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| **Committee:** | Northern A Health and Disability Ethics Committee |
| **Meeting date:** | 09 February 2016 |
| **Meeting venue:** | Novotel Ellerslie, 72-112 Greenlane Rd East, Ellerslie, Auckland |

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| **Time** | **Item of business** |
| 1.00pm | Welcome |
| 1.05pm | Confirmation of minutes of meeting of 01 December 2015 |
|  | New applications (see over for details) |
|  | i 15/NTA/206  ii 16/NTA/6  iii 16/NTA/10 |
| 1.25pm | General business:   * Noting section of agenda |
| 1.30pm | Meeting ends |

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| **Member Name** | **Member Category** | **Appointed** | **Term Expires** | **Apologies?** |
| Dr Brian Fergus | Lay (consumer/community perspectives) | 01/07/2012 | 01/07/2015 | Present |
| Ms Susan Buckland | Lay (consumer/community perspectives) | 01/07/2012 | 01/07/2015 | Present |
| Dr Karen Bartholomew | Non-lay (intervention studies) | 01/07/2013 | 01/07/2016 | Present |
| Dr Christine Crooks | Non-lay (intervention studies) | 01/07/2013 | 01/07/2015 | Present |
| Ms Shamim Chagani | Non-lay (health/disability service provision) | 01/07/2012 | 01/07/2015 | Present |
| Dr Kate Parker | Lay (consumer/community perspectives) | 11/11/2015 | 11/11/2018 | Present |
| Dr Charis Brown | Non-lay (intervention studies) | 11/11/2015 | 11/11/2018 | Present |

## Welcome

The Chair opened the meeting at 1.00pm and welcomed Committee members.

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 01 December 2015 were confirmed.

## New applications

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| **1** | **Ethics ref:** | **15/NTA/206** |
|  | Title: | INS-312 - Extension Study of Liposomal Amikacin in Adults with Nontuberculous Mycobacterial Lung Infections |
|  | Principal Investigator: | Dr Amanda McNaughton |
|  | Sponsor: | Insmed Incorporated |
|  | Clock Start Date: | 26 November 2015 |

Dr Amanda McNaughton 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. This is an extension study following on from INS-212.
2. Three patients in New Zealand. 16 countries overall, with 200 total participants.
3. The study has ethics approval in the USA.
4. Participants who are in the INS-212 study, who have completed 6 months but not responded to the treatment or have relapsed.
5. Assessing the long term safety and tolerability of LAI, a novel formulation of Amilkacin (an established drug)

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 eligible patients are who have completed the month 6 visit in the previous study (INS-212). The Committee queried how many would this be in the New Zealand arm of INS-212? The Researcher(s) stated that there are two patients actively enrolled in INS-212. Both are on study drug, both doing well.
2. The Researcher(s) explained how the extension study allows access to study drug after the 6 month visit on the prior study.
3. The Researcher(s) explained that the study allows patients on the INS-212 study to receive the study drug (as they could be on placebo) after 8 months, adding this is a patient friendly and care friendly aspect of the study.
4. The Committee queried the adverse event data from the participant information sheet, noting the high reporting of events when taking LAI. The Researcher(s) explained that the reported events primarily relate to COPD. The Researcher(s) explained that the two participants have close monitoring for hearing loss and fatigue.
5. The Researcher(s) confirmed they have not had the level of adverse events outlined in the participant information sheet in New Zealand.
6. The Researcher(s) confirmed there is no biobanking.
7. The Researcher(s) confirmed they will use the DSMB from INS-212.

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

1. Remove ‘New Zealand federal government’.
2. The Researcher(s) confirmed the tissue tests were biomarker tests, and were optional. The Committee noted that the tissue sample testing must be clearly explained and clearly stated to be optional.
3. minor typos:

* Pg.8  ‘Pregancy’ should be Pregnant – paragraph 4
* Pg.11 Space needed between ‘New Zealandprivacy’ – paragraph 3.

Decision

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

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| **2** | **Ethics ref:** | **16/NTA/6** |
|  | Title: | AirSpiral and tracheostomy connector usability with myAIRVO 2 |
|  | Principal Investigator: | Dr James Revie |
|  | Sponsor: | Fisher & Paykel Healthcare |
|  | Clock Start Date: | 28 January 2016 |

Dr James Revie 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 Researcher(s) stated they have developed a new breathing tube and connector for the AIRVO device. Provides oxygen or humidified air, as a repertory support mechanism for people at home.
2. The changed design feature is aimed at eliminating condensation in the tube which can lead to alarms going off and disturbing the user
3. The study aims to validate usability of air spiral and new tracheostomy connector in children and adults at home.
4. The study will recruit 15-30 children (new heated breathing tube and tracheostomy connector) and 15-30 adults (with the tube only).
5. The researchers are not treating and not collecting health information.

