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| **Committee:** | Northern B Health and Disability Ethics Committee |
| **Meeting date:** | 02 February 2016 |
| **Meeting venue:** | Novotel Ellerslie, 72-112 Greenlane Road East, Ellerslie, Auckland |

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| **Time** | **Item of business** |
| 12.00pm | Welcome |
| 12.10pm | Confirmation of minutes of meeting of 03 November 2015. |
|  | New applications (see over for details) |
|  | i 16/NTB/8  ii 16/NTB/1  iii 16/NTB/4  iv 16/NTB/12  v 16/NTB/13  vi 16/NTB/15  vii 16/NTB/18  viii 16/NTB/23  ix 16/NTB/24 |
| 5.15pm | Substantial amendments (see over for details) |
|  | i NTY/08/06/055/AM05 |
| 5.30pm | Review of approved studies (see over for details) |
|  | i NTX/10/08/084 |
| 5.45pm | General business:   * Noting section of agenda |
| 6.00pm | Meeting ends |

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| **Member Name** | **Member Category** | **Appointed** | **Term Expires** | **Apologies?** |
| Mrs Maliaga Erick | Lay (consumer/community perspectives) | 14/12/2015 | 14/12/2018 | Apologies |
| Mrs Stephanie Pollard | Non-lay (intervention studies) | 14/12/2015 | 14/12/2018 | 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 | Lay (ethical/moral reasoning) | 14/12/2015 | 14/12/2018 | Present |
| Dr K Parker | Lay (consumer perspectives) NTA Co-opt | - | - | Present |
| Dr Nora Lynch | Non-lay (health/disability service provision) | 01/07/2015 | 01/07/2018 | Present |
| 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 |

## Welcome

The Chair opened the meeting at 12.05pm and welcomed Committee members, noting that apologies had been received from Ms Mali Erik.

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

The Chair welcomed the new members, Mrs Leesa Russell and Mr John Hancock.

Ms Raewyn Sporle teleconferenced into the meeting to farewell the Committee. The Committee thanked Ms Sporle for her time, energy and commitment to the HDECs over her 8 year term.

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 3 November 2015 were confirmed.

## New applications

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| **1** | **Ethics ref:** | **16/NTB/8** |
|  | Title: | AMPLE-2 |
|  | Principal Investigator: | Dr Elaine Yap |
|  | Sponsor: |  |
|  | Clock Start Date: | 22 January 2016 |

Dr Fiona Harward (co-investigator) and Ms Catherine Howie 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 aims to generate evidence to support best practice use of indwelling pleural catheters (IPCs). The catheter is used to drain fluid from around the lungs.
2. Fluid draining protocols vary considerably between centers and internationally. It is unknown what frequency is best for patients.
3. This study will compare frequency of draining by randomizing between two methods. One method is to drain when fluid builds up (symptomatic, could be once a week or every couple of weeks). This method has some negative consequences for patients, for example breathlessness. The other method is aggressive draining. This involves daily draining, where very little fluid accumulates. The idea is that symptoms of fluid buildup are resolved, with the added benefit of the lungs and chest remaining dry. Once completely dry the fluid may sometimes stop producing.
4. The Researcher(s) explained that the patient groups are those at the end of their cancer journey, in the last 3-4 months of their life.
5. The Researcher(s) confirmed target is 5 participants in New Zealand.
6. The Committee noted this study involved a device rather than a medicine.

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 whether there is a standard of care in New Zealand. The Researcher(s) explained that until recently the only option for draining was by needle. This method was not good for patients as it resulted in frequent draining and hospital visits. The catheter could be turned on and off. IPCs are fairly recent in New Zealand, however they are considered a standard of care. They are not available at all New Zealand centers and are generally offered when there is someone with the expertise to deliver the treatment at the site. While they can be considered a standard of care there remain questions about the best way to use it.
2. The Researcher(s) confirmed symptomatic drainage is what they do here at the lead site. The Researcher(s) explained the different methods of drainage internationally.
3. The Researcher(s) confirmed the study is funded in part by academic group in Perth.
4. (A.7.1.1) please explain the relationship with the previous study. The Researcher(s) stated they took part in AMPLE 1.
5. The Researcher(s) confirmed there was no future unspecified use of tissue.
6. The Researcher(s) confirmed if substantial changes occurred from Maori consultation they would make these changes and submit to HDEC for approval.
7. (P.2.9) The Committee queried if there is a process to ensure lay language summary results are not sent to participants that have recently passed away. The Researcher(s) confirmed they could check with GP as well using patient notes. The Researcher(s) would leave the option for a lay language summary on the consent form.
8. The Researcher(s) stated they believe there is no increased risk across both arms of the trial, from clinical point of view.
9. The Researcher(s) confirmed reimbursement provided for parking and travel.
10. The Committee asked if there is a rescue plan for any participants that does not respond to a particular arm. The Researcher(s) noted that the researcher could override the treatment protocol if they felt that it was clinically appropriate.

