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| **Committee:** | Northern B Health and Disability Ethics Committee |
| **Meeting date:** | 06 October 2015 |
| **Meeting venue:** | Novotel Ellerslie |

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| **Time** | **Item of business** |
| 12.00pm | Welcome |
| 12.05pm | Confirmation of minutes of meeting of 1 September 2015. |
|  | New applications (see over for details) |
|  | i 15/NTB/177  ii 15/NTB/178  iii 15/NTB/180  iv 15/NTB/183  v 15/NTB/184  vi 15/NTB/185  vii 15/NTB/186  viii 15/NTB/188  ix 15/NTB/189  x 15/NTB/193  xi 15/NTB/194  xii 15/NTB/196 |
| 5.30pm | General business:   * Noting section of agenda |
| 5.45pm | 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 | Present |
| Mrs Maliaga Erick | Lay (consumer/community perspectives) | 01/07/2012 | 01/07/2015 | Apologies |
| Mrs Stephanie Pollard | Non-lay (intervention studies) | 01/07/2012 | 01/07/2015 | Present |
| Miss Tangihaere Macfarlane | Lay (consumer/community perspectives) | 19/05/2014 | 19/05/2017 | Present |
| Mrs Phyllis Huitema | Lay (consumer/community perspectives) | 19/05/2014 | 19/05/2017 | Present |
| Mrs Kate O'Connor | Non-lay (other) | 01/07/2013 | 01/07/2016 | Present |
| Dr Nora Lynch | Non-lay (health/disability service provision) | 01/07/2015 | 01/07/2018 | Present |

## Welcome

The HDEC noted the Chair was absent. The HDEC members voted Mrs Stephanie Pollard as the Chair 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 Maliga Erick and Ms Raewyn Sporle.

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 September 2015 were confirmed.

## New applications

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| **1** | **Ethics ref:** | **15/NTB/177** |
|  | Title: | WATER Study |
|  | Principal Investigator: | Associate Professor Peter Gilling |
|  | Sponsor: | PROCEPT BioRobotics Corporation |
|  | Clock Start Date: | 24 September 2015 |

Rachael Hamill and Rana Reuther 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.

Mrs Stephanie Pollard raised a conflict for interest; the Committee discussed the conflict and decided it was not substantial.

Summary of Study

1. The study compares safety and efficacy of ‘AQUABEAM’ system and the Transurethral Resection of the Prostate (TURP) in treatment of benign prostatic hyperplasia.
2. The AQUABEAM utilises heat free high pressure water.
3. Participants are under general or regional anaesthesia. The Researcher(s) explained it should result in less damage to tissue, as it is water rather than a heat source.
4. Study will determine feasibility of procedure.
5. The Researcher(s) noted that the FDA conditions have been met. FDA approval is now valid.
6. The Researcher(s) confirmed there is just one system in the country at the moment.

Summary of ethical issues (resolved)

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

1. (A.2.1.1) The Committee noted that this question should have the ‘parallel design’ option ticked. Please note this for future applications.
2. The Committee queried (R.5.4-5.4.1) on conflict of interest. The Committee noted the doctor is also the investigator, which is a conflict. How will you mitigate this? The Researcher(s) explained that there is a sub-investigator who can help when the CI is also the treating clinician. The Researcher(s) explained that the CI has participated in many clinical trials over the years and understands the dual role well.
3. The Committee queried if the experimental treatment is not effective, or a participant is unsatisfied with their treatment, can TURPS procedures still be undertaken? The Researcher(s) stated yes, they would need to review the participant and conduct an assessment, to ensure the problem is the prostate tissue. They would then provide further treatment. The Committee noted that the study is blinded, so if a patient is not happy with their treatment they would not know what treatment they would have had. The Researcher(s) acknowledged this, and noted the assessment would be required.
4. The Committee asked how the blinding works, noting that the CI is conducting all the treatment procedures. The Researcher(s) explained that the blinded sub-investigator does the follow up. The Researcher(s) added that the CI would be involved with the screening visits and treatment. The various staff members work together to maintain the blind. CI will know, but will be trusted not to talk to researchers about it.
5. The Committee noted page 2 has an inconsistency between Participant Information Sheet and application, relating to tissue samples. Are samples going overseas? The Researcher(s) clarified they were not. The Committee noted the Participant information sheet was correct.
6. Please explain the reimbursement figures. The Researcher(s) explained current budget allows 50 dollars per patient. Depending on where they live will depend on how much is given to each patient. Those closer will be given less; those further away will be given more.
7. Page 7 of PIS – ‘tell treating team of involvement of study’. The Committee asked if participation cards would be given to participants. The Researcher(s) stated business cards with the researcher contact cards. The Committee stated it would be a good measure to have a participation card. The Researcher(s) stated they would make one for the study.

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

1. Please review for American spelling.
2. Page 2, rephrase that Medsafe receive reports about the study device but do not ‘monitor’ the study for safety.
3. Page 2 – ‘all receive same treatment’. The Committee noted that is not correct, please revise.
4. The Committee noted that the consent form has a statement about tissue going overseas, and a pregnancy statement, but the study only involves men. Please remove both.
5. The Researcher(s) confirmed there are interpreters available. The Committee asked that this be clearly stated on consent form.
6. Please make reimbursement clear. Currently states ‘may’ be reimbursed.
7. Please add extension number to Maori contact details, for increased accessibility.
8. Page 3 on description of randomisation – please explain the element of chance involved with randomisation.
9. Page 4 – electrolyte test – this is explained ‘as above’ however it is not mentioned above. Please amend.
10. Page 5 - third paragraph down. Add ‘they will follow it up and advice on treatment options’ rather than just recording it (with regards to incidental findings).
11. Page 6 – regarding access to records. States parties will only view de-identified information. Is this correct? The Researcher(s) stated no. The Committee stated make it explicitly clear that identifiable medical records will be available, and explain who these people or groups will be.

