.1) Committee queried the timeframe involved to consider study participation. Researchers clarified ‘as much time as they need’, which will usually be a few weeks. The Committee added that being able to participate is not a benefit. The committee noted for future reference that this question relates to actual health benefits for Maori, not equal participation.
* (P.4.2) Committee commends the response.
* (F.1.2) Committee requested in future applications please be more specific, rather than generic.
* The Committee requested the following changes to the Participant Information Sheet and Consent Form:
* Committee queried if a 28 page PIS is necessary. Committee suggested reviewing and cutting out unnecessary and duplicated information. Committee suggested taking the PIS/CF back to the sponsor, citing the NEAC guidelines, to ensure informed consent is met by this document.
* Pg. 1 use of study drugs in US. Please include information on the use of these drugs in New Zealand. Researchers explained one of the study drugs are freely available and are part of standard of care. The other is only available in research. The Committee requested that this information is included in the PIS.
* Pg. 25 of parent PIS – please make it clear that there will be stored samples that may be used for future research and these samples will only be used when appropriate approval had been sought and given. The Committee noted the current reading was not in lay language.
* Please remove the requirement for participants to withdraw in writing. The Committee feels this is not required – participants can withdraw verbally.
* Please remove the references to US law.
* Please include an option not to participate on the flow chart diagram.
* Pg. 24 second paragraph. Please add *study* doctor, to make it clear that this statement does not refer to the child’s GP.
* Information sheet (more than 16 years pg. 21). Please remove statement about payment for participation. Researchers confirmed this would be removed as there is no payment involved.
* The child assent form – currently reads that the treatment and drugs provided are free as well as being paid for blood draws. Please remove entire section.
* Pregnancy consent form – please include a landline where people can call without paying money. Researchers confirmed they would include a 0800 number.
* Pg.4 of main PIS/CF. Committee commended statement requiring disclosure of vitamins and minerals participants may be taking.
* Committee queried the optional bio-banking component part of the study. Please separate all optional future research. This must have its own PIS consent form.
* Include OPTIONAL in the future unspecified or biobanking PIS/CF.
* Pg.22 – contact numbers. Please include the Maori contact details rather than just including the HDC. Researchers confirmed this was possible, adding they would amend the PIS.
* The Committee queried what age group the assent form was for. The Researchers explained it was for 7 year olds at the youngest, unless in exceptional circumstances.
* The Committee asked if there would be an assent form for under 7 year olds. The researchers explained that currently there was not an assent form.
* The Committee suggested using diagrams to assist the younger participants to be informed about the study. Please create a one page assent form for under 7 year olds.
* Please explain why it is appropriate for under 16 year olds to take part in the optional studies. The researchers stated it is not necessary. Some people want to, some people don’t.
* Committee noted if participants are only assenting it may not be appropriate for the vulnerable population to have their tissue bio-banked. For over 16 year olds who consent it is not an issue.
* Committee queried how re-consent would be conducted if younger participants did provide assent for tissue to be stored. Are there recall measures in place? The researchers explained the sample size is very small, only two participants. As a result it is feasible to re-consent.

Decision

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

* Justify the use of bio banking when the participants are only providing assent. The interests of vulnerable individuals must be protected, and these individuals must not be exploited for the advancement of knowledge. (*Ethical Guidelines for Intervention Studies para* 5.31)
* 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 provide age appropriate information sheets and assent forms for younger participants and amend the existing information sheets and assent/consent form, taking into account the suggestions made by the Committee (*Ethical Guidelines for Intervention Studies* *para 6.22*).
* Address points made by Committee above.

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

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| **3** | **Ethics ref:** | **14/NTB/47** |
|  | Title: | MCAD Children Ethnography |
|  | Principal Investigator: | Ms Pauline Herbst |
|  | Sponsor: | University of Auckland |
|  | Clock Start Date: | 24 April 2014 |

