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| **Committee:** | Northern A Health and Disability Ethics Committee |
| **Meeting date:** | 09 December 2014 |
| **Meeting venue:** | Novotel Ellerslie, 72-112 Greenlane Rd East, Ellerslie, Auckland |

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| **Time** | **Item of business** |
| 1.00pm | Welcome |
|  | Confirmation of minutes of meeting of 11 November 2014 |
|  | New applications (see over for details) |
|  | i 14/NTA/207  ii 14/NTA/208  iii 14/NTA/209  iv 14/NTA/213  v 14/NTA/214  vi 14/NTA/216  vii 14/NTA/217  viii 14/NTA/218  ix 14/NTA/220 |
|  |  |
| 5.25pm | General business:   * Noting section of agenda |
| 5.35pm | 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 |
| Ms Shamim Chagani | Non-lay (health/disability service provision) | 01/07/2012 | 01/07/2015 | Present |
| Mr Kerry Hiini | Lay (consumer/community perspectives) | 01/07/2012 | 01/07/2015 | Present |
| Ms Michele Stanton | Lay (the law) | 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 |
| Mr Mark Smith | Non-lay (intervention studies) | 01/09/2014 | 01/09/2015 | Present |

## Welcome

The Chair opened the meeting at 1.13pm 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 11 November 2014 were confirmed.

## New applications

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| **1** | **Ethics ref:** | **14/NTA/207** |
|  | Title: | An Investigation of Apremilast For Treatment Of Subjects With Active Ulcerative Colitis. |
|  | Principal Investigator: | Assoc. Prof Michael Schultz |
|  | Sponsor: | PPD Global Limited (New Zealand Branch) |
|  | Clock Start Date: | 27 November 2014 |

Assoc. Prof Michael Schultz was not present 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

* Phase II randomised placebo controlled multicentre study.
* The study will investigate the efficacy and safety of Apremilast (study drug) for treatment of participants with active ulcerative colitis.
* The Committee noted the need for further research in this area.
* The study involves use of human tissue, including PK testing.

Summary of ethical issues (resolved)

The main ethical issues considered by the Committee

* The Committee noted an independent DSMC is arranged to monitor study data.
* The Committee noted that the sponsor had agreed to provide the following ACC equivalent compensation in the event of an injury and requested that the sponsor honour this in the event of an injury. Could the researcher please include this information in the PIS.
* rehabilitation (comprising treatment, social rehabilitation, and vocational rehabilitation)
* first week compensation
* weekly compensation
* lump sum compensation for permanent impairment
* funeral grants, survivors' grants, weekly compensation for the spouse or partner, children and other dependents of a deceased claimant, and child care payments.

Summary of ethical issues (outstanding)

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

* Please send Maori support letter to HDEC via email to [hdecs@moh.govt.nz](mailto:hdecs@moh.govt.nz)
* Pg.14 of the PIS: Please explain why personal and health information is being accessed after the study has completed, and in particular address why social media and family and friends are going to be contacted? If there is a sound scientific reason then you must explain this in the PIS.
* Please explain why tissue samples are stored for 5 years. Explain what testing will occur on these samples.
* Please explain the composition of the peer review group and some basic information on the institution that provided the peer review. The peer review information supplied is not on letterhead.
* Pg.10 PIS: please clarify whether 28 days is the correct length of time required to wait post treatment before pregnancy is safe and birth control is no longer required.

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

* Pg.15 section 12: Committee noted that the ACC information is not complete. Please include following statement:

If you were injured as a result of treatment given as part of this study, which is unlikely, you **won’t** be eligible for compensation from ACC. However, compensation would be available from the study’s sponsor, [x], in line with industry guidelines. We can give you a copy of these guidelines if you wish. You would be able to take action through the courts if you disagreed with the amount of compensation provided. If you have private health or life insurance, you may wish to check with your insurer that taking part in this study won’t affect your cover.

* Section 11: Please amend the statement covering the sponsor paying the study doctor. The sponsor pays the institution rather than the individual doctor. Please confirm with investigator first that it is the institution being paid and not the doctor. It is possible that doctors are paid directly if this is the case how the conflict of interest is managed needs to made be very clear for participant
* Please include more information on the tissue samples (pg.10). Make it explicit that these are mandatory samples. Any samples that are used for future unspecified use must include the following:

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| **Future Unspecified Research (FUR) and Biobanking must include** |
| an indication of the type and nature of the research to be carried out and its implications for the donor, where possible, and an explanation of why the potential donor is being approached for their tissue and specifically what tissue is being sought. |
| known possible researchers or institutions that might use the tissue sample, if possible. |
| whether the donor’s sample is going to be, or is likely to be sent overseas, and where possible, to what country or countries. |
| acknowledgement that all future unspecified research in New Zealand will be subject to ethical review. However, when a tissue sample is sent overseas, unless it is sent in conjunction with a New Zealand research project, future research is likely to be considered by an overseas ethics committee without New Zealand representation. |
| whether the donor’s identity and details will remain linked with the sample or whether the sample will be de-linked. |
| a statement that if a donor consents to a tissue sample being unidentified or de-linked, they relinquish their right to withdraw consent in the future. |
| whether the donor may be contacted in the future regarding their tissue sample. Whether or not, and under what circumstances, information about the future unspecified research will be made available to the donor and/or (where relevant) their clinician. |
| acknowledgement that the donor will not own any intellectual  property that may arise from any future research. |
| whether there is provision to withdraw consent for the use of human tissue samples in the future. Where there is provision to withdraw consent, only tissue samples remaining at the time of a request to withdraw and any information held for future unspecified research may practically be withdrawn. Tissue samples or information used in research before the request to withdraw is received is unlikely to be able to be returned or  destroyed. |
| acknowledgement that the donor’s decision regarding the consent for use of their tissue sample for unspecified future research will in no way affect the quality of a donor’s current or future clinical care. |
| where and for how long a tissue sample will be stored, how it will be disposed of and whether there is a cultural protocol for its disposal. For example, information about the institution holding the tissue sample: its aims, research procedures and research governance. |
| whether or not tissue samples could be provided to other researchers and institutions, and whether or not such provision could include sending samples to other countries |
| whether or not collected samples will be provided to commercial biomedical companies or will be used in commercial research collaborations, if known. |
| what provisions will be made to ensure patient confidentiality. |
| that different cultural views may inform choice about donation of tissue; for example, for some Maori, human tissue contains genetic material that is considered to be collectively owned by whanau, hapu and iwi. |
| that cultural concerns may arise when tissue samples are sent overseas, including how tissue samples are stored and disposed of. Processes for monitoring and tracking what happens to samples may not be acceptable to donors. |
| that donors may want to discuss the issue of donation with those close to them, for example; family, whanau, hapu and iwi. |
| **Note:** FUR must be listed as OPTIONAL and must be **distinct** from the main study – this can either be a separate PIS (if there is substantial information that warrants it) or it can be a separate consent area on the consent form (if the additional tests are optional but not that different from the primary study).  **HDEC has a preference for separate PIS/CF for optional sub studies, FUR or bio banking as the information required is often different to the main study.**  For more information see the Guidelines for Future Unspecified Research <http://www.health.govt.nz/publication/guidelines-use-human-tissue-future-unspecified-research-purposes-0> |

* Amend the PK testing consent form as it currently states: ❑ I have read this informed consent and agree to participate in the optional biomarker [genetic] testing.
* Please explain the risks in relation to suicidal thoughts and or psychological state of mind of participants. Please explain why these are risks.
* Pg. 6: Please provide the following information on the additional study sigmoidoscopies with intestinal mucosal biopsies. Explain what this is and the reasoning behind this, the usual risks involved (bleeding, infection, perforation) and explain it is for genetic testing.
* Reword subject to participants.
* Pg.19: please reword the statement on continued use of data to clearly indicate that the participant is consenting to data being used until participation ends, and clarify whether it is possible to withdraw all study data relating to the participant, and or destroy any remaining tissue samples.

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 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 address outstanding ethical issues.

This following information will be reviewed, and a final decision made on the application, by Ms Shamim and Ms Susan Buckland.

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| **2** | **Ethics ref:** | **14/NTA/208** |
|  | Title: | The Human Brain Bank |
|  | Principal Investigator: | Dr Maurice Curtis |
|  | Sponsor: |  |
|  | Clock Start Date: | 27 November 2014 |

Dr Maurice Curtis was present in person for discussion of this application.

Potential conflicts of interest

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

Dr Karen Bartholomew declared a potential conflict of interest, and the Committee decided to that it was appropriate to take part in the discussion and the decision of the application.

Summary of Study

* The Committee commended the discussion document, noting it was written in lay language and covered most of the issues that were relevant to review of tissue banks outlined in the Standard Operating Procedures.
* The Committee acknowledged that the human brain bank was widely considered best practice and had a longstanding history of developing good practice.
* The Committee asked about the number of donations and whether there are any ethnicities that do not donate. Dr Curtis explained that historically Maori and Pacific Islanders do not donate, however a number of cases of Pakeha individuals who have Maori whanau have donated. They have found that wider family, of Maori decent, are more receptive and interested in the whole project (brain banking). The response from hui have been very positive.

Summary of ethical issues (resolved)

The main ethical issues considered by the Committee and addressed by the researcher.