Decision

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

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| **2** | **Ethics ref:** | **15/NTB/178** |
|  | Title: | PeRsonalised Asthma Combination Therapy: with Inhaled Corticosteroid And fast-onset Long-acting beta agonist (PRACTICAL) |
|  | Principal Investigator: | Prof Richard Beasley |
|  | Sponsor: | Medical Research Institute of New Zealand |
|  | Clock Start Date: | 24 September 2015 |

Mark Holliday, Dr Janine Pilcher and Dr Stefan Ebmeier 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

1. The study investigates the safety and efficacy of two treatment regimes in adult patients with asthma (for those who ICS – inhaled corticosteroid reliever therapy maintenance and SABA – short acting beta antagonist therapy is recommended).
2. The Committee commended the lay study title.

Summary of ethical issues (resolved)

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

1. The Committee queried why enrolment of 500 (out of 780) patients was required before a formal safety review of the data occurs, adding monitoring of individuals was 3 months between visits. Is there more regular safety monitoring? The Committee noted there was potential for participants to do worse when taken off their standard treatment (corticosteroids). The Researcher(s) stated that there is a study monitor, site level investigator monitoring and the independent monitor. The Researcher(s) added they have been cautious of who they are enrolling in the study, for instance they don’t have participants with very poor asthma control, adding that if participants get unwell they suggest GP review, or additional study visits between the 3 month scheduled ones.
2. The Committee noted the explanation, adding it primarily addressed individual level monitoring, but asked why the independent review could not start after 200-250 patients have been looked at (or justify 500 people). The Researcher(s) noted the 500 figure was based on event number predications. The Researcher(s) were open to reduce the number of enrolments required for initial review. The Researcher(s) added that there is close relationship between investigators and DSMC. The Researcher(s) confirmed DSMC receives monthly updates, including recruitment numbers, adverse events, SUSAR etc. The Committee discussed the more frequent reporting and was satisfied with the measures in place.
3. Page 24 of application: 50 dollars of reimbursement. The Committee queried if this figure would be enough for those traveling from afar. The Researcher(s) noted they recruit from multiple sites. They are aware of potential for further reimbursement and have a scope for this, via review with sponsor. The Committee noted this.
4. The Committee queried how Maori consultation was going. The Researcher(s) noted they had submitted to Research Advisory Group - Māori committee (within the CCDHB). Other sites will perform a similar review.
5. The Committee queried if trial registration had occurred. The Researcher(s) stated it is still pending.
6. (R.2.1.1) on recruitment. The Committee queried if there was any advertising material. The Researcher(s) stated it was being developed, explaining the timelines for this study: plan to start early next year (January – February). The Researcher(s) noted it would be a post approval amendment. The Committee noted this.
7. (P.2.6) page 23, regarding withholding information – The Committee noted in sub-set study (electronic monitoring) – there is information withheld from them. The Researcher(s) noted that was correct, however they have subsequently decided to inform participants of everything that is recorded by the electronic monitoring.

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

1. Please add document page numbers. The Researcher(s) explained this related to document headers at each site.
2. The withdrawal – please note this does not have to be in writing. The Researcher(s) noted there is the possibility of taking a formal withdrawal pathway, including written withdrawal, but noted that participants do have the right to withdraw verbally.
3. ‘May be given inhalers…’ (Page 4) – Change to first person. Fourth paragraph.
4. Page 5 - please confirm, are samples stored in United States? And how will these be destroyed? The Researcher(s) stated they are collected, shipped off to US for analysis, and will not be stored as such, maybe a couple of days, then analysis – then destroyed as per that laboratory practice. The Committee stated destruction method should be added to Participant Information Sheet.
5. On page 12 please change emphasis of wording, make it clear that participants can withdrawal verbally, else can fill out formal process.
6. Page 12-13: last paragraph on page 12. Can blood samples be withdrawn? Does this relate to the data from the study results? The Researcher(s) stated samples would be stored on site for something along lines of 6 months prior to analysis. The Committee asked about post analysis withdrawal. The Researcher(s) stated that up until the point of publication, there is option to remove data. There is scope to do that. The Committee noted it should be clear that pre-analysis can be removed or destroyed, but once analysed it should be included in the study. The Committee suggests re-wording.
7. Regarding consent form – 8th point down – risks associated with partner or themselves becoming pregnant – are there pregnancy risks for this study? The Researcher(s) stated no, these drugs can be used by pregnant women. In terms of participants becoming pregnant during the study, they would request that they do not take part. The same goes for those breastfeeding or pregnant prior to study, they will be asked not to take part. This relates to asthmas interactions when pregnant. It would impact the study results. The Committee noted it could be clearer that it is not about risks associated; rather it is about management of their asthma, via their GP etc. Also reword that pregnant partners are not at risk but request that if partner becomes pregnant that they inform researchers.
8. The Committee queried what interview (consent form statement)? The Researcher(s) noted there is no interview.
9. Page 13 – please ensure Maori health contact details are included.
10. Page 10 seems to suggest that contraception would be provided by study doctors – is this correct, noting they are probably not best person to provide such advice. The Researcher(s) stated they would remove statement.

