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| **Committee:** | Northern B Health and Disability Ethics Committee |
| **Meeting date:** | 07 July 2015 |
| **Meeting venue:** | Novotel Ellerslie |

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| **Time** | **Item of business** |
| 12.00pm | Welcome |
| 12.15pm | Confirmation of minutes of meeting of 02 June 2015 |
|  | New applications (see over for details) |
|  | i 15/NTB/110  ii 15/NTB/116  iii 15/NTB/117  iv 15/NTB/118  v 15/NTB/119  vi 15/NTB/120 |
| 3.30-3.45pm | General business:   * Noting section of agenda |
| 3.45pm | 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 | Apologies |
| Mrs Maliaga Erick | Lay (consumer/community perspectives) | 01/07/2012 | 01/07/2015 | Present |
| Mrs Stephanie Pollard | Non-lay (intervention studies) | 01/07/2012 | 01/07/2015 | Present |
| Dr Paul Tanser | Non-lay (health/disability service provision) | 01/07/2012 | 01/07/2015 | Present |
| Miss Tangihaere Macfarlane | Lay (consumer/community perspectives) | 19/05/2014 | 19/05/2017 | Present |
| Mrs Phyllis Huitema | Lay (consumer/community perspectives) | 19/05/2014 | 19/05/2017 | Apologies |
| Mrs Kate O'Connor | Non-lay (other) | 01/07/2012 | 01/07/2015 | Present |
| Mr Kerry Hiini | Lay (consumer/community perspectives) | NTA Co-opted member | NTA Co-opted member | Present |

## Welcome

The Committee noted that the Chairperson, Ms Raewyn Sporle, was unable to attend the meeting. Mrs Stephanie Pollard was appointed Acting Chairperson for the duration of the meeting.

The Chair opened the meeting at 12.10pm and welcomed Committee members, noting that apologies had been received from Mrs Phyllis Huitema and Ms Raewyn Sporle.

The Chair noted that it would be necessary to co-opt members of other HDECs in accordance with the SOPs. Mr Kerry Hiini confirmed his eligibility, and was co-opted by the Acting Chair as a member of the Committee for the duration of the meeting.

The Chair welcomed Ms Philippa Bascard, the HDEC Manager.

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 02 June 2015 were confirmed.

## New applications

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| **1** | **Ethics ref:** | **15/NTB/110** |
|  | Title: | Leisure reading in people with dementia |
|  | Principal Investigator: | Dr B Sally Rimkeit |
|  | Sponsor: |  |
|  | Clock Start Date: | 18 June 2015 |

Dr Gillian Claridge 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 Study

* The study investigates what kinds of books are most suitable and enjoyable for those who suffer from dementia.
* The Committee stated that the application was interesting.

Summary of ethical issues (resolved)

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

* The Committee asked for more information about the relationship between the researchers and the company ‘Reminisce Readers’. Dr Claridge explained that Reminisce Readings was a recently founded company. This pilot study was the first project that related to the company.

Summary of ethical issues (outstanding)

