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| **Committee:** | Northern B Health and Disability Ethics Committee |
| **Meeting date:** | 01 March 2016 |
| **Meeting venue:** | Novotel Ellerslie, 72-112 Greenlane Road East, Ellerslie, Auckland |

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| **Time** | **Item of business** |
| 12.00 | Welcome |
| 12.05 | Confirmation of minutes of meeting of 02 February 2016 |
| 12.30-3.00 | New applications (see over for details) |
|  | i 16/NTB/38  ii 16/NTB/35  iii 16/NTB/36  iv 16/NTB/37  v 16/NTB/33 |
| 3.00 | General business:   * Noting section of agenda |
| 3.15 | Meeting ends |

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| **Member Name** | **Member Category** | **Appointed** | **Term Expires** | **Apologies?** |
| Mrs Maliaga Erick | Lay (consumer/community perspectives) | 01/07/2015 | 01/07/2018 | Apologies |
| Mrs Stephanie Pollard | Non-lay (intervention studies) | 01/07/2015 | 01/07/2018 | Apologies |
| 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 | Lay (ethical/moral reasoning) | 14/12/2015 | 14/12/2018 | Present |
| Dr Nora Lynch | Non-lay (health/disability service provision) | 24/07/2015 | 24/07/2018 | Apologies |
| Mrs Leesa Russell | Non-lay (intervention studies), Non-lay (observational studies) | 14/12/2015 | 14/12/2018 | Present |
| Mr John Hancock | Lay (the law) | 14/12/2015 | 14/12/2018 | Present |
| Dr Nicola Swain | Co-opted Non-lay (intervention studies), Non-lay (observational studies) | 27/10/2015 | 27/10/2018 | Present |

## Welcome

The Chair opened the meeting at 12.00 noon and welcomed Committee members, noting that apologies had been received from Mrs Maliaga Erick, Mrs Stephanie Pollard, Dr Nora Lynch.

The Chair noted that Dr Nicola Swain was co-opted from Southern HDEC in accordance with the SOPs. The Chair confirmed her eligibility, and was co-opted by the Chair as a member of the Committee for the duration of the meeting.

The Chair noted that the meeting was quorate.

The Committee noted and agreed the agenda for the meeting. The Chair moved item v 16/NTB/38 to be taken first as Item 1 as Dr Theadom was unavailable to attend the meeting.

## Confirmation of previous minutes

The minutes of the meeting of 2 February 2016 were confirmed.

## New applications

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| **1** | **Ethics ref:** | **16/NTB/38** |
|  | Title: | Impact of Charcot-Marie-Tooth disease in the Auckland Region of New Zealand (ImpactCMT) |
|  | Principal Investigator: | Dr Alice Theadom |
|  | Sponsor: |  |
|  | Clock Start Date: | 18 February 2016 |

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.

The Chair asked that this item be taken first on the agenda as the researcher Dr Theadom is unable to attend the meeting.

Summary of ethical issues

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

* The study is a cross-sectional observational population based epidemiological study of the prevalence and impact of Charcot-Marie-Tooth Disease, a genetic neuromuscular disease. The Auckland study will help provide information to inform service delivery in New Zealand and inform funding and treatment provision and unmet need. It will identify all children and adults diagnosed with Charcot-Marie-Tooth Disease in the Auckland region.
* The Committee noted the applicants are seeking to ask parents on behalf of children for the children who aren’t participants, to be in the study, and that they want to use proxy consent for non-competent adults. The Committee noted it is not legal to use proxy consent for this purpose under Right 7.4.
* The committee also noted that it is not clear that the condition results in a lack of cognitive ability to consent. If it does, then those participants may need to be excluded from the study.
* The committee queried how the researchers will identify the participants is unclear as are the numbers to be recruited into the study.
* The Committee noted PIS sponsor details are incomplete and the detail on where they are recruiting from is lacking. It appears they are being given details from the Neuromuscular Research Foundation but the Committee noted the researchers’ and study details should be passed onto the potential recruits directly and they should be invited to volunteer, rather than personally identifiable private database information being passed directly via the Foundation to the researchers.
* P1.2 states all participants will give informed consent but this is inconsistent with the suggested use of proxy or representative consent in other sections of the application.
* Page 14 r.12.4 stated partially de-identified information will be stored- but that D.O.B and diagnosis will be included in the data set. The Committee asked the researchers to limit the identifiability of the participants and address the confidentiality issues for the participants as referenced as these two approaches do not match.
* The committee observed it was a good safety protocol for the researchers.