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 Phyllis Huitema and Mrs Stephanie Pollard

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| **3** | **Ethics ref:** | **15/NTB/180** |
|  | Title: | Rehabilitation post primary flexor pollicis longus repair |
|  | Principal Investigator: | Dr Ashwini Pondicherry |
|  | Sponsor: |  |
|  | Clock Start Date: | 24 September 2015 |

Elaine Duguid and Shirley Collocott 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 (resolved)

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

1. The Committee queried how the exercise requirements differ from each arm, in terms of type and frequency. Is one arm a bigger burden of discomfort or time? The Researcher(s) noted the immobilisation arm would not have any therapy for first 4 weeks whereas the short duration will start straight away. The Researcher(s) clarified it would be roughly the same amount and type, but at different times, as the immobilisation arm would still have to have the exercise – just later on.
2. The Committee asked about the primary outcomes. The Researcher(s) stated it looks at range of movement for joints. The Researcher(s) noted there is a scale provided to the Committee that outlines outcomes. The Researcher(s) confirmed it would be an assessment conducted by the researchers, against criteria that are worked out later, such as range of movements, adding this method of evaluation is common in hand therapy sessions.
3. The Committee asked if the safety committee has been established, how many members? The Researcher(s) stated the term safety committee may be inaccurate – there is no specific safety committee, rather the researchers have registrars helping with individual level monitoring.
4. The Committee asked whether return to work could be delayed because the surgeon wants to avoid having the hand under pressure (when in the cast). The Researcher(s) stated no, participants are not able to use the hand for anything hands on, even if in a cast.
5. A.6.1 – page 8. The Committee suggested adding DHB as the sponsor.
6. The Committee queried if it will take a few years to accumulate enough people, noting that it is a pilot, which will be underpowered by its definition, but wondered whether the length of time was realistic. The Researcher(s) stated to get proper numbers for statistics point of view it was too long to realistically consider, therefore a pilot design has been chosen. Most of the studies of this nature do last a number of years.

Summary of ethical issues (outstanding)

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

1. The Committee queried who monitors the trial for the rupture rates that would result in termination of the study. The Researcher(s) stated it is a group effort. If they got up to 3 in either group then they will stop the trial. These are recorded in real time. The Committee requested that the internal data safety monitoring is outlined formally in a cover letter. I.e. escalation plans, clarity around frequency of assessment, who is involved etc.
2. (P.4.3) - HDEC note Maori consultation is required for this study, as per HRC Guidelines for Research involving Maori <http://www.hrc.govt.nz/news-and-publications/publications/guidelines-researchers-health-research-involving-m%C4%81ori> . Please describe the process of consultation, i.e. who, where, when. Consultation must occur, but can occur after HDEC approval.
3. **P.4.1. Please describe whether and how your study may benefit Māori.** The answer should include incidence and prevalence of the disorder under study (or treatment indication if a drug trial) in Maori. The Committee notes that some disorders are particularly important for Maori health, while others are relatively rare in Maori and may have less of an impact. If relevant, please include information on how researchers will ensure that Maori benefit at least equally (and actually how they can disproportionately benefit if they are disproportionately burdened) –for example, what extra measures if any are in place to ensure Maori participation (iwi consultation, Maori researchers, active follow up etc.) as well as interpretation of results and presentation of findings back to those consulted.

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

1. The Committee queried the statement about informing ACC. The Researcher(s) stated it related to ACC and going back to work earlier. The Committee requested this is added to the Participant Information Sheet not just in the consent form.
2. Page 2: add that you are looking at the rupture rate. Rupture is a primary aim / outcomes. The Researcher(s) noted that this is not an outcome, rather it is a recognised complication – while they want to improve the outcomes, such as range and function, and they don’t want to do it at the risk of increasing rupture rate. The Committee requested brief information on other outcomes is added.
3. Consolidate ACC compensation information.
4. Correct version of Participant Information Sheet.
5. Consolidate your consent form into your Participant Information Sheet.
6. Page 3 – your / you’re – please amend.
7. Page 4 – ensure Maori health details are included.
8. Change Southern HDEC to Northern B.

Decision

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

* Please amend the information sheet and consent form, taking into account the suggestions made by the Committee (*Ethical Guidelines for Intervention Studies* *para 6.22*).
* Please address how the study may benefit Māori and how cultural issues that may arise for Māori participants in the study will be managed, and explain the consultation process that will occur (*Ethical Guidelines for Intervention Studies* *para 4.7*).

This following information will be reviewed, and a final decision made on the application, by Dr Nora Lynch and Mrs Tangihaere MacFarlane.

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| **4** | **Ethics ref:** | **15/NTB/183** |
|  | Title: | Youth e-therapy implementation |
|  | Principal Investigator: | Dr Theresa Fleming |
|  | Sponsor: |  |
|  | Clock Start Date: | 24 September 2015 |

Dr Karolina Stasiak 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

1. The Researcher(s) explained the SPARX programme to the Committee.
2. The Researcher(s) explained the resulting publications, PhD projects and history of the project.
3. This particular project looks at uptake of the e-therapy. It also looks to validate ideas from RCTs in real life context. It is not about providing interventions, rather it is about gauging interest and ideas from target population.

Summary of ethical issues (resolved)