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 asked if there is a sponsor. The Researcher(s) stated the Australian sponsor is providing some funds and the remainder is provided by the hospital. The Researcher(s) confirmed the head of department takes responsibility for the study. The Committee requested that the sponsorship status of the study is clarified in the response letter to the Committee.
2. The Committee noted the study data is potentially identifiable. The Committee explained identifiably of data and referred the researchers to the National Ethics Advisory Committee Guidelines for Intervention Studies section 7.2.
3. Please submit the participant card to HDEC.
4. The Committee noted that the withdrawal form is not required, nor does withdrawal need to be in writing. Patients can withdraw verbally. The Committee noted the researchers could use a written form but it must be optional.
5. The Researcher(s) confirmed equipment is standard (already used).
6. The Committee queried if there were any comments on peer review, or at least a letter confirming any issues raised in peer review were addressed appropriately. Please submit in response to HDEC.
7. The Committee queried the independent data safety monitoring committee composition. The Researcher(s) stated steering committee is independent, and is associated with and organised through the Australian group. The Committee requested DSMC charter.

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

1. The Committee requested reference to St Gairdner Hospital should be changed to Middlemore (do I have to take part section). Also on the withdrawal form.
2. The Committee queried whether the ‘faster access to a doctor’ should be listed as a benefit; this could be coercive (i.e. you get better care by participating). Please move to what if something goes wrong.
3. The Committee stated there are inconsistences regarding the use and collection of tissue throughout the application.
4. The Researcher(s) clarified that there would be no tissue samples sent overseas, adding the only samples collected are those for pleural fluid, as indicated for infection checks that are standard of care. The Researcher(s) confirmed a sample is taken at initial placement of the drain. The Committee suggested making the collection of tissue being standard of care clear on the Participant Information Sheet.
5. Please add page numbers.
6. The Committee stated information on the legal disclosure should be moved to ‘what will happen to information about me’. The Committee noted disclosure is only necessary for explicit purposes, and noted that due to the context of the patients this information should be presented in a different, softer measure. The Researcher(s) confirmed they would remove this statement – it was from the Australian version of the document.
7. ‘We are required to’ please change to ‘we would like to’ (on informing GP).
8. The Researcher(s) confirmed they would add mobile numbers to contact details.
9. Add lay language title to supplement existing title.
10. Add brief description of quality of life questionnaire – what is involved, length of time to take it etc.
11. Please consider use of word aggressive – consider ‘daily’.
12. The Committee asked if the analogy of tossing of a coin could be changed. Perhaps by chance. The Researcher(s) confirmed that ‘by chance’ would be better.
13. Add generic statement that all alternatives for treatment will be discussed. This means the patient knows there are different treatment options outside of study participation.
14. Add information on the right to access and amend the health information about themselves during the study (in line with health information privacy rules).

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 *(Ethical Guidelines for Intervention Studies para 6.50).*
* Address outstanding ethical issues and submit requests for additional documentation.

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

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| **2** | **Ethics ref:** | **16/NTB/1** |
|  | Title: | Humidified High Flow for CF Pilot |
|  | Principal Investigator: | Dr David McNamara |
|  | Sponsor: |  |
|  | Clock Start Date: | 21 January 2016 |

Dr David McNamara 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 whether humidified high flow air via nasal prongs (HHF) will help children with cystic fibrosis.
2. The Researcher(s) explained anything that can improve weight gain is an important clinical treatment.
3. Children with CF have mild difficulty in breathing at night. By making it easier to breathe at night would mean less energy expenditure which means more weight gain.
4. The Researcher(s) explained this treatment is currently used in NICU and ICU.
5. The Researcher(s) explained this device is designed for home use, developed by Fisher and Paykal.
6. The Researcher(s) explained the study design.
7. The main outcome of study is to compare respiratory rate with and without the device.
8. The study is a pilot study to inform wider study that will be conducted in the home with participants ranging from 6-25 years old.

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 both peer reviewers raised criticisms of the methods. The Researcher(s) noted that the protocol that came to HDEC is the same that went to the reviewers and remains unchanged. The Committee explained that reviewer 1 gave 4/7 for methodology, and stated primary outcome is work of breathing but work of breathing is not being measured, just the frequency of breathing. (Refer to the peer review document).
2. The Committee noted the peer review comments, for instance the study did not define mild-moderate disease, noted confounding factors, i.e. age ranges and questioned whether 5 nights was long enough to get meaningful data.
3. The Researcher(s) stated criteria for participation are laid out in inclusion and exclusion criteria. The Researcher(s) explained lung function and anyone needing lung support or lung transplant (these define extreme) therefore everyone else is mild or moderate. The Committee accepted this response.
4. The Researcher(s) explained getting ‘work of breathing’ measurements is very invasive. The Researchers don’t want to put gastric tubes or pressure bulbs in children. The Committee queried if there were other means of measurement. The Researcher(s) stated the suggested alternatives from peer reviewers are unreliable. The Committee accepted this response.
5. The Committee queried whether the researchers have considered potential embarrassment about housing situations and whether this will this reduce participation in some patient populations. Is there a way to have people participate without having researchers visit participant’s houses? The Researcher(s) stated no, but that they do not anticipate this as a problem.
6. The Researcher(s) stated that the participant group would be used to having the researchers around, explaining they come into clinic often.
7. The Researcher(s) confirmed Maori consultation occurring at DH (localities)
8. The Committee noted the study is a crossover study rather than placebo study (as per application).
9. The Researcher(s) confirmed the study would be registered on a clinical trial registry.

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 sponsor would be the DHB.
2. The Committee queried whether any considerations had been made for risk for others when attending people’s homes. The Committee requested a safety protocol for researchers working in other people’s homes. I.e. working in pairs, carrying a cellphone etc.
3. The Committee requested a formalized adverse event protocol, even though this is a low risk study.
4. The Committee requested information on adverse event management. Better to be prepared in advance – please include in protocol amendment.
5. The Committee requested information on screening practices and recruitment in protocol.
6. The Committee noted GILLICK competence test would be required in cases of clashes between parent and child views on initial or continued participation.