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 that the applicant please remove the terms of representative and/or use of proxy consent in the PIS and consent forms which is not valid in NZ for research.
* For young participants please supply an assent form and separate parent consent form.
* For those children under age 16 please supply an age appropriate information sheet for children. Children over 16 and not able to consent cannot be consented by adults so either be excluded from the study or confirm that they are competent to consent.
* Format of questionnaire needs to be reviewed and age appropriate questions needs and method for data collection and participation to be detailed.
* The committee asked that the reference about “Optional treatments: and if you do not participate” should be deleted from the form.
* The committee asked the researcher to please apply signing details to consent form and that the information sourced from the GP will be consented to and signed for.
* Please overhaul the recruitment and consent form and include locality detail and information.
* The committee noted Maori consultation was held early on with the AUT Maori committee at the design phase but it must also be undertaken as a part of the locality review.
* Please add Maori health support contact details to the PIS.
* The Committee noted online peer review insufficient and asked that independent peer review be provided.
* The committee noted the quality of life forms were good and they did cover education questions to inform the participant’s background.
* The committee recommended the information is de-identified and made anonymous and not able to be re-identified.
* The committee asked for the recruitment protocol to be scoped and revised.

Decision

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

* Please amend the information sheet and consent forms, and provide assent forms, and the recruitment protocol, taking into account the suggestions made by the committee. *(Ethical Guidelines for Observational Studies 6.10, 6.11, 6.20 and also the HDC Code of Rights 7.4).*

This following information will be reviewed, and a final decision made on the application, by Phyllis Huitema and Leesa Russell.

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| **2** | **Ethics ref:** | **16/NTB/35** |
|  | Title: | FibUpFront PPH |
|  | Principal Investigator: | Dr Joreline (Jay) Van Der Westhuizen |
|  | Sponsor: |  |
|  | Clock Start Date: | 18 February 2016 |

Dr Jay Van Der Westhuizen CI was present along with three researchers in person:, and the primary research assistant Davina McAllister and Sirtarish Gharahaman, Research Fellow and Dr Claire McLintock CI, joined 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.

Study Summary

* The Committee confirmed that you are asking to enrol 50 women who have haemorrhaged and seek delayed consent after random and blinded administration of the drug fibrinogen to women following labour.