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

1. The Committee queried the lack of parental consent for those under 16. The Researcher(s) explained that because this is a self-help intervention that is already accessible without parental consent (for those under 16), to ask them what they found useful about the intervention and ask them what else they could provide for them, they feel that to go back to the parents for consent would breach the trust that the young people have with the program, as it does not involve parents. The Researcher(s) explained they found that having young people participate was impacted by requiring parental consent (key barrier to participation).
2. The Researcher(s) explained there are agreements that children consent for, with relation to being contacted in future about this programme for research and evaluation. One part of this study will involve contacting those children who noted that they would like to be contacted.
3. The Researcher(s) confirmed the other group was non-users recruited from schools. The Committee explained that while the management of schools is notified about the children’s involved in recruitment it did not involve parents. The Researcher(s) stated the risks for this part are minimal, they are not looking at mental health or depression, and instead they want to seek views on using technology to help address these problems. The Researcher(s) explained that schools have stated they are comfortable with the approaches set out by the researchers.
4. The Researcher(s) confirmed there are newsletters going out (to children’s homes) about the project, but no specific consent sought from the parents.
5. The Committee stated in the event of a young person being seriously unwell (mental health) and comes into this program and is talked to about the programme, but is not treated due to this being about evaluation of the programme, is there a danger that someone goes undiagnosed, untreated or unsupported if parents are not involved? The Researcher(s) stated that they have good working relationships with school guidance counsellors. The researchers notify the counsellor about the study – when it comes to debriefing from the focus groups or interviews, they make referrals if they need to, or if anyone identifies a safety concern. They would also inform the young person. They give young people a lot of information on options for help or follow-up, at the end of the interviews.
6. The Researcher(s) noted that they want parents to be aware of the project, and could have an opt out process, where parents can be involved by contacting the researchers but there is no requirement for consent from parents for a child to participate.
7. The Committee noted that getting 12 year olds to sign current consent form might be too complex for them to really understand.
8. The Committee discussed the parental rights about consenting for their children to participate in a research programme that is outside of the school curriculum, in cases where there might be a vulnerable group, noting that it is a service evaluation rather than a therapy group (adding this point should be really clear to participants and parents).
9. The Committee stated they agree that those who are pre-existing users who have consented to be contacted can be enrolled without a requirement for parental consent.
10. The Researcher(s) confirmed that during the phone call they confirm it is an okay time to talk (safe), explaining there is an expectation that the use of the program is confidential.
11. The Committee noted that it is currently not that clear that it is about young people and views on technology, rather than potentially vulnerable groups.
12. The Committee noted there is no secrecy around the study – posters, newsletters and researchers interacting with the school; if it is clear that participants are recruited to talk about technology etc. rather than this being an intervention for treatment – it could be justifiable without parents’ consent.
13. The Committee asked if it is one focus group per school. The Researcher(s) stated it depends, but would like a wide range.
14. The Committee noted having parental consent, opt in, for 20 participants would not be unfeasible. It may bias results slightly. The Researcher(s) noted the stigma or terminology used could result in children not taking information home.
15. The Committee queried what physical limitations would exclude participation? The Researcher(s) noted it would be those, which can’t access traditional technology. While they are working on accessibility, currently they are not able to have users with physical disability.
16. The Committee noted consultation with Maori has occurred in developing the protocol.
17. The Committee noted they were comfortable recruiting those active users who had indicated to be contacted for research.
18. The Committee voted on acceptability of an opt out consent model for school children – on condition, that parents get information (serious efforts are made). Four members agreed. One member vote against, requesting parental consent in all cases of enrolment through schools.

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

1. Add Maori health details.
2. Change Participant Information Sheet to make clear that it is about technology and acceptability (service evaluation on a programme that is about stress / feeling down, but that this is not a health intervention).
3. Make the PIS more accessible for younger participants.

Decision

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

* Provide further information on the study design, *in particular Clarify means to adequately communicate study to parents. Submit any related documents* (*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 (*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.

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| **5** | **Ethics ref:** | **15/NTB/184** |
|  | Title: | Effects of irrigation fluid temperature on core body temperature |
|  | Principal Investigator: | Dr Kimberley Sent-Doux |
|  | Sponsor: |  |
|  | Clock Start Date: | 24 September 2015 |

Dr Kimberley Sent-Doux was not 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 (outstanding)

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

1. The Committee stated that it is unacceptable to have someone else consent on behalf of potential participants unable to provide their own informed consent.
2. The Committee noted that the HDC Code of Health and Disability Services Consumers' Rights Regulation 1996 applies to all health research and that a representative is unable to consent for someone on their behalf.
3. Right 7.4 of the HDC Code of Rights states that “Where a consumer is not competent to make an informed choice and give informed consent, and no person entitled to consent on behalf of the consumer is available, the provider may provide services where –
   * a) It is in the best interests of the consumer; and
   * b) Reasonable steps have been taken to ascertain the views of the consumer; and
   * c) Either, -
     + i. If the consumer's views have been ascertained, and having regard to those views, the provider believes, on reasonable grounds, that the provision of the services is consistent with the informed choice the consumer would make if he or she were competent; or
     + ii. If the consumer's views have not been ascertained, the provider takes into account the views of other suitable persons who are interested in the welfare of the consumer and available to advise the provider.”
4. Further, the Committee noted that Right 9 ensures that these rights extend to those occasions when a consumer is participating in, or it is proposed that a consumer participate in, teaching or research.
5. The Committee clarified that it is possible (under Right 7.4) if it can be shown that participation is in the best interest of the consumer and they take into account the views of other suitable persons or believe that the consumer would wish to consent if they were able to. In these cases the consent can be provided by the clinician for this individual to participate in the research.
6. The Committee explained that they did not believe that this study meets the best interest measure and, therefore, could not include participants who are unable to consent for themselves.
7. (P.4.3) - HDEC note Maori consultation is required for this study, as per HRC Guidelines for Research involving Maori <http://www.hrc.govt.nz/news-and-publications/publications/guidelines-researchers-health-research-involving-m%C4%81ori> . Please describe the process of consultation, i.e. who, where, when. Consultation must occur, but can occur after HDEC approval.
8. Please provide more robust evidence of peer review.
9. How is randomisation occurring? Provide a description of the metric and what measurements will be taken. The Committee would like reassurance on the level of peer review and scientific overview (i.e. biostatistician) that has occurred for this research protocol.
10. The Committee noted the application was poorly filled out.
11. The Committee asked about stopping criteria for the study.
12. What are the ‘other’ arrangements for monitoring?
13. (B.3.1) What training and supervisory arrangements for this study, noting this was the CIs first study.
14. Needs evidence on how health data is stored and protected, noting privacy rights.
15. Please store health information for 10 years (not 12 months as indicated in application).
16. Consent process is not clear, is this pre-operatively? How much time is given to participants to consider participation? Provide explanation on consent processes.
17. Please explain how this is checked (R.1.5).
18. Add contact details on final page.
19. Please be clear about what is required of participants, it is not clear what is being asked of participants is. What is standard of care for the site?
20. The Committee noted the risk of hypothermia on application but not in Participant Information Sheet? Please explain.