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) explained adult participants have given consent to be contacted for research. The younger participants are recruited from Starship Hospital. The Researcher(s) confirmed that the researchers do not receive any identifiable health information without consent. The paediatrician approaches parents who then contacts Fisher and Paykel.
2. The Researcher(s) confirmed all participants are on already treatment - no change to therapy provided.
3. The Committee queried the sample sizes. The Researcher(s) stated they are based on an unpublished report FDA ‘guidance on usability studies’.
4. The Researcher(s) confirmed they will consult with ADHB Maori Review Committee.
5. The Researcher(s) confirmed there are no therapy response expectations or data recorded on therapy – the study is only about usability.
6. The Researcher(s) confirmed we have a home care nurse team that visits 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 Peer Review was done by a FPH employee. Whilst the Committee accepts there is no treatment involved and the study design is not testing any scientific principles, the Committee would still like to see an independent peer review. The Researcher(s) confirmed they would provide additional review.

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

1. Please note that HDEC requires studies to provide ACC equivalent study compensation as per the National Ethics Advisory Committee guidelines on Intervention Studies. Please amend compensation statement to reflect ACC equivalent compensation.
2. Please note that health data derived from the study must be stored for a minimum of 10 years following a child turning 16, according to the [Health (Retention of Health Information) Regulations 1996](http://legislation.govt.nz/regulation/public/1996/0343/latest/DLM225650.html).
3. Assent form – The Committee suggests rewording ‘I think’ the participant understands to ‘I believe’ the participant understands.
4. Add details for Starship doctors.

Decision

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

* Please amend the information sheet and consent form, taking into account the suggestions made by the Committee (*Ethical Guidelines for Intervention Studies* *para 6.22*).

This following information will be reviewed, and a final decision made on the application, by Dr Brian Fergus and Mrs Shamim Chagani.

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| **3** | **Ethics ref:** | **16/NTA/10** |
|  | Title: | AVeNew |
|  | Principal Investigator: | Dr Stewart Hawkins |
|  | Sponsor: | Organisation: Bard Peripheral Vascular |
|  | Clock Start Date: | 28 January 2016 |

Dr Stewart Hawkins and Mrs 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. This is a prospective, multi-centre, randomised, concurrently controlled clinical study of the bard covera arteriovenous stent graft in the treatment of stenosis in the venous outflow of av fistula access circuits.
2. Current standard of care treatment for AV stenosis is via a percutaneous transluminal angioplasty or PTA which involves opening the vessel with a small balloon) or surgical revision.
3. An alternative treatment is to use a stent graft which involves placing a self-expanding polytetrafluoroethylene (ePTFE) covered nitinol stent mounted on a flexible delivery system catheter.
4. The system is designed to deliver the implant to the peripheral venous vasculature via a sheathed delivery system.
5. There is evidence from randomised clinical trials that stent grafts are safe and effective.
6. This is significant change for with patients undergoing dialysis, with many return visits. The aim of the trial is to see if the stent gives an improved delivery system with fewer patient returns visits.

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) explained that this is not a standard of care stent. This is a slightly different design to other stents.
2. The Researcher(s) stated the DSMB is international. The Researcher(s) confirmed they assess data real time, with interim analyses 6 monthly.
3. The Researcher(s) confirmed publishing restrictions only relate to publishing pending all sites completion.
4. The Researcher(s) explained Māori consultation did not occur during project development as this was conducted outside New Zealand. Investigators/sites were approached and invited to participate once the protocol had been finalised. Study sites will seek local Māori consultation as a mandatory part of their locality assessment and authorisation. The Researcher(s) confirmed they will submit their consultation document after approval.
5. The Committee asked who will do follow up with patients, and how will they be contacted if they are difficult to follow up. The Researcher(s) stated these patients come in every few days.

Summary of ethical issues (outstanding)

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

1. Peer Review. The Committee accepts that as this is international trial it must rely on the peer review carried out overseas. The committee notes that the use of stents is now commonplace in many surgical procedures. The Committee also notes that the research team in NZ includes several interventional radiologists who have reviewed the Protocol and support the concept of the trial in NZ (as the condition being addressed is serious). The researcher may wish to re-confirm this.
2. The Committee requested a copy of the Peer Review reports from overseas (if possible) and a copy of any discussion notes from the ethics approval in Victoria. The Researcher(s) stated they will try to get copies of the peer review.
3. The Committee is of the view that the principal ethical issue to address is whether this particular stent poses any undue risk over and above what a clinician would normally expect in such a procedure.

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

1. The Committee confirmed the researchers will remove the following statement : CONSENT FOR SUBJECTS WHO CANNOT READ, WRITE OR TALK The study subject has indicated that he/she is physically unable to read, write or talk. The consent document has been read to the subject by a member of the study staff, discussed with the subject by a member of the study staff, and the subject has been given an opportunity to ask questions of the study staff.
2. Statement on page 1: If you are not completely truthful with your study doctor regarding your health history, you may harm yourself by participating in this study. The Committee requested this is altered to something else, e.g.: Please be comprehensive with your study doctor regarding your health history, you may harm yourself by participating in this study if important details are omitted.
3. The Committee noted on the Consent form there is an optional question which is unnecessary. Please remove this.

Decision

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

* Please amend the information sheet and consent form, taking into account the suggestions made by the Committee (*Ethical Guidelines for Intervention Studies* *para 6.22*).

This following information will be reviewed, and a final decision made on the application, by Dr Brian Fergus and Dr Charis Brown.

## General business

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

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| **Meeting date:** | 08 March 2016, 01:00 PM |
| **Meeting venue:** | Novotel Ellerslie, 72-112 Greenlane Rd 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 2.25pm