* The Committee asked for clarification on the governance of the tissue bank. Dr Curtis explained that the bank was established in 1994. Professor Faull founded the bank. Professor Faull and Dr Curtis are the public faces and directors of the bank, with two other full time staff. Every week there is a meeting between the four staff members. Primarily the governance structure is the four staff working and making decisions together. The committee noted that the four staff members work for Auckland University, so the governance is not independent.
* Dr Curtis explained that the brain bank staff works with special interest groups – such as wider medical groups who looks at Huntington disease (Lynette tippet and Richard Roxbrough).These groups are largely independent from the brain bank.
* Dr Curtis confirmed there is no independent governance structure or monitoring board, rather they have an internal monitoring function. Dr Curtis confirmed there is no independent formal monitoring group, explaining the brain bank has relied on informal relationships with interest groups. The committee suggests that in future an independent person may be included (this however is not a condition of the approval).
* Please explain the brain banks view on commercialisation, and how are such policies developed? Dr Curtis explained that the bank had its own research priorities, and that policy was not created on a case by case basis.
* The Committee requested explanation on the process for incidental findings. Dr Curtis explained that transparency is a value that the tissue bank group holds. For instance, the pathology report from the brain goes to the next of kin. This goes some way towards closure for the family. Any future research projects and or results of research do not go back to the family.
* Please explain whether dynamic consent is utilised? Dr Curtis explained they talk to families as a whole about the processes, whether an individual member or the full family. We do not individualise any feedback. In this sense it is dynamic. However there is not provision for the family to come back at a later date and ask for all research information from research on a family member’s brain. This means that the consent used by the brain bank is broad (rather than dynamic) consent.
* Dr Curtis explained that the consent process involves extensive in person discussions.
* The Committee queried whether health information is coded? Dr Curtis explained all information is linked with names but access is limited to the four members of brain bank, any researchers using tissue only have coded information. Only two of the four brain bank members have direct access to identifiable health information.
* The Committee asked about the use of overseas labs in relation to the future unspecified research guidelines. Dr Curtis explained that overseas banks must be able to significantly advance the field, or have an existing collaborative relationship with the tissue bank. Dr Curtis explained that they are careful to ensure any research partnerships which develop will advance their own goals and values. There is a form (material transfer agreement) which governs how the tissue to be used and that it should be returned if it is not all used during analysis.
* The Committee asked for clarification on the terms ‘onerous’ when referred to in the legal endorsement letter. Dr Curtis explained that the Human Tissue Act of 1964 stated that either the next of kin or pathologist became owner of tissue after someone passed away. Under the 1964 guidelines they could take tissue directly from next of kin, with arrangements made before death of donor. The requirement under the current Human Tissue Act 2008 now requires written consent after death, from the family. Hence a split in documentation from what it used to be – one pre mortem and one post mortem. One from the person who donates and one from next of kin.
* Dr Curtis explained the donor pack that is available for potential donors.
* The Committee asked what process is followed when a person agrees to donate and then changes their mind? Dr Curtis explained that often they don’t hear from these people. There is no active follow up – they only have participants approach us.
* The Committee queried what happens when consent is withdrawn. Dr Curtis explained that they locate the tissue and organise an undertaker for appropriate disposal appropriately, or if possible return the tissue.

Summary of ethical issues (outstanding)

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

* The Committee requested that the requirements (set by the brain bank) that are needed to be met by overseas labs (if they are to store brain tissue) be included in the PIS. This will help to explain further( to participants ) information on overseas banks and how the decisions concerning the tissue will be made.
* Committee suggested explaining why left or right handedness was important for participants (in the patient information sheets).
* Change ‘you’ to ‘your family’ when referring to pathology report being sent.

Decision

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

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| **3** | **Ethics ref:** | **14/NTA/209** |
|  | Title: | 14-0104: Study of NGM282 Extended Treatment in Patients With Primary Biliary Cirrhosis |
|  | Principal Investigator: | Dr David William Orr |
|  | Sponsor: | NGM Biopharmaceuticals Australia Pty Ltd |
|  | Clock Start Date: | 27 November 2014 |

Dr Jane Biddulph 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

* Phase II study to test a new treatment (NGM282) for primary biliary cirrhosis (PBC) in people who have failed treatment with ursodeoxycholic acid (UDCA – standard treatment)
* Dr Biddulph explained that previous studies show UDCA treatment has a maximum of 65% effective treatment rate.
* The treatment will be taught to patients with the end goal being a self-administered treatment (injection).
* The Committee commended the PIS.

Summary of ethical issues (resolved)

The main ethical issues considered by the Committee and addressed by the Researcher

* (PIS) Paragraph 5 – what will happen to my test samples? Please explain what will happen if illegal drugs are detected during blood tests. Dr Biddulph explained this information is protected under confidentiality.
* The Committee queried if this is a follow on study. Dr Biddulph explained it is not a follow on for the New Zealand participants. All New Zealand participants receive 6mg dosage.
* Committee noted 6mg is considerably higher than an earlier study. Dr Biddulph explained earlier studies have indicated 6mg is tolerable and safe.