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

1. Add logo, lay title and withdrawal does not need to be in writing.
2. Add page numbers, date and footer.
3. Add translator statement.
4. Add simple statement about where the fluids are going – this may not be obvious for participants.

Decision

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

* Please provide evidence of favourable independent peer review of the study protocol (*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*).
* New Zealand law substantially limits the powers of health practitioners to offer treatment without consent in the context of research. It also substantially limits the powers of others to consent to such treatment on behalf of any person who is not competent. *(Ethical Guidelines for Intervention Studies para 6.26).*
* Please address how the study may benefit Māori and how cultural issues that may arise for Māori participants in the study will be managed, and explain the consultation process that will occur (*Ethical Guidelines for Intervention Studies* *para 4.7*).

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| **6** | **Ethics ref:** | **15/NTB/185** |
|  | Title: | Whānau Experiences of Recurrent Rheumatic Fever |
|  | Principal Investigator: | Dr Anneka Anderson |
|  | Sponsor: | Ministry of Health |
|  | Clock Start Date: | 24 September 2015 |

Ms Anneka Anderson (CI) and Dr Malakai Ofanoa and Dr Alison Leversha were present in person for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. The Committee noted the value of the study.
2. The Committee noted the study is sponsored by the Ministry of Health.

Summary of ethical issues (resolved)

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

1. The Committee noted that the peer review issues have been raised and addressed.
2. The Committee queried if Tongan methodologies are acceptable for other pacific islanders. The Researcher(s) stated there are two main methodologies. While both are Tongan, they are generic for Pacific Islanders and are appropriate.
3. (R.1.1) The Committee noted there is a potential for harm from information being disclosed. The Researcher(s) stated that particularly for mothers, regarding their children’s experience, disclosure could be traumatic at times. They ensured there was support, including Whanau, and the option to turn off recorder and take time to process prior to proceeding. The Researcher(s) stated they have reports from prior study participants that talking about their experiences was a very therapeutic process. The Committee noted there is a trade off in that respect, between talking about it and potential for harm – and noted to mitigate any risk they will ensure support is available.
4. The Researcher(s) confirmed R.1.2 was an error – there is no intention to contact GPs about family involvement. If they ever did contact GP it would be with explicit consent from the family.
5. The Researcher(s) noted it was self-identification for ethnicity. The Committee noted that the DHB statistics might not match the collected ethnicity.

Summary of ethical issues (outstanding)

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

1. The Committee suggested adding very basic assent form for young children. See <http://ethics.health.govt.nz/guidance-materials/assent-guidance> and the Auckland University of Technology assent form guidance <https://www.aut.ac.nz/researchethics/guidelines-and-procedures/appendices/appendix-e-consent-and-assent-form-exemplars> .
2. The Committee queried whether other health practitioners should be funded due to their potential travel. Because they are having karakia, koha and support mechanisms they are focusing on the Whanau and participants rather than supporting nurses. It came down to a budget issue. They have tried to mitigate the cost for them by tagging on the meetings to existing meetings, to reduce travel.
3. The Committee noted that all participants should receive koha, and at least not be out of pocket, for participating in this study. This is an issue of fairness. Please consult with the Ministry and seek a justification of not compensating nurses.
4. Please note only legal guardians can consent on behalf of those less than 16 years old.
5. The Researcher(s) explained the consent forms and Participant Information Sheet and explained that the same main one would be given to the wider family for information.

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

1. Page 2, paragraph 5 – 30 dollar voucher. The Committee queried if this is a specific voucher? The Researcher(s) stated a food voucher.
2. Add extension numbers for contact details.
3. The Committee noted that the assent form did not have a place for children to sign. Please add.
4. ‘You or someone in your whanau’ amend typo.
5. Amend ‘if you don’t what us’ amend typo.
6. Revise Assistant Professor Paparangi.
7. Ensure yes/no boxes on the consent form are truly optional.

Decision

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

* Please provide an assent form for non-consenting participants to sign (*Ethical Guidelines for Observation Studies 6.21)*
* Please amend the information sheet and consent form, and assent forms, taking into account the suggestions made by the Committee (*Ethical Guidelines for Observation Studies* *para 6.11*).
* It is acceptable for investigators to repay the incurred expenses of participants (for example, travel costs). Please justify this for all participants. (*Ethical Guidelines for Observation Studies* *para 6.24*).

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

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| **7** | **Ethics ref:** | **15/NTB/186** |
|  | Title: | BP29948: A study of RO7020322 in healthy subjects and hepatitis B patients |
|  | Principal Investigator: | Prof Edward Gane |
|  | Sponsor: | Covance NZ Ltd |
|  | Clock Start Date: | 24 September 2015 |

Prof Edward Gane and Ms Rebecca Hu 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

1. The study investigates Hep B cure program. The study will look at agent that blocks expression of Hep B. This study is designed to develop a drug for short duration treatment. This is a first in man study with this particular compound.
2. The Researcher(s) explained that the first part of study looks at how drug is stored, metabolism of the drug, as usual for phase I drugs. Second phase is in patients.