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

1. Amend Participant Information Sheet. Revise what kind of voucher – consider supermarket voucher, as this is more appropriate.
2. The Committee noted ‘HHF’ does not explain much about the treatment. Please revise from a layperson perspective.
3. Please add device picture. Add description (noise it makes etc).
4. Explain what the oximeter probe is in lay language.
5. Add page numbers
6. Add details to Maori contact information.
7. Explain humidity – that this means making air warmer. Review for lay language generally.
8. Revise for typos.
9. Number headings as well as pages.
10. Add that research nurse is in daily phone contact. This is important for parents of younger participants as they must take into time commitments into consideration to know if participation is feasible.
11. Add statement about withdrawal. Right to withdrawal etc.
12. Add statement that HFF won’t be available post study even if it is a benefit to them.
13. The Committee requested that adverse events are reported to clinicians when they happen rather than waiting till next appointments. Please make this clear in participant information sheet.
14. The Committee noted that a young participant would not be able to understand the participant information sheet. Below is some information on assent from the Secretariat:

At 16 a person can consent to participate. Even so – they may need a very well written information sheet in lay language to understand, and simple language should be used.

Under 16, some participants may be competent to provide consent. Most will provide assent, with consent given by legal guardian.

No one can consent on behalf of someone 18 or older.

When you have participants that are under 16 they need age appropriate written material to help them understand. The age groupings are somewhat irrelevant, as it is a person’s capacity that determines the level of information that should be given to them.

Some children who are under 16 may be competent to provide their own consent.

The best practice for a study involving children and adults would be to have:

* An adult participant information sheet. This is for anyone providing consent. This means it can be used by a participant who is 15 if it is determined that they can understand it.
* A shorter, simpler, participant information sheet. This is used for adolescents to provide assent. It would support a verbal discussion about the study. The age range could be 13-15. It can also be used for competent 12 year olds, for instance.
* A very simple, pictorial, information sheet. This can be 1-2 pages. This is for young participants, for example 7-12.

The age ranges are a guide, they are not rules. The goal is to help participants understand and to determine if they can understand enough to provide consent, or if they are under 16, provide assent (willingness) and their legal guardian consents for them (after being given an ‘adult’ or full information sheet and consent form).

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 provide age appropriate information sheets and assent forms for younger participants and amend the existing information sheets and assent/consent form, taking into account the suggestions made by the Committee (*Ethical Guidelines for Intervention Studies* *para 6.22*).
* Update protocol taking into account the comments made by the Committee.
* Address outstanding ethical issues in a cover letter.

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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| **3** | **Ethics ref:** | **16/NTB/4** |
|  | Title: | Immune effects of Oral Insulin (TN20) |
|  | Principal Investigator: | Professor Russell Scott |
|  | Sponsor: |  |
|  | Clock Start Date: | 21 January 2016 |

Ms Jinny Willis 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 the immune effects of oral insulin. An earlier study suggested providing oral insulin could provide a benefit for those who are at risk of developing type 1 diabetes.
2. The Researcher(s) explained scientific evidence for the potential benefit for dosing of oral insulin.
3. This study will assess two dose levels and time intervals of oral insulin. Once a day or once a week. This will look at mechanistic outcomes. This will occur beside a related trialnet oral insulin study.
4. Participants will take oral insulin for 6 months then followed up for 6 months.
5. The Researcher(s) explained the inclusion criteria and the different sub-groups within the study.
6. The Researcher(s) explained participants are known to the researchers due to trialnet plan – these potential participants would have been eligible

Summary of ethical issues (resolved)

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

1. The Researcher(s) confirmed no placebo group in this trial.
2. The Committee queried how long the 7.5mg dose was given to participants for (prior trial). The Researcher(s) explained it differed depending on what time they joined the study. Trial started in 2007 and have been followed up for a long time, whereas some joined in 2015.
3. The Researcher(s) confirmed any adverse effects have been picked up during the prior study.
4. The Researcher(s) noted investigator brochure references many studies that shows oral insulin is safe and has no impact on blood glucose.
5. The Researcher(s) confirmed safe in this age group.
6. The Researcher(s) explained rationale for testing in children. The Researcher(s) confirmed it was appropriate to enroll children.
7. The Committee asked if there is really no risk with 500mg dose, even hypothetical risk. The Researcher(s) stated that the insulin is broken down in the gut but the fragments are picked up by the immune system that aims to reestablish tolerance to insulin. There are no documented issues with any of the doses of insulin.
8. The Researcher(s) confirmed all doses in this study have had prior studies confirming safeness of the dose.
9. The Researcher(s) confirmed SCOTT review was planned.
10. (R.4.1) The Committee queried if pregnancy tests would count as an unexpected result. The Researcher(s) noted that the study doctor would discuss that with the participants. The study treatment would cease. The GP would be involved.
11. The Researcher(s) discussed the Maori consultation process.
12. The Committee and The Researcher(s) discussed assent and declining with young children.
13. The Committee queried if there are any unexpected results relating to genetic / genomic testing. The Researcher(s) stated this was related to future unspecified research. These results are not returned to participants.