Summary of ethical issues

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

* The Committee noted the application stated this study met equipoise standard but earlier you stated this is a clinical direction whether or not to administer the drug.
* The researcher explained there is a standard protocol for administration of the drug as well as the use of clinical judgement. The transfusion protocol gets activated and the drug administration gets activated later in the process but can be used earlier by the anaesthetist if indicated. It is not administered to most women. If there are signs of clotting or bleeding stopping they do not need the intervention. If the woman is still bleeding then we test for the fibrinogen level and then decide to administer it.
* The study is to try and determine when to administer it and if it is given earlier then this may reduce the need for blood transfusion so we are trying to refine the process.
* The Committee commented then that the equipoise standard is therefore not met.
* The researcher said it is not consented but you will not be denied the administration of the drug and noted all women will be subject to transfusion if they continue to bleed and not receive the drug. It may be cost effective to use the drug and get a better result than continue the current practice of delayed administration as blood products have a limited shelf life.
* The Committee noted it is the rights of non-consenting patients that we are concerned with as an Ethics Committee, not the cost impact.
* The Researcher advised we would like to be able to inform women and LMCs before they go into labour about PPH as women are not readily identifiable for risks factors, and we can inform women about the risk and process of haemorrhage via posters.
* The researcher stated it may be harmful to the women to discuss the risk of haemorrhage when seeking consent from women in her birth plan as it is anxiety provoking and only 10% of women are at risk of PPH. Also the timing of haemorrhage means getting consent at the time of labour is difficult as it is a rapidly evolving situation and the woman needs to be considered first and treatment decisions, rather than study consent, is the imperative.
* The Committee asked if standard of care compared with care plus was being offered?
* The committee asked that if participants are excluded from the study who do not wish to be included are in the same position as other patients who refuse blood products?
* The researcher responded that we are not asking consent to give the drug, we are asking for consent for data collection. In an emergency situation if the woman was below the normal or safe level for clotting or still bleeding, she would be given the drug fibrinogen in a clinical situation to stop the PPH.
* The Committee asked could it be consented in advance as part of the birth plan so it could be stated in the health record? The Researcher explained it is only in the equipoise situation that we would document if the woman does not want to be part of the study in the healthcare record, it is then printed in the risk sheet if she does not want to be involved in the study and it will be recorded and adhered to, but we will still treat the woman if she needs the drug in a clinically indicated situation.
* The Committee asked for clarification whether ADHB is the study sponsor? The Researcher advised the Clinical Lead is the sponsor.
* The Committee commended the applicants for your Maori consultation section.
* The Committee asked could you please add in the PIS standard interpreter’s box and that language support is available to women.
* Please remove the reference to ‘mickey mouse’ and use more suitable language.
* Consideration of revising the study protocol so that it becomes an observation study of outcomes following treatments provided in the best interests of patients, using a delayed consent mechanism

**Addendum to the NTB Minutes 1 March 2016**

FibUpfront : Teleconference on Friday 11 March commencing at 11.10 am, with Northern B representatives Kate O’Connor Chair, John Hancock, and Researchers Dr Jay Van Der Westhuizen, Dr Claire McLintock, and Davina McAllister. Philippa Bascand Manager, Ethics Committees, In Attendance.

As per the Committee’s instruction of 1 March 2016, the Committee reconvened by teleconference with a delegated subcommittee to seek clarification on key points with the researchers in respect of the provisional approval.

The Committee introduced the purpose of the meeting as seeking clarification of certain points form Tuesday the 1/3/16 meeting and thanked the researchers for having submitted further explanatory information in the form of a diagram showing when fibrinogen is administered to the patient for post-partum haemorrhage as part of standard patient care. The committee are concerned to establish whether or not there is any extra quantifiable risk to the administration of fibrinogen versus saline, and whether the Right 7.4 best interest test for the woman is met.

The Researchers explained that there is evidence of lower fibrinogen levels in the mid-range of women in the bell curve and that they may go onto have more severe bleeds, but we don’t know the cause and effect.

The Committee then sought clarification about the timing and randomising of administering fibrinogen at this point, and whether it may affect the outcome for women versus those women who would continue to receive the placebo (saline)?

Then Researchers explained that we know in the best interests of women the standard of care is met through the standard care arm (saline administration). The aim is to test if it improves care or not by giving Fibupfront (earlier and slightly higher dose)? So far a small study has shown a lower and smaller dose on women had no positive effect but we plan to test on a select group of women a higher dose on women with a lower Fibrinogen level.

The Committee asked then is this standard care versus standard care plus? Is there any extra risk to this group?

The Researchers said no extra risk as just giving it earlier and it may improve outcome, we don’t know. All women will have the ROTEM test to measure fibrinogen levels and all will receive usual care as per the clinical protocol– the saline being the control arm but is standard care and if they still bleed as per the protocol will get fibrinogen administered as usual, but just not as early. This step will not impact our usual standard practice and only be triggered in 2% of eligible cases. It may bring timing forward of administration of fibrinogen for all women still bleeding post the ROTEM test due to the closer monitoring underway as part of the study.

The Researchers went on to explain, all women will be treated as they would have ben and the additional step to standard care would improve outcomes and we may find a way to make it safer for these women prior to emergency maternity transfer if they are at rural maternity units or have a long way to travel prior to transfer to a main maternity unit and risk on-going bleeding on route.