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

* (P.4.6) The Committee asked if the ethnicity will be collected using the New Zealand Census questions. The Committee stated that it was the preferred method of collection as it provides a standardized dataset that is relevant for a New Zealand context. Dr Claridge confirmed that they would use the New Zealand Census.
* The Committee noted that an enduring power of attorney can only be cited and provide consent for a non-consenting adult if the study is in their best interests. Please view the code of rights and ensure the study is legal. Dr Claridge stated that the study activities would be enjoyable and that there was not a risk of harm.
* The Committee clarified that Dr Claridge has agreed to alter the recruitment methodologies from using interRAI and instead to use day centers and advertising posters. The Committee requested the new processes in writing.
* The Committee requested a peer review from a psycho-geriatrician. Please provide an independent peer review. Dr Claridge responded that the CI had cited that there is one on the researcher team and that this is mentioned in the application. The Committee noted this and requested a separate document with a peer review is submitted to support the application. The Committee suggests using the peer review template at <http://ethics.health.govt.nz/>
* The Committee asked if the study is for English speakers only. Dr Claridge responded that they would start with English, as this is a pilot study. If the project is successful they will introduce other languages.
* The Committee requested that information about the commercial nature of the study in the PIS, adding that it should state that commercial products may develop from information gained from participants and that participants have no claim to resulting profits etc.
* Please reference that the information generated from the study will be shared with the company, adding it was important to disclose commercial interests.
* Make it clear that withdrawal can occur at any point in time during the study, that participants can refuse to read the books and that study participation is entirely voluntary.
* The Committee asked if the participants can keep the books. Dr Claridge stated that they could. Please add this in the PIS.
* (P.4.1) The Committee noted that this question was not adequately answered. For example you should include Maori prevalence of dementia. Dr Claridge stated that the study, if successful, will benefit everyone. The Committee noted that the question is about Maori in particular, not about ‘everyone’. Identifying the incidents of Maori dementia would be a good start.
* The Committee noted that there might also be some cultural considerations that should be considered. These will be raised during Maori consultation that is planned.
* The Committee asked about the Maori consultation process – Dr Claridge explained that she was not certain about it but would follow up with the CI.
* The Committee noted that the care providers are also participants in the study. The care providers should have a specific PIS and provide consent to participate. The caregiver PIS can be substantially more detailed than the current PIS for dementia sufferers. Please refer to the HDEC template PIS found at <http://ethics.health.govt.nz/>
* The Committee noted that the EPOA might not be the care provider or a family member, but a lawyer. Given the low level of risk involved in this study it may not be appropriate to initiate EPOA for a participant who cannot provide informed consent. EPOA is typically not required for low risk activities that pose no harm and provide a benefit.
* The Committee noted that the researchers must seek assent from those who have are identified as not being able to consent.
* The Committee noted that recruiting through the day centers rather than the interRAI database should be feasible due to this being a pilot study, adding that if a potential participant contacts the researcher about the study from the posters then they have already indicated that they want to participate (by making contact).
* The Committee noted that this is a lifestyle intervention and is not necessarily something the GPs need to know about. Dr Claridge agreed to remove the contacting of participant’s GPs about study involvement.
* (A.5.1) The Committee asked why the study does not have a sponsor, noting that there were three institutions involved in the study and in particular the CI – Otago University, the DHB and the commercial company. The Committee also stated that the PIS has the Otago University on the header. Dr Claridge explained that the CI teachers at Otago University. Dr Claridge understood that the study might in fact have a sponsor. The Committee suggested talking with the CI and determining who should be listed as the sponsor.
* The Committee noted that the localities where the study will occur are day centers. Are these centers privately owned or are they part of the DHB facilities? Dr Claridge stated she was not sure and that the CI was organising the local sites, adding that some may be privately owned.
* The Committee asked if this is a pilot study? Dr Claridge stated it was. The Committee suggested having one center be the ‘home base’ of the study. This center could gather a database of potential participants.
* The Committee expressed their concern with using the interRAI database as a way of finding potential participants. The Committee noted that these potential participants were also potential customers. Using interRAI would constitute using a public database that is intended for standard care for both research and potential commercial interests, without authorisation from the individuals identified. The Committee suggested that the researchers use posters at the day-centers or alternatively the institutions, such as the DHB, could recruit and introduce the study on behalf of the researchers. This mitigates direct recruitment that is currently planned.

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

* The Committee noted that there is a lot of information missing in the PIS. For instance, what the participant is required to do. Add how long the sessions are, how many people will be present and explain that there will be audio recordings.

Decision

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

* Evidence of new recruitment measures outlined in protocol. (*Ethical Guidelines for Intervention Studies* 6.2).
* Submission of a PIS for care givers with more detail and information than the existing PIS. Add some basic, lay language, information in the dementia PIS (*Ethical Guidelines for Observation Studies* *para 6.11*).
* Please provide further evidence of favourable peer review of the study protocol (*Ethical Guidelines for Intervention Studies* Appendix 1).
* Commercial aspects clarified both for participants and for the Committee (*Ethical Guidelines for Intervention Studies* 4.20).
* Address outstanding ethical issues in a cover letter.