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 noted the protocol states samples drawn and stored for future analysis are mandatory. The Researcher(s) acknowledged that the protocol is not worded correctly but confirmed future unspecified research is optional. Only blood tests that are required for main study are mandatory. The Committee stated the protocol should be amended to reflect this.

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

1. Add basic information on process for unexpected findings (pregnancy etc.).
2. The Committee noted that there could be an area for parents to sign on the assent form for children.
3. The Researcher(s) noted adult form could be re-titled.
4. Add how long samples stored for, how disposed of, what happen if withdrawal in future unspecified research document.
5. Remove as ‘required by US law’.
6. Make clear insulin treatment not available post study.
7. The Committee noted the future unspecified research for children information could be further simplified, suggesting a one page sheet. The Committee acknowledge what was submitted is guidance on the HDEC website and thanked the researcher for using the model participant information sheet in the first instance, adding that the end goal was ensuring children understand.

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

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

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| **4** | **Ethics ref:** | **16/NTB/12** |
|  | Title: | Lactoferrin Infant Feeding Trial |
|  | Principal Investigator: | Dr Nicola Austin |
|  | Sponsor: |  |
|  | Clock Start Date: | 21 January 2016 |

Dr Nicola Austin and Ms Rebecca Brown 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 a product (prophylactic bovine lactoferrin) that has potential to reduce difficulties for infants during neonatal stay.
2. Infants are randomly allocated the study product (200 mg/kg/d added to breast milk or formula milk) or control (no bLF added to breast milk or formula milk) within 7 days after birth with 1 daily dose added to feeds until 34 weeks corrected gestation.

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 the protocol is from 2013 and the references are out of date. Please explain why this study should go ahead, as it appears similar studies have already completed.
2. The Researcher(s) acknowledged there is a growing body of evidence that the lactoferrin is beneficial. However we are adding to that evidence base, and this trial is much larger. Based on current recruitment we will have 1100 participants by June 2017.
3. The Committee queried whether the study is in clinical equipoise.
4. The Researcher(s) confirmed Middlemore uses the study product, though it is not used routinely – but we have reason to believe there is a benefit. The Researcher(s) stated they believe there is equipoise between the arms.
5. The Committee asked why only SUSARs are reported, not SAE. The Researcher(s) clarified deaths and all illnesses and major outcomes are collected from routine data collection, and are reported. SAE are reported; just not on the expedited pathway.
6. The Committee queried what the process is for managing unexpected findings. The Researcher(s) explained that any issues identified during a research follow up would result in discussion, follow up and referrals.
7. The Researcher(s) explained the peer review (SCOTT).
8. The Researcher(s) confirmed consultation has occurred with Maori and noted the changes that had been made as suggested.
9. The Researcher(s) confirmed low birth weight have a higher incidence in Maori.
10. The Committee asked what the approval status of the study product is, in New Zealand. The Researcher(s) responded it is not approved for this indication.

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 discussed sending NHI to Australia. The Researcher(s) explained why they wanted to send the NHI. The Committee stated there is no justifiable reason to send the NHI. Remove NHI from being sent to Australia.
2. The Committee queried if there is a sponsor, noting conflicting information in the application ‘study sponsor provided peer review’ from b.2.2.2 but a.5.1 states ‘no sponsor’. Please clarify.

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

1. The Researcher(s) explained that if any red flags were identified the caring pediatrician will be notified. The CI will take responsibility to get in touch with treatment providers if there is something unexpected or not in follow up. Either GP of the pediatrician. The Committee request this is clearly explained to participants in the participant information sheet.
2. The Committee queried if survival as an outcome could be alarming for parents. The Committee noted only infants expected to survive are being recruited. Because survival is not an outcome measure please remove from Participant Information Sheet. It could be unduly distressing for low weight birth parents.
3. Remove ‘baby personal medical details’ pg.3 as this relates to Australia.
4. Explain what ‘confidential’ is in the Participant Information Sheet (refers to their data being kept confidential, not that the study itself is confidential).
5. Add offer for lay language summary results as a yes/no box on consent form.
6. Give patients the option of informing their GP about participation.
7. The Committee noted application is silent regarding benefits of breastmilk. Add breastmilk information.
8. Add statement that breastmilk contains lactoferrin but note bovine could add more benefit (for instance due to the time it takes for breast milk to become high in lactoferrin).
9. Amend ACC statement in line with the HDEC template participant information sheet.
10. Remove reference to STH.
11. The Committee noted part of the study relates to cost efficacy. The Researcher(s) explained this is Australian only. The Committee noted information on this aspect of the study is in the Participant Information Sheet – please remove.
12. The Committee noted that confidentiality on health information should explain storage and applicable law if sent overseas. I.e. what changes when data goes overseas?

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*).
* Confirm no identifiable data will be sent offshore.
* Clarify sponsor status in New Zealand.

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

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| **5** | **Ethics ref:** | **16/NTB/13** |
|  | Title: | TicToc |
|  | Principal Investigator: | Dr John McMenamin |
|  | Sponsor: | Whanganui Regional Health Network |
|  | Clock Start Date: | 21 January 2016 |

Dr John McMenamin 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 will compare the response rate of increased frequency of SMS text messages that offer support to patients who smoke to quit with a single SMS text messages (current best practice).
2. A secondary measure is to compare the response rate of a SMS text messages containing a link to a YouTube video of the patients GP making an offer of support to quit smoking with a single SMS text messages (current best practice).
3. The study will also assess patient’s acceptability of the messages.