Ms Pauline Herbst 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

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

* Committee noted the study sample size was very large.
* Ms Herbst explained that there were 35 core children who have been diagnosed with the illness. The researcher explained that the parents will be involved too, as breastfeeding is a fundamental part of treatment for newborns. The involvement of supporting parties increases the participant size, for example teachers may be included.
* Committee queried how contact details are being sought for potential participants. Ms Herbst stated Starship is willing to disclose information once ethics approval has been sought. Ms Herbst explained that the Marsden project she is affiliated with has been renewed by Otago ethics committee. The Marsden project has contact with parents, involved with the New Zealand society for children with unique disorders. The researcher also has a child of her own with MCAT so she has independent contacts.
* The Committee asked for more information about the Facebook group. Ms Herbst responded the Facebook group is a closed group and will be used to look at how communities function online. The Committee queried if it is only consented study participants who are allowed in the group. Ms Herbst confirmed this, as well as only being New Zealand or Australia participants. To join they must correspond with the CI. After the study has completed the group will be turned over to the community to govern.
* Committee queried if this group was for parents or children. Ms Herbst stated both.
* The Committee noted you must be 13 to join Facebook. Ms Herbst acknowledged this.
* Committee queried the age group of study population. Newborns to up to 18 years old. The age group will vary.
* The Committee queried the philosophical analysis mechanism. The study is based on FRANK. Methodologically the study will involve recording and various means of observation – an anthropological method. Structured interviews, spending time with participants as well as gathering information about treating the children from medical professionals. Ms Herbst will look at how children understand their disorder and how they express this to others. It also included medical professional’s views. Committee noted this is a lot of observation.
* Committee asked about the observation in schools. Ms Herbst explained that after speaking with parents and children we will approach school to request to observe a lunch time. The study wants to assess how the children relate MCAT and food management to other students.
* Committee queried if video will be taken at school. Ms Herbst stated no.
* Committee queried over how long the observation will occur. Ms Herbst stated two years.
* The Committee queried if hospitalized children will be observed. Ms Herbst stated yes, based on informed consent. The Committee noted this was not very clear on the PIS in its current form. Ms Herbst clarified they would seek further consent, even if the PIS had been signed, as situations may change. Please make explicit in PIS.
* (P.4.2) The Committee requested why Maori were not likely to be participating. Ms Herbst explained she had consulted with specialists and was informed it would be unlikely to have Maori participants as it is a genetic disorder and there were no records of Maori with MCAT. Ms Herbst acknowledged the study may have wider implications for children with genetic illness.
* The Committee queried whether it was assumed that the Facebook group would result in the children understanding the group members are involved in a research project. Ms Herbst explained that this was the understanding.
* Ms Herbst reiterated the varying levels of study involvement – participants could just be parents and no interaction with the children, or just be participating in hospital etc.
* The Committee noted the study was conducting home visits which may pose risks for third parties or researchers. Please explain the processes in place to mitigate any risk. The Committee suggested having someone know where you going, when, to report when you are finished, to not enter when you feel unsafe. The Committee suggests consulting with the university to ensure appropriate measures are in place to mitigate risk.
* Committee queried if researcher is 100 per cent sure there are no Maori participating in the research. The Committee queried who would be consulted if it did turn out there were Maori participants. Ms Herbst stated they would come back to HDEC if there were Maori participants to ensure appropriate consultation took place.
* The Committee requested the following changes to the Participant Information Sheet and Consent Form:
* How old are the young adults? Researcher stated 12-13 upwards. Please refer to these participants as adolescents rather than children.
* Committee noted children under the age of 16 typically give assent.
* The Committee queried if ‘life threatening’ was appropriate to tell children – do they know their condition is life threatening? The Committee suggested removing this explanation. The researcher agreed.
* Add the inclusion of schools as a site of observation (as a general rule list everything that may happen in the research).
* List the explicit degrees of assent (such as allowing hospital visits but not school).
* Note that participants have option to withdraw fully and also withdraw all of their study data.
* Please make it clear how much video footage will actually be taken.
* Is the data anonymous? Particularly the video? The Researcher explained that the video would not include faces and would include a graphic representation with audio voice over. Please make this explicit in the PIS.
* The Committee queried if the very young participants have an assent form. The researcher stated there were no formal documents, however they would seek assent to sit with them each day.
* The Committee noted there are examples of assent forms for younger participants at Starship adding that it would be a good idea to get assent in writing. Please submit assent forms for the younger participants.
* Amend families to legal guardian.
* Change consent to assent where appropriate.
* Amend the young adult form to be for the adolescents. Currently is inconsistent and refers to their consent, implying it is the parents or guardians reading it.
* Break down the levels of consent and which parts the participants are happy to agree to.
* The Committee suggests removing the reference / title to ‘age of designer babies’.
* Include further information in relation to the Facebook group, to ensure the children or parents know what they are getting into.
* Please include information on counsellors so the participants don’t need to ask the CI for them.