As per Provisional approval, the Committee asked for the following items to be submitted to the Committee for final approval:

1. Re-submit diagram with control arms and standard care and clinical protocol clearly illustrated and timing of events/administration of drug after ROTEM test 5 minutes, whole protocol 20-30 minutes;
2. Strengthen the PIS – to explain to the woman you were given best practice standard of care,
3. Review the Consent forms and amend the protocol as to the wording round standard of care and care plus,
4. Socialize the study with LMCs.
5. The Committee asked that participant information sheet changes, and process for confirming recording non-participation in the health record, a consent process for the data collection be provided and the researchers are to come back to the Committee for review. The Committee then further considered the equipoise issue and blinded aspect of the study drug administration and asked for further clarification be sought from the researchers on meeting Right 7.4. (Addendum – teleconference with the researchers to be scheduled to seek clarification).

It was noted that it will be advertised and LMCs will be informed and briefed on the study, and where possible LMCs should seek to ascertain women’s views about participation in the clinical trial without adding undue pressure or creating anxiety as PPH is an unpredictable condition (about 1% of women of 7-8000 cohort for the study will present but unpredictable which women will have a PPH). The researchers noted that undue stress could result from seeking informed consent but agreed the study meets the Helsinki Code section 30 for delayed consent.

The teleconference closed at 11.55 am.

Decision

This application was *provisionally approved* by vote with 4 for and one against (Dr Swain) and one abstension (Mr Hancock) subject to the following information being received.

* Please amend the information to be provided to participants, taking into account the suggestions made by the Committee, for example to explain to the women you were given best practice standard of care *(Ethical Guidelines for Intervention Studies, para 6.22).*
* Please provide further clarification on the equipoise issue and blinded aspect of the study drug administration (refer to the discussion above). *(HDC Code of Rights 7.4).*
* Please resubmit the diagram with control arms and standard care, the clinical protocol clearly illustrated and timing of events/administration of drug after ROTEM test 5 minutes, whole protocol, (*Ethical Guidelines for Intervention Studies, para 5.41*).
* Please amend the protocol as to the wording around standard of care and care plus. (*Ethical Guidelines for Intervention Studies, para 5.41*).
* Please submit posters and briefing that you will use to inform LMC’s. *(Ethical Guidelines for Intervention Studies, para 5.33).*
* Please provide information about your process for confirming and recording non-participation in the health record, and a consent process for the data collection. *(Ethical Guidelines for Intervention Studies, para 6.11).*

This following information will be reviewed, and a final decision made on the application, by Kate O’Connor, Leesa Russell and John Hancock.

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| **3** | **Ethics ref:** | **16/NTB/36** |
|  | Title: | HCV sero-prevalence in Northland |
|  | Principal Investigator: | Dr Arlo Upton |
|  | Sponsor: |  |
|  | Clock Start Date: | 18 February 2016 |

Dr Arlo Upton [PI] was present and Mijoo Kim (CI) 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.

The Chair declared a potential conflict of interest and noted that she has an involvement with AUT and that studies that go through AUT come to her for review following HDEC approval. The Committee decided to continue as the decision by HDEC precedes the AUT locality review.

Summary of Study:

* The study aims to estimate better estimate the prevalence of HCV in Northland and predict the burden of disease for more accurate planning and targeting of resources. Fewer than a quarter of people with acute HCV infection clear the infection spontaneously, the others go onto chronic infection which can lead to hepatocellular carcinoma. Only acute HCV infection is notifiable in NZ and most HCV cases remain undiagnosed.
* Dr Arlo Upton is the CI for the study, Mijoo Kim is the other CI for the study and also a master’s student at AUT, both attended by telephone.
* The Committee advised the study being at masters’ level is normally outside of scope for HDEC review but the use of tissue and data without consent has meant it has met our threshold for review.