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 whether the research was necessary, asking whether it was already known that texting helps quitting smoking. The Researcher(s) stated they don’t know the details. They don’t know the outcomes of different types of interventions, the number (of texts) that should go out, whether personalized messages are effective or whether it doesn’t matter, and lastly whether sending a youtube video has not been done before.
2. The Committee queried how this is ethical, as participants don’t provide consent for research (only consent for updates or clinical care messages).
3. The Researcher(s) stated when enroll in clinic they consent to be offered items of service. Common practice over entire country for people who are overdue for health smoking target (not been offered support prior) to be communicated with phone or text to be offered support. This is existing practice. Our enrolment process builds on the current practice by not just providing that service to smokers but also those who are identified as smokers.
4. The Committee stated it was a leap to consider that consent to receive clinical care updates was also consent to be approached for research. The Researcher(s) asked the researcher to make the case for the Committee to consider allowing health information to be used to identify potential research participants.
5. The Researcher(s) stated that stopping smoking is important, and can be the most significant health decision an individual makes. It is also a serious issue in New Zealand, with widespread public health issues. This research will inform and generate information in line with our health target, smokefree by 2025. In any given year 1/3 of smokers indicate they want to stop. 1/3 of these have more than one attempt at quitting. We have existing quit programs, many involve texts. What we don’t have is quality parameters around this. The goal is to find out what works best.
6. The Researcher(s) stated the study involves up to 600 people, confirming it was not practical to seek consent. The Researcher(s) confirmed he felt the public good outweighed the right to privacy, and thought it was justifiable to send an initial text without consent to see if potential participants wanted to take part.
7. The Researcher(s) and The Committee discussed the use of information. The Researcher(s) confirmed no identifying information is shared between DHBs. The issue is waiver of consent to use health information to know who to approach to ‘participate’.
8. The Committee queried if there is an option to request not to participate. The Researcher(s) stated this could be done. The Committee requested it was clear that participants can easily communicate that they don’t want to be contacted.
9. The Committee clarified – first message is to ask to participate, second message is the ‘research intervention text’.
10. The Committee was comfortable with approving the initial test to ask potential participants if they wanted to participate.

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 noted Maori consultation is required due to relevance of health issue to Maori. Please outline plan to consult.

Decision

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

Please explain the plans for Maori consultation in a cover letter. The answer should include incidence and prevalence of the disorder under study (or treatment indication if a drug trial) in Maori. The Secretariat 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.

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

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| **6** | **Ethics ref:** | **16/NTB/15** |
|  | Title: | TARGET3D |
|  | Principal Investigator: | Professor Edward John Gane |
|  | Sponsor: | UNSW Australia |
|  | Clock Start Date: | 21 January 2016 |

Victoria Robertson and Amy Cole 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 purpose of the study is to examine whether patients who have recently acquired HCV infection can be treated effectively and safely with a regimen that does not include interferon but instead combines new directly acting antiviral drugs (3D regimen) with or without one of the standard treatments for chronic hepatitis C (ribavirin).
2. The study involves a partnership with the Kirby institute.
3. The study aim to treat marginalized populations with acute Hep C and will include HIV patients. 5 participants in New Zealand. The Researcher(s) added this group well researched – 95-100% clearance for short duration.

Summary of ethical issues (resolved)

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

1. The Committee confirmed peer review was acceptable.
2. The Committee noted the study data is potentially identifiable. The Committee explained identifiably of data and referred the researchers to the National Ethics Advisory Committee Guidelines for Intervention Studies section 7.2.
3. F.1.1 and F.2.2 – will this reduce inequalities, citing the conflicting information. The Researcher(s) stated no – incidence is the same between populations.
4. F.2.2 - The Committee queried the exclusion of spontaneous clearance. The Researcher(s) explained what this referred to and noted there is a 4 week screening phase to take this into account.
5. The Committee query if there were any risks of stopping medications (to avoid contra indications). The Researcher(s) stated we have DDI tool on an app for every patient that comes in – this helps us with degrees of interaction. The Researcher(s) swap drugs to suitable alternatives. We would not stop straight away, for instance with benzos.
6. The Researcher(s) confirmed they are not recruiting out of prisons
7. The Committee queried if 30 dollars is enough for reimbursement. The Researcher(s) explained most potential participants are central Auckland. The Committee noted participants should not be excluded if they live a bit further out. Is it possible to add any more funds on case-by-case basis? The Researcher(s) stated no, it is not budgeted for.
8. The Committee discussed the ‘by law notifications’. The Researcher(s) explained for acute Hep C it is required, though for chronic it is not. For HIV it is not reportable. The Committee request this is all made clear for participants.
9. The Researcher(s) confirmed Abbvie is not on steering committee.

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 it is necessary to send initials, DOB and unique code – this could be potentially identifiable. Please send what is required to maintain a link but not be linkable at the destination.
2. (B.4.5.1) please explain whether the storage of tissue falls under future unspecified research. The Researcher(s) stated long term storage in the Hepbank. The testing will be hepatitis C related. The Committee noted this was a case of storage for undefined research in a specified area. While the area was specified the participants had no information
3. The Committee discussed the storage of tissue. Biobanking is defined by storage of tissue beyond a particular research project. The Committee requested that the storage of tissue in the Hepbank is optional, and is a separate document. The reasoning is because it is not required for the intervention study.
4. The Committee requested that the sponsor confirms ethnicity data is collected according to New Zealand 2006 census categories. This is in line with the Ministry of health ethnicity protocols.
5. The Committee queried if participants can choose to not answer any particular questions in the questionnaire. The Researcher(s) stated they would ask the sponsor.
6. Add New Zealand as country of birth option (questionnaire).