Decision

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

* Please provide age appropriate information sheets and assent forms for younger participants and amend the existing information sheets and assent/consent form, taking into account the suggestions made by the Committee (*Ethical Guidelines for Intervention Studies* *para 6.22*).

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

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| **4** | **Ethics ref:** | **14/NTB/49** |
|  | Title: | A research study to find out if rFIXFc is safe and works well when taken by children and young adults with Haemophilia B. |
|  | Principal Investigator: | Dr Mark Smith |
|  | Sponsor: | Quintiles Pty Limited |
|  | Clock Start Date: | 24 April 2014 |

Dr Mark Smith 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

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

* The Committee requested clarification on the age groups.
* Committee noted 16-17 year olds can consent. Amend PIS to have assent forms for 12-15 year olds and consent forms for 16 and above,
* Please provide a 16-17 year old consent form that is not written from the perspective of the parents.
* Please justify using this particular vulnerable population for bio-marker testing, noting that there should be a good reason why the younger participants are being asked and not just those that can consent.
* Please provide under 12 and under 7 PIS that are more age appropriate.
* Please include assent forms for future optional research that are age appropriate. Note that this is contingent on having good reason to bio-bank participants tissue without their consent, only assent.
* Committee queried if SCOTT had been received.
* Committee noted the data may be potentially identifiable if the data is linked.
* (P.2.9) Will the summary be in a lay language.
* The Committee queried if the ethnicity questions was based on the NZ Census to ensure the data is relevant for to a New Zealand context.
* (F.1.2) – please answer the question in relation to the study rather than a generic response.

Decision

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

* Please provide age appropriate information sheets and assent forms for younger participants and amend the existing information sheets and assent/consent form, taking into account the suggestions made by the Committee (*Ethical Guidelines for Intervention Studies* *para 6.22*).
* 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*).
* Respond to questions raised by committee

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

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| **5** | **Ethics ref:** | **14/NTB/52** |
|  | Title: | Meropenem versus Piperacillin-Tazobactam for Bloodstream Infections |
|  | Principal Investigator: | Dr Hasan Bhally |
|  | Sponsor: |  |
|  | Clock Start Date: | 23 April 2014 |

Dr Hasan Bhally 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 commended the plain English summaries in the application.
* The study will look at particularly resistant bacteria in an attempt to find alternative treatments.
* Participants are those with a bloodstream infection. The degree of ‘unwellness’ varies a lot in this patient group.
* Committee queried how researchers will ensure participants have not passed away before the 30 day follow up, noting this could be stressful for the family. Dr Bhally explained they could check the database before calling so they will not disturb the family.
* Dr Bhally explained the participants who are recruited are expected to stay at the hospital for at least 4 days, as the study requires this length of treatment.
* The Committee queried who will be recruiting. Dr Bhally explained himself (the CI) and a registrar will be recruiting. The Committee queried if the CI would be the treating physician of the participants. Dr Bhally explained that he would not likely be the treating physician but he will be required to approve the use as policy requires regulated use of these antibiotics to prevent over use.
* The Committee queried the level of vulnerability of these participants. Dr Bhally stated that recruitment will not occur for those who are too vulnerable. The Researchers will stratify the participants based on level of illness.
* No one will be consented who is unable to provide informed consent or would have a risk too high with relation to treatment using study drugs.
* (F.2.1) Committee queried the ‘proxy consent’ mentioned. Dr Bhally stated this was from the Australian protocol.
* Please remove the proxy consent requirement.
* Committee noted that participants can withdraw consent verbally. Please remove the revocation of consent form.
* (P.4.2)The Committee noted that for some Iwi the taking of blood is a cultural issue. Please note in future applications that you need to consider these better.
* The Committee queried if the ethnicity questions was based on the NZ Census to ensure the data is relevant for to a New Zealand context. Dr Bhally stated there is no scientific benefit to recording this information. The Committee noted this information could be useful for knowing which ethnicities are participating in clinical research. The Committee recommends using the NZ Census ethnicity question as a template to record this information.
* The Committee requested the following changes to the Participant Information Sheet and Consent Form:
* Please run a spelling and grammar check.
* Please make it clear that the study is a pilot.
* Committee asked if the yes/no answers are truly optional. Please consider reviewing the options and remove any of the options that would preclude study involvement.