Summary of ethical issues (outstanding)

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

* Please explain what data safety monitoring arrangements are in place.
* Please include a data safety monitoring committee, even with the small sample size. If not, please advance a reason.
* The PIS states patients cannot be pregnant prior to joining the study and must withdraw if they become pregnant during. Could the investigator also please confirm whether any safety concerns re becoming pregnant within a certain timeframe from last dose and what safety guidelines should be provided

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

* Please add what lab the study samples will be sent to. Pg.5
* Section 3 pg.2 – please make the dose explicit (currently has information not relevant to New Zealand participants). The PIS should be tailored to the New Zealand participants.
* Please amend page numbers (1of1 and 5of1 etc).
* Pg.7 PIS – include information on how long data will be kept for.
* On consent form – please review yes or no questions and remove the option if they are not optional.

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 Ms Susan Buckland and Ms Christine Crooks.

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| **4** | **Ethics ref:** | **14/NTA/213** |
|  | Title: | An Open-label Cinacalcet Study for Children 28 days - 6 yrs Receiving Dialysis |
|  | Principal Investigator: | Dr Chanel Prestidge |
|  | Sponsor: | Amgen Australia |
|  | Clock Start Date: | 27 November 2014 |

Dr Chanel Prestidge was present in person for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

* Dr Prestidge explained that there would be only 1 New Zealand participant.
* 7000 adults had been treated with the study drug in trials worldwide but there is limited data for children (<50).
* Study is phase II.

Summary of ethical issues (resolved)

The main ethical issues considered by the Committee and addressed by the Researcher

* The Committee noted the fatality of one child and the subsequent halt of the study. Dr Prestidge explained that the case of hypocalcaemia resulted in a large number of changes procedures, which have all been implemented in new procedures.
* The Committee queried whether the internal data safety monitoring is sufficient. Dr Prestidge explained that the dose information is based on weekly assessment, blood returns and compliance to study requirements. These checks mitigate risk. Dr Prestidge stated the design is satisfactorily protecting patient safety as medication is not dispensed unless the patient meets these specific criteria.
* The Committee asked for Dr Prestidge to address potential for coercion or pressure due to conflict of interest between small, vulnerable patient population and treatment provider being recruiter. Dr Prestidge explained the close relationship with patients and herself, suggesting that she did feel it could be appropriate for external person to approach and discuss initial contact about study noting it is easier for them to say no to someone outside of the team. The Committee agreed.
* The Committee noted that in New Zealand participants have right to access and correct their health information during the study.
* The Committee queried the standard practice for discussing study participation with parents, to facilitate good informed consent. Dr Prestidge explained the significant amount of time set aside to discuss with the patients and parents to run through the information thoroughly, in detail. The sponsor is also strict on this requirement.

Summary of ethical issues (outstanding)

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

* Please explain if PK testing will involve future unspecified research. If it does then HDEC requires modifications to PIS to make it in line with the Guidelines for Future Unspecified Research.
* Child assent forms for under 6 are not appropriate. Please revise, the Committee suggested contacting someone at Starship for guidance.
* Please address why participants need to give an additional tissue sample at 24 weeks. The committee recognises the need for the PK testing at the start of the study but is concerned at the extensive sampling on these young people at week 24.

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

* Please consider 1a (why is study being done) as your opening paragraph, encourages the parent to read further.
* The Committee requested more information on the safety, the fatality and what happened as a result. I.e. in order to restart this drug x y and z safety features had to be implemented.
* Review the risks section and review terminology used. Please use lay language.
* Please review personal pronouns – ‘my child’ not you.
* Add lay language study title.
* Change to NTA from CEN HDEC as approving committee.

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*).
* Justify the use of bio banking of children’s tissue. The interests of vulnerable individuals must be protected, and these individuals must not be exploited for the advancement of knowledge. (*Ethical Guidelines for Intervention Studies para* 5.31). At this stage the Committee is not convinced of biobanking on this age group, and would some solid arguments as to why it should change its stance
* Confirm whether PK testing will involve any future unspecified research and if so, 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*).

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

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| **5** | **Ethics ref:** | **14/NTA/214** |
|  | Title: | A Cinacalcet Study for Children 6yrs - 18yrs Requiring Dialysis |
|  | Principal Investigator: | Dr Chanel Prestidge |
|  | Sponsor: |  |
|  | Clock Start Date: | 27 November 2014 |

Dr Chanel Prestidge was present in person for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

* The study is Phase III.
* Randomised to standard of care or study drug and standard of care.

Summary of ethical issues (resolved)

The main ethical issues considered by the Committee and addressed by the Researcher

* Committee believes that due to the on-going need for communication and the complex nature of the study it will be inappropriate to use an interpreter in this study.

Summary of ethical issues (outstanding)

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

* Please have an age range for the assent forms. For instance 7-11, 12-15.
* Please ensure the wording is age appropriate
* Include a PIS/CF for 16-18 year olds who are able to consent for themselves.
* Provide clarification on data safety monitoring committee arrangements.
* Please consider whether Future Unspecified Use (biobanking) is appropriate for children, and provide an appropriate rationale if you believe it is.