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

1. The Researcher(s) explained that there is no specific trial consent for follow up with partners but this is standard practice in relation to the label use of the drug. The Committee stated this should be very clear in the Participant Information Sheet, both the risks to unborn child and need for follow up outside of the study.
2. ‘see pregnancy section below’ but info is 2 pages along – revise for formatting.
3. Page 15 – please remove statement about stopping for commercial interests. This is not acceptable, as per National Ethics Advisory Committee Guidelines.
4. Please reword purpose of the study. Reduce length.
5. Make it clear what people should do regarding missing a dose. i.e. time period as to avoid having a double dose. Currently confusing.
6. The Committee asked what the process was for unexpected findings. The Researcher(s) stated they will diagnose and refer. They are doing safety tests, blood pressure tests. They could identify hypertension, or have a positive urine test for glucose abnormalities. The Committee requested information added to Participant Information Sheet to outline process participants can expect.
7. The Committee noted questionnaires are both very long and very personal. Please be explicit about information asked in the Participant Information Sheet.
8. Short lay language title.

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*).
* Update questionnaires.

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

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| **7** | **Ethics ref:** | **16/NTB/18** |
|  | Title: | Community-based group anxiety treatment |
|  | Principal Investigator: | Dr Jennifer Jordan |
|  | Sponsor: |  |
|  | Clock Start Date: | 21 January 2016 |

Dr Jennifer Jordan 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 group therapy for treatment of anxiety. The Researcher(s) explained that this delivery method is novel as usually 1-1. The Researcher(s) clarified, novel at this site but generally the notion of group/community therapy is gaining traction for anxiety, but in the context of it being the first application in primary care in New Zealand it was novel..
2. The Researcher(s) have done group therapy in anxiety clinics in New Zealand with success.
3. This study is look at pre-post outcomes, acceptability etc. This is a pilot study to inform a larger randomized controlled trial, pending HRC funding.
4. The way we have packaged it is different but it is not wildly different to what we have been doing.
5. The Committee commended the Participant Information Sheet, noting it was in lay language.

Summary of ethical issues (resolved)

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

1. The Researcher(s) confirmed ethnicity is collected in line with the Ministry of Health guidelines.
2. The Researcher(s) confirmed consent was documented by researchers if it was verbal on the phone.

Summary of ethical issues (outstanding)

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

1. Remove personal identifiers on questionnaires.
2. The Committee queried who sponsor? The Researcher(s) stated DHB will provide some funds. The Committee asked who governs the study (initiation and management). The Researcher(s) stated the DHB.
3. The Committee ask researcher to contact DHB research office to confirm sponsorship.

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

1. Remove any ‘yes/no’ on the consent form that are not truly optional.
2. Add how to withdraw from the study.
3. Explain what happens to data that is collected if a participant withdraws.
4. The Committee asked about adding info in Participant Information Sheet about keeping items discussed in-group as confidential. Chatham house rules etc.
5. Add size of group – administrative information i.e. time of day, where etc.
6. Add facilitators or their role in the group.
7. Add what is involved – a brief overview.

Decision

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

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| **8** | **Ethics ref:** | **16/NTB/23** |
|  | Title: | ATHENA |
|  | Principal Investigator: | Dr Stephen Best |
|  | Sponsor: | Allergan Inc. |
|  | Clock Start Date: | 21 January 2016 |

Ms May Mendoza 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 members.

Summary of Study

1. This is a multicenter, paired eye, randomized, masked Phase III study to investigate the intraocular pressure (IOP) lowering effect and safety of Bimatoprost SR compared with selective laser trabeculoplasty (SLT) in patients with openangle glaucoma (OAG) or ocular hypertension (OHT) who are not adequately managed with topical IOPlowering medication for reasons other than medication efficacy (eg, due to intolerance or non-adherence).
2. The goal is to have a treatment that reduces visits for patients who may be non-compliant or find it difficult to be compliant with their current treatment options.
3. The difference in treatment is not with the drug but with the delivery method (implant).

Summary of ethical issues (resolved)

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

1. The Committee asked why the side effects would be different for participants when the drug was the same. The Researcher(s) stated we are hoping to have less side effects, and have some reason to believe the side effects will be less, adding they will monitor this closely.
2. The Committee query if optional studies are offered in New Zealand. The Researcher(s) stated two of three are offered. The Researcher(s) confirmed they are optional.
3. The Committee asked if potential participants can talk to anyone independent about participation, noting conflict of interest with treating clinician also being the researcher. The Researcher(s) confirmed no time pressure and The Researcher(s) explain they can talk to family, friends or their own GP and optometrist.
4. The Researcher(s) confirm no antibiotics pre-procedure, adding there was no incision.
5. The Researcher(s) confirmed patients with serious glaucoma would not be participants.
6. The Committee asked about the washout periods and keeping participants off medications. The Researcher(s) stated if it is either not safe or not comfortable for them to washout we will not recruit them. Some require 28 days off their standard treatment. The Researcher(s) can either replace their current treatment with a similar medication with smaller washout period – but it is generally the clinician who will make a call where a patient should or should not participate for safety reasons.