Summary of ethical issues

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

* The Committee asked can you please explain the difference between the antibodies for HCV present and the presentation for acute disease? The researcher advised it is usually acquired via dirty needles and occasionally though maternal transmission. About 20% who get Hepatitis C will clear it on their own accord. Those of Asian and some other ethnic groups clear the virus at a higher rate and in NZ we have a higher clearance rate. Having the antibody means you have been exposed to the virus. Also 70% may be antibody positive but only a certain % may go onto get the disease.
* The Committee asked how the researchers propose to mitigate this fact of not telling those who are screened via the use of their non-consented samples and have HCV but are not told of the diagnosis? The researcher responded there is no national screening programme for HCV in NZ.The USA has found it to be economic beneficial to screen in a limited age range but in NZ it would not be done unless the GP had a concern about the patient. The researcher acknowledged this is an issue but sees the study could help us target the population better.
* The Chair noted it is a diagnosis without informing the person.
* The researcher stated laboratories have done this in the past, and routinely this process occurs in labs without consent and it has not gone past an Ethics Committee before. This testing is often anonymous of left over samples and doesn’t routinely go through ethics and this is not an uncommon process for lab samples.
* The Committee noted that the use of human tissue under the Human Tissue Act requires Ethics Committee review.
* The Committee noted its lack of comfort with the process described and the numbers of patients quoted are inconsistent in the application.
* The researcher confirmed the power should be 2000.
* The researcher referred to a previous study that had gone through HDEC Central along similar lines with non-consented testing. The Committee has initially declined the previous application.
* The researcher stated that has now been approved by the Committee via a teleconference with no changes.
* The Committee then noted that the question about other ethics applications should have been ticked yes.
* The Committee asked is this study commercially funded by ABBvie? What is their interest in the research? The researcher advised combination funded therapy for the drug is not currently PHARMAC funded. The Committee advised this would affect the commercial aspect of the study.
* The Committee asked the researchers about testing on liver and platelets tissue? The application is inconsistent on this. In reply, the researcher advised the answer was she had originally planned to do this but in discussion with Dr Ed Gane decided it was unnecessary. The Committee informed the applicant she could write a letter in future with any protocol amendments prior to review. The researcher advised there is an intention to get sponsorship funding from Abbvie or jointly with the Hepatitis C Foundation.
* The Committee asked under R1.2.1. non- consenting patients – in terms of reporting how will this rate of prevalence be reported sympathetically to the Northland community given they are not giving consent? The Researcher advised it is important to identify health disparities. Often people are frequently stigmatised by infections and Hepatitis C may lead them to feel stigmatised by it, but that is not a reason not to do the study or to identify the higher rates in a community.

Summary of ethical issues (outstanding)

* The Committee suggests you seek engagement from people in Northland, make use of community adverts and forums and inform people about the study.
* The Researcher responded that is what the Hepatitis C Foundation does and the Ministry is pushing in a big way for more confirmed Hep C diagnosis. We consulted with Maori researchers and Prof Ed Gane, and they are supportive of the study.
* The Committee noted there were no cultural issues stated in the application, and clearly there are, and wider consultation is advised. The committee were concerned about stigmatisation in Northland. The researcher stated she cannot undertake that level of community engagement.