Summary of ethical issues (resolved)

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

1. The Committee queried the reimbursement, noting it is quite high. The Researcher(s) agreed it was quite high, but noted participation required multiple blood tests and days stayed as an inpatient. The amount of calculated based on inconvenience and length of stay. This calculation is also used by Christchurch Clinical Studies Trust.
2. The Committee asked how the Maori consultation had been going. The Researcher(s) noted that the study has gone through Maori review at ADHB.
3. The Committee queried if part 1 is exclusively in New Zealand. The Researcher(s) confirmed it was, explaining that Part 2 (with patients) is at many sites (including New Zealand). They would not be able to recruit that number of patients solely in New Zealand.
4. (F.1.1) why would this study not impact inequalities, noting that the disease is burdensome for Maori. The Researcher(s) noted that this was an error.
5. The Researcher(s) confirmed medication is not withheld, standards of care are maintained during the study.

Summary of ethical issues (outstanding)

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

1. The Committee queried if part 1 and 2 is sought for approval in this application. The Committee noted that the final Participant Information Sheet is not submitted for part 2. The Researcher(s) stated that this could be an amendment and is currently in progress / development. Dosing levels etc. is dependent from part 1. This is partly the reason why the ICF is not submitted for part 2.
2. The Committee requested a template with areas for future information about part 2.
3. The Committee noted Participant Information Sheet for part 1 a b and c together was very confusing. The Committee suggested that 1 a and b is together and 1 c is separate. This is because different reasons for participation, payments, outcomes etc.

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

1. Page 7 – screened, but not eligible – you don’t get paid. What about people who are screened, eligible, but don’t go forward? The Researcher(s) stated they would not over recruit as it is a single centre site for part 1. The Committee suggested rewording to cover the above scenario (withdrawal).
2. Page 10 – remove commercial interest of sponsor (termination criteria).
3. The Committee queried why there was a need for a pregnancy test if they are not of childbearing potential (for part 1). The Researcher(s) stated they will remove (page 8 Participant Information Sheet). Also remove mention to male partner affirmation of responsibilities, as also irrelevant.
4. Add how HIV, Hep and alcohol and drugs (incidental findings) will be managed.

Decision

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

* Please provide a separate Participant Information Sheet and Consent Form for the use of tissue for future unspecified research (*Guidelines for the Use of Human Tissue for Future Unspecified Research Purposes, para 2*).
* Please amend the information sheet and consent form, taking into account the suggestions made by the Committee (*Ethical Guidelines for Intervention Studies* *para 6.22*).

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

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| **8** | **Ethics ref:** | **15/NTB/188** |
|  | Title: | Assessment of the investigational coeliac disease drug Nexvax2, when given in multiple doses to men and women with coeliac disease |
|  | Principal Investigator: | Dr Timothy King |
|  | Sponsor: | ImmusanT, Inc |
|  | Clock Start Date: | 24 September 2015 |

Ms Margaret Joppa and Dr Timothy King 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 (resolved)

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

1. The Committee queried how a vaccine for coeliac would work? The Researcher(s) stated that it is more accurate to term it as a slow tolerance building exercise, than a vaccine, which may reduce severity of responses. This theory is being tested with coeliac disease.
2. The Committee queried if it could lead to more gluten consumption. The Researcher(s) stated yes, but the concept is at a very early stage of development.
3. The Committee queried are participants avoiding gluten currently. The Researcher(s) explained participants are fit and are not undergoing serious treatment for their disease.
4. The Researcher(s) confirmed participant card is contactable 24/7.
5. The Committee noted Health and Disability Commission details would not be appropriate for Maori support contact details. The Researcher(s) noted this issue was resolved.
6. The Committee queried how incidental findings are managed? The Researcher(s) stated that they will be discussed individually, offered to discuss with GP or other referrals.
7. The Committee noted plain English would be appreciated for 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.

1. The Committee queried if there should be pregnant partner information release sheets. The Researcher(s) stated they would upload these.
2. R.1.5 – R.1.4: DSMC arrangements. Is there a Committee that has oversight of this data? The Researcher(s) stated yes, there is a plan to review all study data. This was not available at the time of submission. This is an independent group (but will confirm).

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

1. Add lay language title.
2. Remove commercial interests of sponsor (stopping study). Remove statement.
3. Page 16 – please amend wording about pregnancy information, as currently is potentially coercive.
4. The Committee noted the document should explain what happens when study ends.
5. Add information of management of incidental findings.
6. Add responsibilities relating to pregnancy on the consent form (bullet point).

Decision

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

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

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

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| **9** | **Ethics ref:** | **15/NTB/189** |
|  | Title: | A research study to find out what happens to rFVIIIFc in the body and if it is safe when made in larger batches and at higher strengths for patients with Hemophilia A |
|  | Principal Investigator: | Mr Mark Smith |
|  | Sponsor: | Quintiles Pty Limited |
|  | Clock Start Date: | 24 September 2015 |

Dr Mark Smith 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

1. The study investigates two different manufacturing processes and two different strengths of a treatment (rFVIIFc).
2. Please confirm manufacturing is GMP compliant. The Researcher(s) confirmed it was. To continue to be compliant the larger reactor must be shown to be equivalent to the smaller reactor.

Summary of ethical issues (resolved)

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

1. The Committee queried if there any risks of washout. The Researcher(s) confirmed there were bleeding risks – if participants do bleed, they get treated. The Researcher(s) explained this was a standard risk, not limited to the study.
2. The Committee noted that the drug is not available post study; however there is an extension study that will allow continued treatment for those who want it. This is approved and running in New Zealand. The Researcher(s) noted most participants would want to access the extended duration of treatment. This extension study is the only way they can get access to it.
3. The Committee noted participants should be re-consented once they turn 16. The Researcher(s) noted that this would happen.
4. The Committee noted parental consent is for children under 16 not under 18.
5. P.4.6 – please collect ethnicity information. Please collect this data according to the New Zealand census ethnicity collection format.
6. The Committee queried who is completing the E-diary for the 12-15 year olds. The Researcher(s) noted that it might be parents of the children – whoever will reliably do it. The Researcher(s) explained how intuitive and easy to use (e-diary). The Committee requested it is clear that parents should be responsible to ensure the e-diary is completed, but that both parent and child get training on how to use it.