Summary of ethical issues (outstanding)

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

1. R.1.5 – The Committee noted the onsite monitoring was explained well. Please explain the internal data safety monitoring committee, who is on the committee and what is their role regarding safety for participants. Please clarify.

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

1. Add information on management of washout period.
2. The Researcher(s) confirmed they provide anti-inflammatory medicines if needed. Add ‘what happens if there is an infection’ – in Participant Information Sheet.
3. R.4.1 – the Committee note this study could generate unexpected findings. Please explain management plan and explain to participants in Participant Information Sheet as to what might be found and how it would be managed.
4. The Committee noted that the optional sub studies have specific criteria for eligibility. Please ensure patients are eligible before having them consent. Currently because the information is in the main participant information sheet they may consent without being eligible.
5. Please revise dose schedule information. Please have visual diagram for what happens in each eye. The Committee noted the GP letter is very clear – take some wording from that as guidance.
6. Add ‘and this will not effect the care you receive’ after withdrawal information.
7. Add where SLT fits as a treatment (after eye drops etc.). Make it clear that the implant is the experimental component.
8. Review font sizes.
9. Explain why the researchers are testing for sickle cell.
10. Pg.9 – two at bottom – please explain what the procedures are.
11. Explain acronyms (IOP for example).
12. Explain what ‘loss of corneal cells’ is in terms of significance for participants.
13. Pg 19 – ACC limitations – remove ACC limitations. ACC equivalent compensation must be provided for commercially sponsored clinical studies.
14. Remove the information on the need to tell Allergan prior to dosing. This is not a patient obligation.
15. Remove reference to US law.
16. Explain what is involved for the videotaping, what form is it stored, how long etc.
17. Remove withdrawal in writing – can be verbal. Writing is allowed but must be optional.
18. Add info on storage of samples, how they are destroyed and make it clear there will be no cultural considerations if the samples are destroyed overseas.
19. Remove flipping a coin analogy and replace with ‘by chance’.
20. The Committee noted Participant Information Sheet is long. Please try to reduce length.
21. Add how data privacy will be protected (generally and when it is sent offshore).
22. Add the length of time any data will be stored and in what form.

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 *(Ethical Guidelines for Intervention Studies para 6.50).*

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

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| **9** | **Ethics ref:** | **16/NTB/24** |
|  | Title: | A Phase 2 Study of Abemaciclib in Patients with Brain Metastases Secondary to Hormone Receptor Positive Breast Cancer, Non-Small Cell Lung Cancer or Melanoma |
|  | Principal Investigator: | Dr Rosalie Fisher |
|  | Sponsor: | Eli Lilly Australia Pty Ltd |
|  | Clock Start Date: | 21 January 2016 |

Dr Rosalie Fisher 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. Phase 2 trial of Abemaciclib (study drug) in patients with brain metastases secondary to HR+ breast cancer, HR-ve breast cancer, Non-small cell lung Cancer & melanoma.
2. The Researcher(s) stated the study drug has shown promising clinical activity in phase I.
3. The Researcher(s) explained there are no standard therapies once patients have had radiation treatment, adding these patients are almost always excluded from clinical trials. This study will give this patient group an opportunity to receive a novel drug.
4. Participation involves twice daily medication as a tablet.
5. The Researcher(s) noted number of cohorts makes the study appear complicated, particularly for those scheduled for surgery, however apart from those patients the remainder of the study is quite straight forward.

Summary of ethical issues (resolved)

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

1. The Committee asked about evidence to support phase II study. The Researcher(s) stated some preclinical data and animal studies, noting some participants in phase I had brain metastasis.
2. The Researcher(s) explained these patients have generally exhausted their standard therapies.
3. The Committee noted sponsor would continue to provide drug outside of trial if there is a benefit. The Committee commended this.
4. The Researcher(s) stated trial specific assessments would not be done routinely, and confirmed that they are only conducted after consent is given.
5. The Committee ask who will conduct the informed consent process with patients. The Researcher(s) stated it will be CI or co-investigators (clinicians). The Researcher(s) explained the participants are streamed by tumor type. The clinician will be consenting and they will be very familiar with the complex protocol.
6. The Committee queried how the Researcher(s) would confirm a participant was alive prior to conducting follow up. The Researcher(s) stated noted there are checks on patient records before the research nurses call, adding the researchers get updates from palliative care and hospice.
7. The Researcher(s) confirmed Maori consultation had not been received yet.
8. The Researcher(s) stated SCOTT was pending.

Summary of ethical issues (outstanding)

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

1. Please update insurance certificate.
2. Please either justify or remove the exclusion criteria regarding Eli Lilly family members.

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

1. Page 3 – outlining samples. The Researcher(s) confirmed blood storage for additional testing was optional. The Committee requested these are clearly marked as optional and refer to the separate participant information sheet.
2. Please make it clear to participants that they can withdraw verbally.
3. Please make it clear that tissue is archived tumor tissue (attachment 2 schedule).
4. Please amend ATTACHMENT 2 to indicate the frequency of MRI falls to second monthly after Week 8
5. Add further details for contact – currently hospital switchboard. Please add 24/7 contact number.
6. Clarify whether it is either a paper or electronic diary and add requirement for diary to PIS.
7. Make clear no additional tissue taken except in Arm C. That archived sample will only go if it is appropriate, and that the researchers will retain samples for clinical testing.
8. The Committee noted it could be confusing to refer to cycles as the cycle does not end. Please reconsider language used

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*).
* Update insurance certificate, or confirm it will be updated.
* Respond to outstanding ethical issues in a cover letter.