Decision

This application was *approved* by consensus.

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| **6** | **Ethics ref:** | **14/NTB/54** |
|  | Title: | The AVERT Trial |
|  | Principal Investigator: | Dr Peter Ruygrok |
|  | Sponsor: | Osprey Medical, Inc |
|  | Clock Start Date: | 24 April 2014 |

Ms Jan Bird (primary contact) 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.

* Ms Bird described the device.
* Ms Bird explained the goal was to reduce the amount of dye going into the bloodstream by having the dye travel back to the reservoir rather than pressure resulting in leakage.
* Ms Bird noted the application referenced the NTX HDEC and stated they will amend to NTB.
* Committee queried if any healthy patients are at risk having any dye leak. Ms Bird stated no, only those who have renal impairment.
* The Committee queried the independent data safety monitoring committee. Ms Bird stated it was situated in the US but not sure where yet.
* (F.1.2) For future applications the Committee noted that the question is not answered correctly, adding there was detailed statistics earlier on relating for Maori and Pacific participants that could have been used here.
* The Committee noted the patient information would be potentially identifiable, rather than de-identified, due to the code / link existing between health records and study data.
* Committee confirmed the summary would be lay language.
* Committee confirmed the ethnicity data collection would be similar to the NZ Census.
* The Committee requested the following changes to the Participant Information Sheet and Consent Form:
* Pg.5 please clarify the additional radiation, noting these participants may have less scans due to the dye working more effectively. Ms Bird agreed it is not very likely that there will be any extra radiation due to less scans being required. Researcher noted it is in the protocol as a potential risk so it should be in the PIS to accommodate informed consent.
* Committee asked if the yes/no answers are truly optional. Please consider reviewing the options and remove any of the options that would preclude study involvement.

Decision

This application was *approved* by consensus.

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| **7** | **Ethics ref:** | **14/NTB/55** |
|  | Title: | A Study Evaluating the Efficacy and Safety of Lebrikizumab in Adult Patients With Mild to Moderate Asthma |
|  | Principal Investigator: | Dr Simon Carson |
|  | Sponsor: | Roche Products (New Zealand) Limited |
|  | Clock Start Date: | 24 April 2014 |

Dr Simon Carson 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 conflict of interest. The Committee decided Dr Tanser would abstain from discussion and voting on the application.

Summary of ethical issues

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

* (B.2.2.2) for future reference the committee noted the application has a SCOTT application pending which was sufficient for peer review, however a signed protocol is not peer review.
* (B.4.4.1) for future reference please review the NEAC guidelines as the data may be potentially identifiable.
* (R.2.1.1) provide detail on the procedures that are in place.
* (R.4.1) outline processes in place to mitigate the conflict of interest – are participants being recruited by the study team or a treating physician.
* Please confirm study summary will be given in lay language.
* Please confirm the study participation patient card phone number will be a 24/7 phone number.
* (F.1.2) for future reference please answer the question relating to the study. Not a general answer.
* The Committee requested the following changes to the Participant Information Sheet and Consent Form:
* Pg.13 – discrepancy between PIS and application (3 months or 6 months) for chest x-ray. Please clarify.
* Remove italics regarding interpreters. This is from the HDEC template and is for researchers not participants.
* Step 2 – add ‘if you agree to participate’. This is to show that this timeline has options in it.

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*).

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

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| **8** | **Ethics ref:** | **14/NTB/56** |
|  | Title: | The EpiNet-First trials of new onset epilepsy |
|  | Principal Investigator: | Dr Peter Bergin |
|  | Sponsor: | EpiNet Study group and Auckland District Health Bo |
|  | Clock Start Date: | 24 April 2014 |

Dr Peter Bergin 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.