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

1. The Committee queried whether the wording is age appropriate (12 year olds+). Consider whether side effects, inhibitors descriptions etc. – this might be a bit complex. Simplify. Shorter, user friendly. Guidance is found at <http://ethics.health.govt.nz/guidance-materials/assent-guidance> and the Auckland University of Technology assent form guidance <https://www.aut.ac.nz/researchethics/guidelines-and-procedures/appendices/appendix-e-consent-and-assent-form-exemplars> .
2. The Committee queried if higher concentrations relate to higher inhibiter development. The Researcher(s) stated no, no higher concentration that normally receive. No increase in amount given. Only difference is the treatment is being made in the bigger bioreactor. The Committee requested this is very clearly explained in the Participant Information Sheet.
3. The Committee noted that they could reiterate what should happen in the event of a bleed (assent form).
4. Page 5 (adult consent). States as of Jan/Dec 2014. Please update this if possible, or if this data is still valid, reword to ‘as of now’.
5. Tidy up fronts etc. (minor admin review required).
6. Page 9 of adult Participant Information Sheet. Compensation statement. Please remove statement that limits the compensation ‘*or if the law limits Biogen’s legal responsibility’*. This is not in line with ACC equivalent ACC as required by NEAC Guidelines.
7. Please remove ‘as required by US law’. Not relevant for New Zealand setting. Page 10.
8. Page 10-11 – please provide an explanation about what happens if the study was stopped. Reassuring language.
9. The Committee noted no need for initialling each page. Sign on consent form is sufficient to affirm consent.
10. The Committee requested it is clear that parents should be responsible to ensure the e-diary is completed, but that both parent and child get training on how to use it.

Decision

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

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| **10** | **Ethics ref:** | **15/NTB/193** |
|  | Title: | A healthy life starts with a bio-energetically healthy placenta |
|  | Principal Investigator: | Prof Larry Chamley |
|  | Sponsor: | The University of Auckland |
|  | Clock Start Date: | 24 September 2015 |

Professor Larry Chamley was present in person for discussion of this application.

Potential conflicts of interest

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

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

Summary of ethical issues (resolved)

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

1. The Committee noted that the tissue is being stored beyond the length of the study, though the tests would be limited to those on preeclampsia, and noted that this storage should be in a registered bio bank, or standard practice laboratory.
2. The Researcher(s) explained that they are looking at preeclampsia (placental malfunction).
3. The Researcher(s) explained the history of preeclampsia, noting that much is unknown about it, in particular what causes it and how to prevent it.
4. The Researcher(s) explained that this tissue is taken from early stage termination.
5. The Researcher(s) explained the existing approvals for tissue collection at variety of stages of pregnancy.
6. The Researcher(s) explained that this is an HRC funded study.
7. The Researcher(s) explained that scientific context of the study.
8. The Committee noted that the information provided in the Participant Information Sheet is likely to be too technical. Please review for use of lay language.
9. The Committee noted that having tissue placed with someone else’s terminated tissue might be problematic, or misleading.
10. The Committee asked how long tissue was stored. The Researcher(s) explained that it was not defined, and was often used up.
11. The Committee and The Researcher(s) discussed the storage of the tissue, noting that it was banked at the lab for future, defined, research. This was acceptable, noting that any future use required further HDEC review, via an amendment. The Researcher(s) agreed.
12. The Committee discussed aPL antibodies and whether a positive result is not an automatic warning sign for bad outcomes. The Researcher(s) noted these patients are high risk so it suggests that it would have an impact.
13. The Committee queried why this study would not reduce inequalities, noting that it was a prevalent disease for Maori. The Researcher(s) stated that this study may reduce inequalities.

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

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| **11** | **Ethics ref:** | **15/NTB/194** |
|  | Title: | Risk factors for undescended testes |
|  | Principal Investigator: | Dr Jason Gurney |
|  | Sponsor: |  |
|  | Clock Start Date: | 24 September 2015 |

Dr Jason Gurney 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

1. The study is part of a larger group of studies into risk factors for testicular cancer.
2. In New Zealand Maori men have the highest rates of testicular cancer.
3. The Researcher(s) explained the interest around Maori and testicular cancer, and how understanding the risk factors may lead to more generalizable knowledge for other populations.
4. The Researcher(s) explained that either directly or indirectly exposures that cause Maori men to have high rates of testicular cancer, will be directly related to risk factors generally.
5. The Researcher(s) explained that it is one of the only cases where Maori and Pacific populations are very different; in Maori it is 3 times higher than Pacific Island men.
6. The Researcher(s) explained there is no ability to compare between Pacific Island and Maori as there are only a few cases of Pacific testicular cancer.
7. Study is not due to start next year (2016).