The above information will be reviewed, and a final decision made on the application, by the full Committee (as an electronic sub-committee).

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| **2** | **Ethics ref:** | **15/NTB/116** |
|  | Title: | Extraordinary Children |
|  | Principal Investigator: | Mr Andrew Thompson |
|  | Sponsor: | The Starship Foundation |
|  | Clock Start Date: | 18 June 2015 |

Mr Andrew Thompson was present in person for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

* Mr Thomson explained his background; training and prior work in the proposed research setting.
* Mr Thompson explained that part of the philosophy around this project is openness and transparency. The study aims to identify how parents obtain information and support ( as a snapshot in time) including the role of doctors and hospital systems in this process. He noted the potential for paternalism to be identified.

Summary of ethical issues (resolved)

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

* Committee noted that there may be risks associated with talking about the videos with focus groups and also potential for stigma. Please be aware of these risks.
* The Committee asked why video was being taken? Mr Thompson explained it was to transcribe the reactions and behavior of parents.
* The Committee asked about the management of parents who have their child pass away during the study. Mr Thompson explained that he had worked in the Starship bereavement group for many years and was familiar with such contexts. He stated that parents will be referred to this group. With respect to the research, the parents will be asked if they want their data withdrawn and will be given the option to have their data remain in the study, and if they wish they may remain in the study however there is no requirement to remain enrolled. Mr Thompson added that this would be made very clear.
* The Committee asked how Mr Thompson would know about the diagnosis of children, and requested clarification around the process of identification of potential participants. Mr Thompson explained that the research team will liaise with the teams involved in the hospital. Most often a family will go through the emergency department who will then refer them to a general pediatrician. From there they will be referred to a neurologist. At that point I will know they are potentially eligible. The Committee noted that this process was not explained in the protocol.
* Mr Thompson explained that the research team will work closely with the consultant groups and mental health teams which are comprised of multidisciplinary members. These groups talk with parents who are traumatized about their children being in hospital as well as providing support for children who are adjusting to treatment. This is not a social work team but a therapy team.
* The Committee asked if Mr Thompson required permission to look at case records. Mr Thompson explained that this is why we are here (at HDEC) – to seek permission to screen for potential participants via hospital processes. Mr Thompson added he will also need permission from the locality.
* Mr Thompson explained that it is important to get consent from parents and doctors involved prior to observation, adding he will likely approach the clinician for consent prior to the family.
* The Committee talked about the responsibilities between clinicians and patients, and confidentiality.
* The Committee asked whether anyone, apart from researchers, will see the video? Mr Thompson stated no it will be coded and transcribed.
* Please ensure the PIS refers to both the parent and the child as both are participants.
* One member of the Committee stated that he was not comfortable with researchers being present during consultations between the family and the clinician, citing the Hippocratic oath.
* The Committee noted that the family could have anyone that they wanted in the consultations and or meetings with clinicians. Autonomy of those who would provide consent must be respected. Because informed consent would be sought this was not a concern for the wider Committee.

Summary of ethical issues (outstanding)

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

* The Committee asked for clarification on when exactly the researcher would become involved. Mr Thompson explained that they wanted to observe undiagnosed neurological disorders. The Committee and Mr Thompson discussed at length the best method to avoid undue stress and respect the initial consultation between the clinician and the family. The Committee suggested that Mr Thompson approach the family after the initial consult as it meant that he would not accidentally recruit diagnosed neurological disorders, nor would he recruit during perhaps the most vulnerable high stress time for the family. Please amend the protocol to clearly describe the pathway from reviewing of health information to seeking informed consent.

Decision

This application was *provisionally approved* with one member voting against the decision, subject to the following information being received.

* Provide further information on the study design, *in particular* Amend the protocol to clearly outline the consent procedures and recruitment methods(*Ethical Guidelines for Intervention Studies para* 5.4).
* Please amend the information sheet and consent form, taking into account the suggestions made by the Committee, and review wording to ensure that both children and parents are identified as participants and consent for both is included (*Ethical Guidelines for Observation Studies* *para 6.11*).