Decision

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

* **1.** The Committee must be convinced that the use of tissue without consent is for a good reason, and has a strong public good consequence, and that all mitigations for harm had been considered and addressed. Observational Research Ethical Guidelines; Para 4.9 – 4.10 – The risks of a study should be reasonable in the light of the expected benefits. Investigators should consider the features of a proposed study in the light of ethical considerations, and satisfactorily resolve ethical issues raised by the study. Not all ethical considerations weigh equally. A study may be assessed as ethically justifiable, even if a usual ethical expectation, such as confidentiality of data, has not been comprehensively met; provided the potential benefits clearly outweigh the risks and the investigators can minimise the risks.
* The Committee noted that it was important to know about the prevalence of disease in order to better target interventions, and that the goals of the research were to help others. However, the Committee felt that the benefit of screening for prevalence was not high enough to justify accessing clinical samples without consent, due to the following reasons:
* - there was no planned intervention or solution outlined once the prevalence was identified,
* -no plans to notify individuals if clinically relevant findings were identified. Current ethical guidance states “If it is reasonably foreseeable that health problems previously unknown to an individual will be identified during the study process, then arrangements for referral, with the individual’s consent, should be made. When findings suggest serious disease, study participants who have not given permission for the transfer of the information to their medical advisor should be urged to seek further advice.” – Ethical Guidelines for Observational Studies para 9.1
* -these tests are potentially very different from what the tests the sample was collected for so therefore must have a high social benefit to justify a very different secondary use.
* The Committee welcomed a further argument from the researcher explaining the social benefit of conducting the research, and why the social benefit to others would outweigh the public interest in privacy of health information and bodily autonomy, focusing on the reasons given by the Committee.
* **2.** The Committee noted the Central HDEC decision had been reconsidered due to the researcher’s inability to attend that meeting on the day, and to respect natural justice, and heard the applicant’s case in a teleconference. The Committee noted there are important ethical differences between this application and the central application. These differences are that:
* - The Central application involved testing for a disease that was contingently related to what the samples were collected for (STIs).
* - The central application required the researcher to feedback any clinically important findings from the testing to the GP to follow up with patient.
* - Both of the above conditions are not met in the Northern B application. The comparison between the two studies is not relevant to the decision making for this application.
* **3.** The Committee noted they would be more comfortable with the use of the tissue if there was a plan to follow up clinically relevant findings, and a stronger case was made as to why consent was not feasible either with respect to the scientific validity or causing undue harm to participants. It was unclear why following up clinically relevant findings was not possible, given the tissue was linked with identifiable health information. The Committee felt it would be unethical to identify something through the testing that would impact a patient’s health or life and not disclose it to them. The Committee noted in a new application the Researcher(s) could explain why they felt non-disclosure was justifiable in this instance.
* **4**. The Committee noted that the sponsored status of the study was unclear, though ethically important, and felt that the Committee should be aware of whether a commercial company was sponsoring the research or not. This would impact the acceptability of use of health information and tissue without consent, noting that it may lessen the public interest and instead become a private interest. Please advise the Committee of the agreed funding and sponsorship arrangements proposed.
* **5.** The Committee noted the discussion on the consultation with Maori and consultation with wider Northland community. The Committee noted HRC Guidelines for research that do not involve human participants state that consultation is required if the focus of a study is of relevance to Maori. The Committee explained that the study will be of particular relevance to Maori, and ensuring that the results do not stigmatise the local community and the study would benefit from further Maori consultation.
* **6**. The Committee noted that wider consultation could occur through other established pathways, such as the Hepatitis C Foundation, if that were a more appropriate as a means of communication.

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| **4** | **Ethics ref:** | **16/NTB/37** |
|  | Title: | Outcomes Study of Persona Knee System in Total Knee Arthroplasty |
|  | Principal Investigator: | Mr Neville Strick |
|  | Sponsor: | Zimmer Pte Ltd |
|  | Clock Start Date: | 18 February 2016 |

Mr Neville Strick [PI] 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.

Study Summary

* The Committee confirmed the researchers are asking to follow up on device performance in 20 people over the long term. It is a fully consented study.

Summary of ethical issues

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

* The Researcher joined the committee by telephone at the end of review and clarified points the Committee made.
* The purpose of the study is to collect information on the performance of persona knee prosthesis over a period of 5 years, approved for use in knee replacement surgery in Waikato DHB.
* The committee noted the peer review should be independent and it is not best practice to have it reviewed by another company doctor but the level of risk is low in this case, so the Committee allowed it in this instance as it is a review of the device’s long term performance by the said company Biomet Zimmer (an outcomes study).
* The committee noted the liability insurance dated January is expired now at time of review.
* The researcher advised they were happy to provide and upload a new insurance certificate.