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

## Substantial amendments

|  |  |  |
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| **1** | **Ethics ref:** | **NTY/08/06/055/AM05** |
|  | Title: | Growing Up in New Zealand |
|  | Principal Investigator: | Dr Susan Morton |
|  | Sponsor: |  |
|  | Clock Start Date: | 21 January 2016 |

Dr Susan Morton Associate Professor Susan Morton – Director, Growing Up in New Zealand

Associate Professor Cameron Grant – Associate Director, Growing Up in New Zealand

Dr Sarah Berry – Senior Research Fellow, Growing Up in New Zealand

Vasantha Krishnan – Director Knowledge, Superu – Contractor/Funded on behalf of Govt

Teresa Dickinson - Deputy Government Statistician, Statistics NZ

Hamish James - Statistics NZ were present in person for discussion of this amendment.

Potential conflicts of interest

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

Mrs Leesa Russell declared a potential conflict of interest, and the Committee decided to have her leave the room for discussion of this amendment.

Summary of Study

1. The Researcher(s) explained the amendment. In summary the project dataset is proposed to be de-identified and stored within the Statistics New Zealand datalab. The identifying link would be retained by the researchers. The need for new storage arrangements is due to the scale of the data and on-going feasibility of the project.
2. Currently all data is stored with the University, and is released after vetting from the University and research team. Under the new arrangement the Statistics group would be able to release aggregate, di-identified data to other researchers – and would have a co-management arrangement. The researchers maintain control over use of the data, however how this works in practice was unclear to the Committee.
3. The Researcher(s) and The Committee discussed the confidentiality of the datalab. The Committee noted the confidentiality protection measures provided by datalab were acceptable.
4. The Researcher(s) discussed the guardian role they held for the sensitive study information, and wanted to maintain the progress of the study while also maintaining this protector role.
5. The Researcher(s) promised participants that the data would be widely used, to help inform policy and produce good research – so we are looking at this as a way to facilitate greater utility of the resource while protecting the integrity of the relationship.
6. The Committee discussed the communication plans from the researchers to the study participants. The Researcher(s) acknowledged the importance of trust with participants, citing the 97% retained after 7 years. The Researcher(s) confirmed the university will always be the liaison link between use of data and the participants.
7. The Researcher(s) explained that the anonymisation prior to release to DoS. We can still stop release of information if the research question is not in line with what the data was collected for.

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 noted they needed information around how the data access protocol, data access committee and Statistics New Zealand planned to manage external access of data. Please submit the memorandum of understanding draft so the Committee can make comment.
2. The Committee requested a draft of the communication plan to participants.
3. The Committee stated they did not believe the change should occur prior to communications.
4. The Committee thought the best practice would be to discuss the change with participants during next collection round. The Researcher(s) stated this was not an option due to timelines.
5. The Committee felt that they needed to know more about how the researchers maintained adequate control over the use of the data to ensure the use was in line with what was consented to.
6. The Committee was supportive of the project as a whole and acknowledged that changes were required to continue the study, and stated they were happy to work with the researchers to facilitate a good practice transition.

Decision

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

* Submit the MoU, and clarify how data use would be protected in conjunction with the datalab and the University of Auckland’s continuing role as being guardian of the data..
* Submit communication plan to participants, and any draft wording.

This following information will be reviewed, and a final decision made on the amendment, by full electronic committee.

## Review of approved studies

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| --- | --- | --- |
| **1** | **Ethics ref:** | **NTX/10/08/084** |
|  | Title: | Rituximab in Primary Central Nervous System Lymphoma (NHL24) |
|  | Principal Investigator: | Dr Samar Issa |
|  | Sponsor: |  |
|  | Clock Start Date: | 02 October 2012 |

Dr Samar Issa was present by teleconference for discussion on this item.

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 reason for review

Approval for this study was reviewed on the basis of the following issues, which were raised by an amendment.

* This application was brought to the Committee for review to confirm that the non-consenting participants were able to be enrolled by meeting right 7(4) of the Code of Rights.
* The Committee noted the letter submitted to ethics covering the justification for how the study meets the best interests test.
* The Researcher(s) explained the kind of participants enrolled and their capacity for consent.
* The Researcher(s) explained the patient population’s current treatment options.
* The Committee noted important scientific value of recruiting those with this particular tumor placement.
* The Researcher(s) confirmed they will go back to patient when cognitive functions get better.
* The Researcher(s) noted that this is standard treatment and standard treatment plus study drug.
* The Researcher(s) confirmed the multidisciplinary team will consider best interests in cases where it is not clear by a sole clinician. The Committee were satisfied that it was possible for participation to be in the best interests of some patients. The Committee noted that the researchers had a plan to consult with family, in line with Right 7(4).
* The Committee noted minor admin changes could be made to the participant information sheet to help family members understand the study, and it could be a participant information sheet without any notion of consenting on behalf of another.

Decision

The Committee decided that approval for enrolment of non-consenting participants for this study should remain in place. This decision was made by consensus.

## 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:

|  |  |
| --- | --- |
| **Meeting date:** | 01 March 2016, 12:00 PM |
| **Meeting venue:** | Novotel Ellerslie, 72-112 Greenlane Road East, Ellerslie, Auckland |

The following members tendered apologies for this meeting.

* Dr Nora Lynch

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 6.15pm