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

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| **3** | **Ethics ref:** | **15/NTB/117** |
|  | Title: | HYDRA |
|  | Principal Investigator: | Dr Rajesh Nair |
|  | Sponsor: | Vascular Innovations |
|  | Clock Start Date: | 18 June 2015 |

Dr Rajesh Nair, Study Co-ordinator Kristy Abercrombie and Ms Liz Low 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 Study

* The researchers noted that in A.1.6 of the application there was an error / typo regarding the risk of SAE. It states 51% but this is actually 21%.

Summary of ethical issues (resolved)

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

* The Committee asked for information on the patient population, noting the confusion around participants being both inoperable and unsuitable for conventional therapy yet being deemed suitable to receive TAVI procedure as part of trial. The researchers explained that the patient group is those who are inoperable or unsuitable for conventional artery surgery and not considered eligible to receive TAVI as per NZ guidelines The researchers clarified that in this case not being eligible for TAVI based on these guidelines was a financial restraint as TAVI (one standard treatment option) is not funded for high risk patients in New Zealand. Because of this these patients are not offered TAVI, and are instead offered medical treatment. Most people who only receive medical treatment die within a year. Therefore this patient population has no realistic therapy options – but this is due to New Zealand financial restrictions and patients are considered clinically suitable for TAVI
* The researchers confirmed the experimental valve is similar to most valves, but has some technical differences, adding that in New Zealand there are 3 commercially available styles of valve. This one is similar to one of the three commercially available types.
* The Committee queried if the study had received any registrations. The researchers explained that the study is safety and efficacy trial, part of first in man group of trials, so no CE mark. The Committee noted there is no requirement for registration in New Zealand and accepted this response.
* The Committee queried if the NHC reviewed the product? The researchers stated they had not, adding that they review standard practice options such as TAVI but not research or experimental devices.
* The Committee requested a plan to mitigate the conflict of interest between the researcher also being the treating physician (R.5.4.1). The researchers explained that while the researcher will be primarily responsible for each particular patient and will be enrolling them they have no invested interest in their recruitment to the study. The Committee asked if potential participants could talk to anyone independent from the study about participation. The researchers explained that all participants will be referred by their own cardiologist, as well as having a meeting with all colleagues in the unit who will discuss and explain why the research is in the best interests of the patient group. This would involve independent clinicians.
* (P.4.2) The Committee noted that this question could have been answered more in depth. For future applications please refer to Te Ara Tika guidelines provided by the HRC and in particular the four cornerstones of Maori health.
* (F.1.1) The Committee noted that Maori have high level of CVD is high. Will the study not impact health inequalities? The researchers stated that aortic valve disease is similar in prevalence across communities. It is true that CVD is more prevalent but this specific valve disease is the same for Maori and non-Maori.
* (P.4.6) The Committee asked if the ethnicity would be collected using the New Zealand Census questions. The Committee stated that it was the preferred method of collection as it provides a standardized dataset that is relevant for a New Zealand context. The researchers confirmed that they would collect ethnicity and use the New Zealand Census.
* The Committee asked if the peer reviewer comments been addressed? The researchers explained that they had.

Summary of ethical issues (outstanding)

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

* The CI confirmed that he has used / implanted the specific research device and many comparable devices. The Committee asked if anyone else will perform the procedure? The CI responded that one of my colleagues will assist and that both himself and his colleague are trained. Researchers confirmed that the other surgeon will be trained for this device specifically.
* (R.1.6) The Committee asked for clarification on the DSMB and its composition. Researchers explained that the DSMB is a group in France. Please submit their charter.