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

* Change to NTA not CEN HDEC as approving committee.
* Committee noted first 2 pages are much more readable than the 213 study PIS. Please review whole document and make similar changes to make them easier to read.
* Pg.9 – drug is not approved for children – please amend.
* Reword terminology when discussing death.
* Regarding human tissue, please include the following information:

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| **Human tissue** |
| outline participants access (or lack of) to their tissue during the study |
| what happens to tissue if a participant withdraws? |
| is tissue going overseas? Is the location included? |
| what tests are conducted on the tissue? |
| who will have access to tissue? |
| how long the tissue will be stored? |
| how will tissue be disposed? |
| how will unexpected results or findings be communicated / managed? |
| are cultural considerations relating to use of tissue outlined? |
| explain concepts like genetics if relevant |

* For future unspecified research, please include the following:

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| **Future Unspecified Research (FUR) and Biobanking must include** |
| an indication of the type and nature of the research to be carried out and its implications for the donor, where possible, and an explanation of why the potential donor is being approached for their tissue and specifically what tissue is being sought. |
| known possible researchers or institutions that might use the tissue sample, if possible. |
| whether the donor’s sample is going to be, or is likely to be sent overseas, and where possible, to what country or countries. |
| acknowledgement that all future unspecified research in New Zealand will be subject to ethical review. However, when a tissue sample is sent overseas, unless it is sent in conjunction with a New Zealand research project, future research is likely to be considered by an overseas ethics committee without New Zealand representation. |
| whether the donor’s identity and details will remain linked with the sample or whether the sample will be de-linked. |
| a statement that if a donor consents to a tissue sample being unidentified or de-linked, they relinquish their right to withdraw consent in the future. |
| whether the donor may be contacted in the future regarding their tissue sample. Whether or not, and under what circumstances, information about the future unspecified research will be made available to the donor and/or (where relevant) their clinician. |
| acknowledgement that the donor will not own any intellectual  property that may arise from any future research. |
| whether there is provision to withdraw consent for the use of human tissue samples in the future. Where there is provision to withdraw consent, only tissue samples remaining at the time of a request to withdraw and any information held for future unspecified research may practically be withdrawn. Tissue samples or information used in research before the request to withdraw is received is unlikely to be able to be returned or  destroyed. |
| acknowledgement that the donor’s decision regarding the consent for use of their tissue sample for unspecified future research will in no way affect the quality of a donor’s current or future clinical care. |
| where and for how long a tissue sample will be stored, how it will be disposed of and whether there is a cultural protocol for its disposal. For example, information about the institution holding the tissue sample: its aims, research procedures and research governance. |
| whether or not tissue samples could be provided to other researchers and institutions, and whether or not such provision could include sending samples to other countries |
| whether or not collected samples will be provided to commercial biomedical companies or will be used in commercial research collaborations, if known. |
| what provisions will be made to ensure patient confidentiality. |
| that different cultural views may inform choice about donation of tissue; for example, for some Maori, human tissue contains genetic material that is considered to be collectively owned by whanau, hapu and iwi. |
| that cultural concerns may arise when tissue samples are sent overseas, including how tissue samples are stored and disposed of. Processes for monitoring and tracking what happens to samples may not be acceptable to donors. |
| that donors may want to discuss the issue of donation with those close to them, for example; family, whanau, hapu and iwi. |
| **Note:** FUR must be listed as OPTIONAL and must be **distinct** from the main study – this can either be a separate PIS (if there is substantial information that warrants it) or it can be a separate consent area on the consent form (if the additional tests are optional but not that different from the primary study).  **HDEC has a preference for separate PIS/CF for optional sub studies, FUR or bio banking as the information required is often different to the main study.**  For more information see the Guidelines for Future Unspecified Research <http://www.health.govt.nz/publication/guidelines-use-human-tissue-future-unspecified-research-purposes-0> |

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*).
* 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*).

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

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| **6** | **Ethics ref:** | **14/NTA/216** |
|  | Title: | Collection of Plasma Samples for Aptima HBV Quant Assay |
|  | Principal Investigator: | Professor Ed Gane |
|  | Sponsor: | Pharmaceutical Solutions Ltd |
|  | Clock Start Date: | 27 November 2014 |

Prof Ed Gane, Dr Faye Manu and Dr Sum Team Lo 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

* Plasma samples are collected from patients who are initiating therapy for treatment of chronic hepatitis B.
* Collected samples will be used to clinically evaluate the Aptima HBV Quant Assay.
* This is not a treatment, rather the taking of samples from participants who are in an existing trial and using these samples to validate a new array, which may or may not give improved biomarker information.

Summary of ethical issues (resolved)

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

* The Committee stated that the PIS is more confusing and complex than it needs to be, in that it is essentially the testing and comparison of a new assay with existing tests.
* The Committee asked why samples were being taken for future unspecified research? The researchers explained that assays can vary across genotypes. The additional tissue will further refine the assay.