Summary of outstanding ethical issues

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

* Please change protocol and information sheets to NZ terms and dollars, not shillings and remove all Americanisation’s.
* Page 6 9.5 of the protocol: Please delete the ‘deviation clause’.
* Please update and upload a renewed company insurance document or show that it has been renewed.
* Correct spelling of the word ‘confidentiality’. Please check for, and correct all typographical errors.
* Please specify how long study documentation will be retained?
* Remove notion of ‘alternative treatment’ on page 2 of the information sheet.
* Remove the notion that references the Biomet Zimmer data security information sheet. Please just include relevant aspects of the company’s data protection policy for the lay person.

Decision

The Committee *approved* the study by consensus with non-standard conditions. Please complete these requirements on-line and update your application and forms and submit these to the Secretariat for approval.

* Please change protocol and information sheets to NZ terms and dollars, not shillings and remove all Americanisation’s.
* Page 6 9.5 of the protocol: Please delete the ‘deviation clause’.
* Please update and upload a renewed company insurance document or show that it has been renewed.
* Correct spelling of the word ‘confidentiality’. Please check for, and correct all typographical errors.
* Please specify how long study documentation will be retained?
* Remove notion of ‘alternative treatment’ on page 2 of the information sheet.
* Remove the notion that references the Biomet Zimmer data security information sheet. Please just include relevant aspects of the company’s data protection policy for the lay person.

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| **5** | **Ethics ref:** | **16/NTB/33** |
|  | Title: | ASD2 Study |
|  | Principal Investigator: | Dr Ian Crozier |
|  | Sponsor: | Medtronic Australasia Pty Ltd |
|  | Clock Start Date: | 18 February 2016 |

Dr Iain Melton CI was present by teleconference for discussion of this application. He apologised for Dr Crozier’s absence.

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.

Study Summary:

* The study aims to generate information from high quality electrical traces of the heart using a wire lead medical device implanted and placed under the breastbone. The study seeks to characterize the efficacy of giving a 30-joule electrical shock to stop irregular fast rhythms, via the lead under the breastbone, and show the electrical pacing thresholds to pace the heart with the lead inserted, and summarize the degree of unintended muscle stimulation outside of the heart tissue during pacing.
* Dr Iain Melton joined the meeting as Co-investigator. It is a requested closed meeting. Dr Crozier apologised that his colleague, Dr Ian Crozier CI, is unable to attend.