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

* The Committee asked what the diagram on pg.3 of the PIS was depicting. The researchers explained that it is the stent frame and shows how the treatment is delivered. The Committee requested that some information about what this is and how it works is included to support the diagram.
* Please include information on who will be performing the procedures and their experience in the PIS.
* The Committee requested that under ‘who pays for the study’ it is explained that there is no payment as well as no cost for taking part. Please be clear about reimbursement.
* The Committee asked whether it was truly optional that the GP is notified about study participation. Researchers stated standard practice Is to identify GP. Committee agreed it was appropriate and requested that the yes or no tick box was removed. Similarly, please review the last 5 tick boxes and only include an option if they are actually optional.
* Please revise pg.2 of the PIS that covers why participants are eligible, in particular that they are at high risk for surgery and that TAVI is not funded but that it is a viable treatment option.
* The Committee noted that the PIS requires a major overhaul as it does not include crucial information, such as benefits and risks. Please review the HDEC template and include the suggested information. This can be found at <http://ethics.health.govt.nz/>
* The Committee noted that if there is limited data available about the particular device then both similar device risks and hypothetical risks should be included.
* The PIS requires procedure information.
* Please make it clear what withdrawal means at different points of the study, for instance that once the device is inserted that it can’t be taken out. Explain the follow up and monitoring involved in the study and how this works if someone withdraws.
* Add brief description of eligibility information, such as basic inclusion and exclusion criteria.

Decision

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

* Please amend the information sheet and consent form, taking into account the suggestions made by the Committee (Ethical Guidelines for Intervention Studies para 6.22).
* Provide details of the Data Safety Monitoring Committee’s charter *(Ethical Guidelines for Intervention Studies para 6.50).*

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

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| **4** | **Ethics ref:** | **15/NTB/118** |
|  | Title: | Effectiveness and Safety of MEDI9929 in Adult's with Atopic Dermatitis |
|  | Principal Investigator: | Dr Dean Quinn |
|  | Sponsor: | MedImmune |
|  | Clock Start Date: | 18 June 2015 |

Dr Dean 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 Study

* The committee commended the PIS and the application.

Summary of ethical issues (resolved)

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

* The Committee talked with Dr Quinn about remuneration, noting the time taken to participate will be considerable. Dr Quinn confirmed that the sites would reimburse for travel costs, time and provide food. Please add this info in the PIS so people know costs and benefits for participation.
* Committee confirmed acceptability of remuneration.
* (A.1.5 and R.1.1) The Committee requested that in future these answers are submitted in lay language and plain English responses, adding these were quite difficult and complex.
* Researcher confirmed SCOTT was submitted.
* (R.1.3) States not withholding standard treatment. This is incorrect.
* (A.1.6) The Committee noted that the application states there are no ethical issues – this is incorrect. The Committee noted that ethical issues were later discussed in the application (placebo, withholding treatment) but requested that in future they are acknowledged earlier in the application.
* Dr Quinn confirmed that they will be recruiting from existing databases and will submit any print advertising if the research team need more participants.
* The Committee queried if participants would be reimbursed if, on the placebo arm, their condition worsened to the extent that they either needed further treatment or sustained increased costs of returning to standard treatment. Dr Quinn explained that the short duration would likely not result in worsening of their symptoms, adding they can remain on some medications. Dr Quinn added any change would be reversible and returning to standard treatment would be considered standard of care costs, not research costs, and would not be reimbursed.
* (P.4.3.1) The Committee requested information on the ‘Maori body’. Dr Quinn explained that it was different at each site. In Wellington it would be Professor Chris Cunningham.

Summary of ethical issues (outstanding)

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

* The Committee requested more information on the DSMC, for instance where are they based. Dr Quinn stated they are overseas but not sure where they are based. Dr Quinn explained that the membership is a mixture of independent people and sponsor representatives. Please provide the membership and or charter.
* (P.4.1) The Committee requested prevalence of atopic dermatitis for Maori.

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

* Pg.2 Amend from 18 to 12 participants in New Zealand (in line with application).
* Pg. 7 Add where tissue samples are going and where they will be stored.
* Pg. 15 Add that the GP will be informed of study participation. Include how incidental findings will be managed and who will be informed of them.
* Ensure Maori health support details are included.
* Make it clear that study medication will not be provided post study, even if there is a benefit.
* Pg.1 – remove reference to US law.
* Please update the date ‘as of May 2014’ noting this information is still relevant. It is currently misleading.
* Please note pregnant partner PIS is for data, not an intervention, and that it is for both the partner and the child. Please review wording to make this clear.
* The Committee noted that the statements concerning informing regulatory agencies of positive findings for Hepatitis, HIV and TB may not be relevant for New Zealand participants. Please amend for a New Zealand audience, and be clear about what findings ( if any) you would be required to report to government health authorities.
* The Committee noted that the NEAC guidelines clearly state that studies should not be terminated purely for commercial reasons. Please remove this statement from the PIS (pg.14).