Summary of ethical issues (outstanding)

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

* Please note that health data derived from the study must be stored for a minimum of 10 years according to the [Health (Retention of Health Information) Regulations 1996](http://legislation.govt.nz/regulation/public/1996/0343/latest/DLM225650.html).
* An optional PIS is required with the following information:

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| **Future Unspecified Research (FUR) and Biobanking must include** |
| an indication of the type and nature of the research to be carried out and its implications for the donor, where possible, and an explanation of why the potential donor is being approached for their tissue and specifically what tissue is being sought. |
| known possible researchers or institutions that might use the tissue sample, if possible. |
| whether the donor’s sample is going to be, or is likely to be sent overseas, and where possible, to what country or countries. |
| acknowledgement that all future unspecified research in New Zealand will be subject to ethical review. However, when a tissue sample is sent overseas, unless it is sent in conjunction with a New Zealand research project, future research is likely to be considered by an overseas ethics committee without New Zealand representation. |
| whether the donor’s identity and details will remain linked with the sample or whether the sample will be de-linked. |
| a statement that if a donor consents to a tissue sample being unidentified or de-linked, they relinquish their right to withdraw consent in the future. |
| whether the donor may be contacted in the future regarding their tissue sample. Whether or not, and under what circumstances, information about the future unspecified research will be made available to the donor and/or (where relevant) their clinician. |
| acknowledgement that the donor will not own any intellectual  property that may arise from any future research. |
| whether there is provision to withdraw consent for the use of human tissue samples in the future. Where there is provision to withdraw consent, only tissue samples remaining at the time of a request to withdraw and any information held for future unspecified research may practically be withdrawn. Tissue samples or information used in research before the request to withdraw is received is unlikely to be able to be returned or  destroyed. |
| acknowledgement that the donor’s decision regarding the consent for use of their tissue sample for unspecified future research will in no way affect the quality of a donor’s current or future clinical care. |
| where and for how long a tissue sample will be stored, how it will be disposed of and whether there is a cultural protocol for its disposal. For example, information about the institution holding the tissue sample: its aims, research procedures and research governance. |
| whether or not tissue samples could be provided to other researchers and institutions, and whether or not such provision could include sending samples to other countries |
| whether or not collected samples will be provided to commercial biomedical companies or will be used in commercial research collaborations, if known. |
| what provisions will be made to ensure patient confidentiality. |
| that different cultural views may inform choice about donation of tissue; for example, for some Maori, human tissue contains genetic material that is considered to be collectively owned by whanau, hapu and iwi. |
| that cultural concerns may arise when tissue samples are sent overseas, including how tissue samples are stored and disposed of. Processes for monitoring and tracking what happens to samples may not be acceptable to donors. |
| that donors may want to discuss the issue of donation with those close to them, for example; family, whanau, hapu and iwi. |
| **Note:** FUR must be listed as OPTIONAL and must be **distinct** from the main study – this can either be a separate PIS (if there is substantial information that warrants it) or it can be a separate consent area on the consent form (if the additional tests are optional but not that different from the primary study).  **HDEC has a preference for separate PIS/CF for optional sub studies, FUR or bio banking as the information required is often different to the main study.**  For more information see the Guidelines for Future Unspecified Research <http://www.health.govt.nz/publication/guidelines-use-human-tissue-future-unspecified-research-purposes-0> |

* Please add sponsor insurance information relating to ACC in the PIS as the study requires a ‘treatment procedures’ (blood draw) which could cause injury.

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

* Add short lay language study title.
* Please introduce study first – why patient is selected etc.(the second section) Purpose and Description etc” would be a better opening statement.
* Review consent form statements and ask whether all the points are relevant for this particular study.
* Pg.2 PIS – please explain ‘approved and not approved blood tests’ for participants – currently confusing.
* CF – 4th point. The investigator was asked who received payment and confirmed it was the institution. Therefore the CF needs to be amended.

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 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*).

This following information will be reviewed, and a final decision made on the application, by Dr Christine Crooks and Ms Michele Stanton.

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| **7** | **Ethics ref:** | **14/NTA/217** |
|  | Title: | Prophylactic administration of vancomycin prior to total knee arthroplasty in the obese patient via the intraosseous route |
|  | Principal Investigator: | Mr Simon Young |
|  | Sponsor: |  |
|  | Clock Start Date: | 27 November 2014 |

Dr Seung Joon Chin was present in person for discussion of this application.

Potential conflicts of interest

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

Ms Shamim Chagani declared a potential conflict of interest, and the Committee decided to have Ms Chagani take part in the discussion and decision of the application.

Summary of Study

* Project will be run at the North Shore Hospital.
* A near identical study has been completed. The study is being repeated on obese patients, as the amount of tissue concentration of antibiotics in this study population due to the different BMI is not known. Prior study had no inclusion exclusion criteria for BMI.
* Dr Chin explained that it was important to know whether this route of antibiotic administration was effective due to the increased risk of infection due to high BMI.
* Doses of study drug are routine, however using the drug for this procedure is novel.