* Please confirm for the Committee that the platform is sufficiently capable to run five trials in tandem. Dr Bergin explained that the platform is very good at recording information of people with epilepsy, for instance the date of most recent seizure and number of seizures per month. What it can’t record is multiple seizures with explicit dates. The database itself is working well but we do want to improve it using algorithms that help provide eligibility criteria.
* The Committee queried if these database changes were being made for these trials or the database in general. Dr Bergin explained that the governance of the database is under the control of the EpiNet steering committee, two of which are in New Zealand. The Committee suggested having a data analyst involved to ensure data quality was sound.
* Committee queried if there was a statistician for the trials. Dr Bergin confirmed there was.
* The Committee noted that the investigators believe there is clinical equipoise however please comment on the participants GPs and their bias? Dr Bergin did not expect the GPs to have much of an influence. Dr Bergin acknowledged some people may be influenced, which is a limitation that is accepted with such a pragmatic trial.
* Dr Bergin explained patients will be followed over 2 years as part of the trial. GPs will also be seeing the participants who may change the treatments. The Committee queried what information went to the GPs to ensure they don’t unnecessarily change the treatment for study participants. Dr Bergin explained that through emails and magazines the GPs would be informed.
* Committee queried if all adult participants can provide their own informed consent. Dr Bergin stated that everyone who is able to provide informed consent will do so. The Committee explained that there would need to be a strong justification to include non-consenting adult participants in the trial. Dr Bergin stated there was no specific reason and decided that they would not recruit any adults who can’t provide informed consent.
* Committee queried if the prior validation studies had been completed. Dr Bergin explained that one of the validation studies had not been completed, though a large number had participated. 140 from other countries with 20 from New Zealand. Dr Bergin confirmed there will be consistency in diagnosis.
* The Committee confirmed that only accredited and validated people will be able to participate and diagnose.
* Dr Bergin confirmed the results provided to participants will be in lay language.
* The Committee commended the detailed scientific peer review.
* Committee queried the consistent concern from reviewers about being underfunded with respect to the amount of work required. Dr Bergin felt this study would not be underfunded.
* The Committee asked about the proxy reporting analysis up until 18 years of age which conflicts with 16 year olds and above being able to consent on their own. How does this work with proxy reporting? Dr Bergin was not sure – citing international guidelines (UK). The Committee requested that the PIS are reviewed to reconcile 16-18 year olds and proxy reporting.
* The Committee queried the plan to get information on treatment adherence. Dr Bergin stated they would just be asking them if they have taken the drug. No plan for pill counts or measuring blood levels. We will rely on the patients.
* The Committee asked whether the diary for recording seizures could be used for treatment adherence, even if a rough measure. Dr Bergin said they had not thought about that. The Committee noted this was just an option, or suggestion, not an ethical requirement.
* Committee queried why diary had area for name and address of participants. Dr Bergin acknowledged this information is not essential, adding the purpose was that it was only for the patients themselves. Dr Bergin confirmed this data is kept at site level and is not sent anywhere. The Committee was satisfied with this response.
* The committee queried if the ethnicity questions was based on the NZ Census to ensure the data is relevant for to a New Zealand context. Dr Bergin confirmed it had the NZ census as well as further options.
* The Committee noted the patient information would be potentially identifiable, rather than de-identified, due to the code / link existing between health records and study data. Please see (*Ethical Guidelines for Intervention Studies para* 7.2) for more information on levels of data confidentiality.
* The Committee requested the following changes to the Participant Information Sheet and Consent Form:
* Committee asked if the yes/no answers are truly optional. Please consider reviewing the options and remove any of the options that would preclude study involvement.
* Please remove reference to UK law (data protection).
* Is there a process to re-consent once participants became of legal age to consent? The Committee requested a plan to re-consent.
* The Committee queried whether ‘valproate’ was taken into consideration as being appropriate for participants who were of child bearing potential. Dr Bergin explained that it was a real consideration and there would be guidance on whether it is safe and appropriate for each individual participant.
* Committee queried if diagrams could be used for the youngest PIS. Would it be possible to make it more child friendly? Dr Bergin agreed and stated he would follow up with Starship for guidance.

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*).

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

## General business

1. The Committee noted the content of the “noting section” of the agenda.
2. The Committee discussed non-consensual research.
3. The Chair reminded the Committee of the date and time of its next scheduled meeting, namely:

|  |  |
| --- | --- |
| **Meeting date:** | 03 June 2014, 12:00 PM |
| **Meeting venue:** | Novotel Ellerslie, 72-112 Greenlane Road East, Auckland |

The following members tendered apologies for this meeting.

No members away.

1. **Problem with Last Minutes**

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

The meeting closed at 4.45pm.