Decision

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

* Please amend the information sheet and consent form, taking into account the suggestions made by the Committee (Ethical Guidelines for Intervention Studies para 6.22).
* Provide details of the Data Safety Monitoring Committee’s charter *(Ethical Guidelines for Intervention Studies para 6.50).’*
* Provide Maori prevalence information (*Ethical Guidelines for Intervention Studies* *para 4.7*).

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

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| **5** | **Ethics ref:** | **15/NTB/119** |
|  | Title: | Acerta 007 |
|  | Principal Investigator: | Dr David Simpson |
|  | Sponsor: | PPD Australi Pty Ltd |
|  | Clock Start Date: | 18 June 2015 |

Dr David Simpson 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 Study

* The study will assess whether the experimental drug is safe and effective as a treatment for CLL.
* The study drug is expected to have less side effects than current treatment options.
* The study has three arms. Standard treatment, study drug alone and study drug with antibodies, with a 1:1:1 ratio.
* All participants are previously untreated.

Summary of ethical issues (resolved)

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

* The Committee queried if there was any second line data. Dr Simpson clarified that there is some second line data on the study drug. This is not a first in human study. The data comes from single arm studies.
* The Committee asked about the crossover options outlined in the PIS. What happens if disease worsens while on study drug arm? Dr Simpson stated that the comparator arm is available in cases where the study drug does not result in benefit.
* The Committee queried if the study is only for over 65 year olds. Dr Simpson stated in most cases yes, but it is also open to people who are younger but who, for various reasons, are unable to have standard, more intensive treatment.
* The Committee asked why Facebook information was being sought in the follow up? Please remove this as the social media data is not public information and is not relevant.
* (P.4.1) The Committee asked for Maori incidence of disease. Dr Simpson stated no difference between Maori and non-Maori. Committee acknowledged this and requested such information is included in future applications.
* Dr Simpson explained that Waitemata North Shore Maori research groups will be consulted.
* (F.1.2) The Committee noted that while the first statement is relevant to the question the remainder is not.

Summary of ethical issues (outstanding)

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

* B.2.2 – Please confirm SCOTT review will be sought.
* (R.1.5) The Committee asked for information on the DSMC. The Committee noted the application mentions blinded safety data – but there is no blinded safety data for this study. Do you know composition and or what they will be looking at as far as data goes? Dr Simpson stated he was unsure but a top expert in CLL research has designed this study. The FDA has also mandated the DSMB. Please provide HDEC with a charter of the DSMC.

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

* Provide information on treatment pathway if they do not improve on study drug arm (i.e. going back to standard care etc.)
* Add Maori support contact details.
* Add short lay language title (to all PIS).
* Review and amend to New Zealand English.
* Pg.1 – add voluntary statement that participation won’t affect their care if they say no to participation. Please review HDEC template for guidance.
* Add table for site study visit procedures.
* Please review for American language.
* Amend may not be eligible to will not be eligible (ACC).
* Please have contact details at end of PIS.
* Pg.11 under what is expected – please add medication restrictions in broad, lay terms (for visits or duration of the study).
* Add that study doctor will discuss individual medications with you.
* Please amend the yes/ no boxes are truly optional.
* On sub-studies please add, upfront, bolded ‘OPTIONAL’ and make it clear that can take part in main study and say no to sub studies.
* Paragraph on pregnancy pg.15 – ‘security reasons’? Dr Simpson stated this is taken from template – not sure what this actually refers to, and agreed to remove it.
* The Committee asked whether the antibodies are available in New Zealand? Researcher stated that they were approved but unfunded. Committee noted that the PIS had incorrect information about this point – please review and amend.