Summary of ethical issues (resolved)

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

* Dr Chin confirmed all relevant groups at the localities have been informed and have signed off on the study.
* The Committee queried why age group chosen (55-85)? Dr Chin explained this will ensure the reason for surgery will consistently be osteoarthritis.
* Is a feasibility study as the title indicates? This was suggested as the title because of the interest in whether it was feasible to perform this procedure in a hospital setting in this patient group. The committee noted that it is actually a small RCT (feasibility studies do not evaluate the outcome of interest, this study does), and should be presented as such.
* The Committee asked how the data safety information and adverse events be monitored? Dr Chin explained that an experienced research nurse will record any AE and follow them up.

Summary of ethical issues (outstanding)

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

* Please explain how conflict of interests will be mitigated as study doctor will be treatment doctor. This relates to recruitment and consenting processes.

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

* Please include more basic, general, information in PIS as to why you are doing the study and why people have been chosen for the study. For example, explain that obesity is a risk factor for infection. High infection rates = longer hospital stays etc.
* Explain why higher levels of antibiotics are a good thing (PIS).
* Pg.2 – top paragraph. The Committee noted that the PIS states that only 20 patients have had this procedure but that it was a ‘common technique’ – please explain to participants how it can both be common but only studied in 20. Dr Chin explained this refers to prior study and that it is a commonly used technique but not for this particular procedure. Committee acknowledged this, and requested this explanation be included.
* Change ‘asleep’ to ‘anesthetised’.
* Please include more information on timeframes, for example in relation to analysis and how often tissue samples will be taken throughout the operation.
* Pg.3 add some context to the statement about known risks in relation to the prior study.
* Include information on how long health information will be kept.
* Please include how long follow up will be, and the full duration of the study.
* Add information on where samples will be held.
* Please add the additional blood tests, and add information about storage and destruction of these samples.
* Revisit wording on abnormal findings and or consider whether it is required.
* Add information on ACC: “If you were injured in this study, which is unlikely, you would be eligible for compensation from ACC just as you would be if you were injured in an accident at work or at home. You will have to lodge a claim with ACC, which may take some time to assess. If your claim is accepted, you will receive funding to assist in your recovery.”

If you have private health or life insurance, you may wish to check with your insurer that taking part in this study won’t affect your cover.

* Clearly state that vancamicin is not the standard antibiotic (usual knee joint surgery patients don’t get this), in either arm of the study.
* Be specific about how participants can withdraw until surgery after which they can only withdraw data.

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*).
* Explain how the conflict of interest resulting from care provider being the researcher is addressed *(Ethical Guidelines for Intervention Studies para 4.19)*

This following information will be reviewed, and a final decision made on the application, by Ms Michele Stanton and Dr Mark Smith.

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| **8** | **Ethics ref:** | **14/NTA/218** |
|  | Title: | Staphylococcus aureus transmission in New Zealand schools |
|  | Principal Investigator: | Prof David Murdoch |
|  | Sponsor: |  |
|  | Clock Start Date: | 27 November 2014 |

Prof David Murdoch, Mr Steve Chambers and Pippa Scott were present by teleconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

* The committee commended the application noting that the research an important area which needed more development.
* Participants are school children between 9 – 11 years old and adult teachers. There are four classrooms involved and about 100 participants.
* The study primarily aims to test the methodology of using sensors to gather data. The reason for the sensors is due to the fact that children of this age will not report good quality data in the online diary.

Summary of ethical issues (resolved)

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

* How will you be recruiting teachers and children? The researchers explained that a school has been approached and four classes will participate.
* The Committee queried whether observing people’s behaviour will result in changing their behaviour? Particularly in relation to the teachers. The researchers explained that this is mitigated by having two forms of observation – the questionnaires and the sensors. Prior studies show that teachers get used to them quickly and revert to what ‘seems to be’ normal behaviour.
* The Committee asked how long the participants will wear the sensors. The researchers explained that there is a 3 day ‘burn in’ period and then 2-7 days of data collection. About 2 weeks in total. Prior studies show that children also get used to them quickly and revert to what ‘seems to be’ normal behaviour.
* The Committee queried why the researchers had decided not to inform participants that they are carriers? The researchers explained that they know a high proportion of people are carriers anyway, around 20% of people in New Zealand and there is no current health intervention .A clear infection would be followed up; however being a carrier would not be medically relevant.
* The Committee queried whether the open sores may lead to a serious infection. The researchers explained that infections come and go and in most cases do not lead to any problems.
* The Committee asked for information on the burden of disease. The researchers explained that Maori and Pacific Islanders are overly burdened in having problems with the disease but as far as carriers go there is no significant difference across ethnicities.
* The Committee asked how swabs will be taken during the school day? This information is not in the protocol. The researchers stated the plan was to take 4-5 children out at a time – each classroom has a suitable area away from the remainder of the class.
* The Committee asked how the online questionnaire works, as some children may not have access to the internet. The researchers stated the school will provide online accessible tablets.
* Pg.10 protocol. Please explain how you will avoid stigma, noting the small sample size. Researchers explained they are consulting with Pacific women’s health group to help with data interpretation and dissemination of results. Researchers explained the balance between generating important knowledge to address the health inequalities as well as preventing stigma.
* Please note that health data derived from the study must be stored for a minimum of 10 years after the youngest participant turns 16 according to the [Health (Retention of Health Information) Regulations 1996](http://legislation.govt.nz/regulation/public/1996/0343/latest/DLM225650.html).
* Committee noted the closed letter that children are given to take home could pose a stigmatisation risk and should be treated with care.