Summary of ethical issues

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

* The Chair thanked the researcher for the well compiled study application and good PIS and explanatory use of a diagram. The committee noted the peer review is satisfactory and thanked the investigator for an application they found understandable.
* The Committee confirmed with the researcher that the device will go into the chest cavity.
* Dr Melton as the CI stated the leads used in the past have a limited life and there have been problems with them over time. The usual implanted device with leads takes a lot of energy. The study is trying to see if the lead can be inserted outside of the heart but then have more favourable parameters for energy use and to pace the heart.
* The Committee asked if this device would this be permanently placed in the chest if the study shows good results?
* Dr Melton said yes and it could also be used for young people at risk of sudden death.
* The Committee asked about the extra 50 minutes required on the table under anaesthesia?
* The researcher replied some patients are already under anaesthesia, and some are under sedation. Dr Melton responded the participant’s extra time is more likely to be under sedation and that the time under anaesthesia will likely not change but the Chair asked for this explanation to be included in the PIS.
* The committee queried the use of identifiable data may be given to a off-shore company as stated in the application. The committee advised NZ privacy laws do not apply once the data is off-shore so please consider whether the data needs to be identifiable to go off-shore?
* The committee asked is there a better way to explain simply the application of radiation 0.1 % in a more easily understood way i.e. less than - 1 in 1000. The researcher explained these are older patients so we need to give this in a simpler format and the risk of fatal cancer from the extra dose of radiation is very low.
* The Researcher confirmed all participants will be adults for this study.
* The Committee asked is the GP to be informed?
* The researcher advised yes he was happy to include this point in the form and for study participants to be advised their GP will be notified in the consent form.
* The Committee queried the option included to review the video and if participants could have the option to not approve its use?
* Page 9 of PIS – the Committee asked to clarify can a person restrict their consent after seeing the video? When does this occur?
* The Researcher explained the participant would be asked prior to the procedure if they are willing to consent to video-taping and subsequently the person can view the video-tape and can either consent to the use of the tape or withdraw that consent at that point. The purpose of video-taping is for training and education purposes.
* The researcher confirmed he will make it more explicit that the consent process is for video-taping at the point in time of procedure and also consent separately and later when they view it for future training purposes.
* The Committee noted the indemnity certificate had expired.
* The Committee noted the Addendum to clinical investigation plan – why was this specific to NZ and Australia? Please clarify this.
* Please advise your and colleagues experience in terms of intervention studies?
* The researcher confirmed we do become involved in this type of early treatment work and feel we can contribute in this area as heart rhythm is a specialty area. We have low complication rates in the types of procedures we undertake so are able to contribute to a study of this type. We are familiar with subcutaneous devices and the earlier ones developed have limitations. Initially we thought this procedure was too invasive and we consulted about the risks with cardiac surgeons - it is counter-intuitive to work better in terms of heart energy levels but the study is worthwhile.
* Page 5 risks and benefits – could the 2 consents be done at the same time?
* The Researcher explained participants/patients will be undertaking quite different procedures and will be recruited from the list waiting for defibrillators and that the study may benefit future patients. So it is not one pathway for participants but we could keep the treatment consent form separate to the research study so the Researcher could attach it as an addendum to the consent form for the roughly 1 to 5 procedures open to the patient.
* The committee noted on page 19 R 2.5 noted health information stored for min 10 years – what is the maximum planned for?
* The researcher explained 20 years as per DHB policy.
* The Committee queried on the PIS and consent form – if you withdraw consent as per page 10 to be a study participant, can you add the option to withdraw consent to the use of the study data as well? Please clarify in the form if they withdraw can they also withdraw their study data?
* The Researcher agreed that the participants should have the right to withdraw their data if they withdraw their consent. The participants understand they may not benefit from the study but generally are very altruistic. He agreed to update the consent form.
* The Committee noted 10 other countries are taking part and none have ethics approval as yet – is NZ lead site?
* The researcher stated the lead site is UK. The company is trying to co-ordinate this across countries and at the same time. We expect UK ethics application to be submitted soon and in the USA as well and the study will be run concurrently.
* How much family friend support is open to the participants?
* The Researcher stated he had no issue with family members to support patients or also be reimbursed for expenses during the invasive process.

Summary of ethical issues (outstanding)

* Please include data safety monitoring committee names and contacts and provide details on terms of reimbursement.
* Please include 24 hour contact details on the PIS.
* MPs certificate has expired so please send a renewed certificate and the sponsor’s insurance is close to expiry in May so please address this.
* Please provide the option to withdraw consent to use of data as well as withdrawal of consent to the study.
* Please mention any extra risks related to the extra time under anaesthesia or sedation.
* Please explain ICD in full and ensure fonts and spacing are consistent in the PIS and consent forms.
* Please include the option to consent to video-taping and also consent separately to use for training purposes.
* Please make it clear that participants can be supported through the process, and if there costs will be reimbursed.
* PIS - Please change wording to ‘will be’ reimbursed not ‘may be’.
* Make explicit the exclusion of scarring from insurance cover.

Decision

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

* Please amend the information to be provided to participants, taking into account the suggestions made by the Committee, *(Ethical Guidelines for Intervention Studies, para 6.10, 6.11, 6.12, 6.19 6.22).*

## General business

1. The Committee noted the content of the “noting section” of the agenda.
2. The only items of General Business noted were new member training date confirmed for 17 March and GCPO training on 24 March.
3. The Chair reminded the Committee of the date and time of its next scheduled meeting, namely:

|  |  |
| --- | --- |
| **Meeting date:** | Tuesday 5 April 2016 |
| **Meeting venue:** | Novotel Ellerslie, 72-112 Greenlane Road East, Ellerslie, Auckland |

1. **Problem with Last Minutes**

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

The meeting closed at 3.15 pm.