Decision

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

* Please amend the information sheet and consent form, taking into account the suggestions made by the Committee (Ethical Guidelines for Intervention Studies para 6.22).
* Provide details of the Data Safety Monitoring Committee’s charter *(Ethical Guidelines for Intervention Studies para 6.50).’*

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

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| **6** | **Ethics ref:** | **15/NTB/120** |
|  | Title: | GS-5745 for the Treatment of Moderately to Severely Active Ulcerative Colitis (GS-US-326-1100) |
|  | Principal Investigator: | Assoc. Prof Richard Gearry |
|  | Sponsor: | Gilead Sciences, Australia & New Zealand |
|  | Clock Start Date: | 18 June 2015 |

Claire Arandjus was present by teleconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of ethical issues (resolved)

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

* Ms Arandjus confirmed that while interpreters were available the sites would recruit prefer English speakers. The interpreters were to help explain the PIS but only English competent speakers would be recruited (due to need to fill out questionnaires).
* The Committee confirmed composition of DSMC is suitable for the study.
* The Committee queried if all 26 participants are enrolled in the induction part of the study? Ms Arandjus stated it depends when the study starts and referred to pages 8-9 of the protocol.
* The Committee commended the tables in PIS.
* The Committee discussed the recruitment arms with Ms Arandjus. Ms Arandjus explained that the participants will be recruited into cohort 1 or 2 depending on the stage of the study. Cohort 2 has part A and B. Screening will be halted to assess information in part A and then part B will commence.
* The Committee asked how unblinding works – in particular for those in the induction study. Ms Arandjus explained that a participant does not become unblinded. An assessment occurs at week 8. Based on the clinical information from that assessment the participant may either continue on blinded treatment or if they don’t have acceptable remission rates or response to the treatment they will be offered a choice to go on open label treatment.
* (R.3.1.2) The Committee noted the transport of the tissue (for FUR) is a potential cultural issue for Maori.
* (P.3.1) Ms Arandjus explained this is reimbursement for reasonable travel costs incurred from participating. Explained that this will vary site to site.
* (P.4.3.1) Has Maori consultation started? Ms Arandjus stated that it is different per site and will occur in tandem with ethics.
* (F.1.1) The Committee noted this was answered no. The Committee explained that F.1.2 answer could be qualified with p.4.1 in future applications.

Summary of ethical issues (outstanding)

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

* The Committee asked if the study drug was available to participants after the study. Ms Arandjus was not sure as this was a phase II and III study. She continued that generally the end of the study is the end of the drug being supplied. The Committee noted that the PIS is clear that the drug is not available, but asked Ms Arandjus to check with the sponsor.

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

* The Committee requested a flow chart is used to explain how the study arms and recruitment processes work. One that participants can understand, not the one in the protocol. It should explain the pathway for participants. It must explain difference between cohort 1 and 2 and the randomisation in cohort 2 – randomisation for placebo or extension study.
* In application form it is clear participants are not responding to treatments – please make it clear that they are being invited to the study because they are not responding to usual / existing treatments. Please also make it clear that some existing medication can remain active.
* Explain what medications are okay to continue and what ones are not.
* Pg.9 – describe questionnaires briefly – length of time involved for them.
* On OPTIONAL studies – under what will happen to the samples – make it clear about the overseas labs / moving around of samples.
* Explain what info will be passed to GP – etc. what you will do, who will receive them (results) etc.
* Describe abnormal or incidental findings – what these could be, how they will be managed and who will be notified.
* The Committee suggests using the HDEC template for compensation wording.
* Please explain jargon – i.e. ‘genomic’.
* Please review information birth control / breast-feeding – put it in the same section.

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 Ms Kate O Connor.

## General business

1. The Committee noted the content of the “noting section” of the agenda.
2. Please follow up governance arrangements and level of access for interRAI for the Committee.
3. The Chair reminded the Committee of the date and time of its next scheduled meeting, namely:

|  |  |
| --- | --- |
| **Meeting date:** | 04 August 2015, 08:00 AM |
| **Meeting venue:** | Novotel Ellerslie, 72-112 Greenlane Road East, Auckland |

The following members tendered apologies for this meeting.

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 3.34pm