Summary of ethical issues (outstanding)

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

* HDEC requires assent forms as the children are old enough to understand the study. Please create simple, 1-2 page assent forms for the children to read and sign to indicate their willingness to participate.
* Please explain treatment access if a sore is identified as significant, as GP visits will cost. Researchers explained that they wanted to only observe and not provide any interventions. Please explain the schools usual process with relation to sores and injuries and how the study meets minimum treatment requirements.

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

* Please amend the titles of each PIS to make it clear that one is for teachers and one is for parents of children.
* The Committee requested that information on how study participation will involve in-class time is included in the PIS.
* Regarding the withdrawal rights at end of the CF – please add a right not to answer all questions.
* Add information regarding parents likely needing to help children fill them out.
* Include more information on samples being taken on the PIS for parents in relation to genetic testing (on the bacteria). Please review the HDEC checklist for informed consent found at <http://ethics.health.govt.nz/home>

Decision

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

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| **9** | **Ethics ref:** | **14/NTA/220** |
|  | Title: | FX006 for the Treatment of Pain in Patients with Osteoarthritis of the Knee |
|  | Principal Investigator: | Dr Dean Quinn |
|  | Sponsor: | Flexion Therapeutics |
|  | Clock Start Date: | 27 November 2014 |

Dr Dean Quinn was present by teleconference for discussion of this application.

Potential conflicts of interest

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

Dr Christine Crooks declared a potential conflict of interest, and the Committee decided that it was appropriate to take part in the discussion and the decision of the application.

Summary of Study

* The study is a randomised, double blinded, single dose study design to assess the safety and efficacy of FX006 (study drug) in patients with osteoarthritis of the knee.
* There are three arms 40 mg FX006 (study drug), normal saline (placebo), or 40 mg TCA IR (standard treatment).
* 84 New Zealand participants.

Summary of ethical issues (resolved)

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

* Dr Quinn confirmed standard treatment is also a steroid, explaining that the study drug is the same drug but in an extended release form. The amount given is the same (40mg).
* The Committee requested a justification of the placebo arm noting this was a 27 week study. Is this fair given the pain resulting from this disease? Dr Quinn explained that when subjective pain is an outcome in a study it needs a placebo arm to validate the reported pain. The placebo arm is scientifically required.
* Dr Quinn confirmed risk of infection is low.
* The Committee asked how side effects will be managed. Dr Quinn explained that the participants will be monitored frequently during the study.
* Dr Quinn confirmed that the DSMC was provided by the sponsor.

Summary of ethical issues (outstanding)

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

* Please explain whether the FDA clinical hold has been released on this trial.
* R.5.4 The Committee noted that there will be conflicts of interest in recruitment. Please explain how conflicts of interest will be managed.

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

* Please remove duplication.
* Suggest your opening paragraph should be “What is the Aim of this Research Project” and move the existing opening paragraph to the end where you thank them for showing interest in the project etc”
* Heading 17 – compensation and ACC. Please amend to ensure ACC equivalent coverage is available and make it clear to participants.
* Include dosages of radiation. The Committee suggests using the information from the application.
* Change emergency number from 999 to 111.
* Pg.3 there is a word missing ‘urine sample selection…and a drug (test).

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*).
* Explain how the conflict of interest resulting from care provider being the researcher is addressed *(Ethical Guidelines for Intervention Studies para 4.19)*
* Confirmation that the FDA clinical hold has been removed

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

## General business

1. The Committee noted the content of the “noting section” of the agenda.
2. The Committee discussed sponsored trials, injuries and the relationships between sponsors, insurance companies and participants. The Committee discussed how a sponsor should assure the Committee that participants will be adequately supported during any disputes made by the insurance company in relation to a participant claim, and that it is the sponsor’s obligation to satisfy the participant (the participant is indifferent to any business between the sponsor and the insurer).
3. The Committee discussed bio-banking and the need for the conditions of chapter 13 of the SOP to be met by future unspecified research.
4. The Chair reminded the Committee of the date and time of its next scheduled meeting, namely:

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| --- | --- |
| **Meeting date:** | 10 February 2015, 1pm |
| **Meeting venue:** | Novotel Ellerslie, 72-112 Greenlane Rd East, Ellerslie, Auckland |

The following members tendered apologies for this meeting.

1. Ms Michele Stanton
2. **Last Minutes**

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

The meeting closed at 5.20pm