Summary of ethical issues

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

1. The Committee asked if there will be a pilot, noting many aspects of the study (recruitment, questionnaires etc.) were not explicitly defined. The Researcher(s) stated yes, two funding applications have been made. Otago University funding is sought for the first 30 cases. The major concept of the study would not change, though recruitment processes, questionnaires and specific details will be developed. For example response rates will be very important. Identifying ways to maximise response rate is one goal of the pilot study.
2. The Researcher(s) explained that the New Zealand Health Survey rolled out an electronic questionnaire; this is an option to consider. Our target population will be in their 30’s and should therefore be tech savvy.
3. The Committee asked if there was Whakama to be considered with regards to this study. The Researcher(s) explained there is, particularly because of the sense of guilt – if being questioned about smoking, drugs etc. it could result in a difficult context of recruitment.
4. The Researcher(s) acknowledged the potential to cause harm due to guilt – noting this would be mitigated by showing that they don’t actually know what causes undescended testes and would result in a display of empathy.
5. The Researcher(s) noted the importance of a woman contacting mothers due to the subject matter.
6. The Committee noted data on perinatal factors would be reviewed prior to consent to participate. 6.4.5 states that seeking consent prior to accessing these health information The Researcher(s) explained that the details of cases is released, they then send the letter, once consent is given, they access the information.
7. The Committee requested further evidence of peer review, noting the need for controls to be well designed. The Researcher(s) explained the on-going dialogues that have occurred with leading experts with case control studies. The Researcher(s) noted the peer reviews occurring for funding, as well as HRC funding applications.
8. The Researcher(s) noted it would be easy to seek further peer review.
9. The Committee asked what the conditions were in releasing data to notify cases. The Researcher(s) explained that there was an ongoing discussion with Ministry. The sensitivity of the link between researchers contacting the mother. The Researcher(s) will send email correspondence to HDEC between Ministry and research team to clarify the discussions.
10. The Researcher(s) explained the purposeful vagueness of the introduction letter; it is about being sensitive of the subject matter, as to only reveal why contact had been made once interest in participation had been gauged. The Committee noted it was a deception to minimise harm – but that this needed a sound justification.
11. The Committee queried why the application stated no risk of stigmatisation? The Committee thought this was incorrect, due to the subject matter. The Researcher(s) agreed, that this answer was not correct.
12. The Researcher(s) noted recall bias if participants are looking for a reason for why this disease occurred.
13. Amend Participant Information Sheet – explain the study is looking at pregnancy overall. It is important not to focus on all the potential negative aspects of a woman’s pregnancy. The tone of the document should be generalised, softer.
14. Participant Information Sheet does not have balance or reassurance. I.e. doesn’t state if uncomfortable you don’t have to answer questions, not enough information about confidentiality.
15. P.4.2 – no cultural issues? The Researcher(s) noted that it was about the approach to the study and reducing inequalities. The team has half Maori researchers and has a good track record of increasing response rate and being acceptable. The Committee noted the Maori involvement was of a high quality.
16. The Committee discussed the initial disclosure of contact information, to send the invite letter, and wanted a firm plan in terms of justification of disclosure of health information without consent.
17. The Committee concluded that the study was not complete enough to result in a decision, but that they supported the concept and the focus of the study. The Committee suggested the researcher withdraw their application and re-submit to the NTB HDEC when information was available, such as a plan to disclose health information, a justification of this, a final copy of the questionnaire, a re-worded participation sheet.

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| **12** | **Ethics ref:** | **15/NTB/196** |
|  | Title: | MN and malignancy in Auckland region |
|  | Principal Investigator: | Dr Basil Alnasrallah |
|  | Sponsor: |  |
|  | Clock Start Date: | 24 September 2015 |

Basil Alnasrallah was present in person for discussion of this application.

Potential conflicts of interest

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

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

Summary of ethical issues (resolved)

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

1. The Researcher explained there are 200 participants. It was unknown how many of these samples 200 developed malignancy.
2. The Researcher(s) explained the scientific background of the study.
3. The Committee queried how many are contactable? The Researcher(s) stated they have contact details from last follow up, but generally don’t know. The Committee asked if they would follow up if diagnosed. The Researcher(s) stated they would not in all cases, adding they may inform their GP.
4. The Committee noted that this would effectively identify to the participants who had been enrolled without consent. The Researcher(s) noted that they don’t expect any finding that will impact the patient’s care.
5. The Committee asked would it only be those who developed malignancy who you need to go further regarding data analysis. The Researcher(s) stated no, they would look at control too, to compare.
6. The Committee asked about the tissue testing, noting there is not very much information in protocol on testing. The Researcher(s) stated that standard of care tissue has option for future diagnostic testing, or research with approval for ethics committees. The Committee noted that this might be true for more recent samples but not for prior samples (pre 2003).

Summary of ethical issues (outstanding)

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

1. The Committee queried why the researcher was not seeking consent for secondary use of data or tissue. The Researcher(s) stated that there are some questions that remain to be answered on MN and malignancy in Auckland region. The Researcher(s) hoped that the benefit of doing the study outweighed the risks involved, mainly because the data is only available researcher (CI). Co-investigators will probably not be involved in the data collection itself.
2. The Committee asked again, why the researchers were not seeking consent. The Researcher(s) stated the data is very old, it would be difficult to get consent from all the participants, adding some patients may have died.
3. R.3.1.1 – The Committee noted tissue should be returned to bank.
4. Queried sponsor status – The Researcher(s) will update.
5. The Committee requested a revised protocol that clearly outlines what will occur. This should cover ethical issues, analysis, use of tissue without consent, consultation practices.
6. The Committee requested a justification of use of tissue and access to health information without consent. Please review the National Ethics Advisory Committee Guidelines for Observational Research for further information.
7. The Committee requested that the samples are checked against the consent given for the 200 samples.
8. The Committee queried whether you would seek Maori consultation, noting the tissue may belong to Maori. The Committee noted protection of health information and use of tissue are both cultural issues, and broader issues.

Decision

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

* Issues relating to Māori cultural and ethical values should be addressed in discussion with Māori concerned (*Ethical Guidelines for Observation Studies* 4.4)
* The study design must minimise risk of harm - please justify not seeking consent (*Ethical Guidelines for Observation Studies* *para 5.5*).
* Provide a detailed study protocol taking into account the considerations of the Committee.

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

## General business

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

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| --- | --- |
| **Meeting date:** | 03 November 2015, 08:00 AM |
| **Meeting venue:** | Novotel Ellerslie, 72-112 Greenlane Road East, 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 5.40pm