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| **Committee:** | Northern A Health and Disability Ethics Committee |
| **Meeting date:** | 10 June 2014 |
| **Meeting venue:** | Novotel Ellerslie, 72-112 Greenlane Rd East, Ellerslie, Auckland |

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| **Time** | **Item of business** |
| 1.00pm | Welcome |
| 1.10pm | Confirmation of minutes of meeting of 13 May 2014 |
| 1.30pm | New applications (see over for details) |
|  | i 14/NTA/77  ii 14/NTA/81  iii 14/NTA/82  iv 14/NTA/85  v 14/NTA/86  vi 14/NTA/83  vii 14/NTA/76  viii 14/NTA/87 |
| 4.50pm | General business:   * Noting section of agenda |
| 5.10pm | 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 | 01/07/2014 | Present |
| Mr Kerry Hiini | Lay (consumer/community perspectives) | 01/07/2012 | 01/07/2014 | Present |
| Ms Michele Stanton | Lay (the law) | 01/07/2012 | 01/07/2014 | Present |
| Dr Karen Bartholomew | Non-lay (intervention studies) | 01/07/2013 | 01/07/2016 | Apologies |
| Dr Christine Crooks | Non-lay (intervention studies) | 01/07/2013 | 01/07/2015 | Present |

## Welcome

The Chair opened the meeting at 1.12pm and welcomed Committee members, noting that apologies had been received from Dr Karen Bartholomew.

The HDEC Secretariat will send members the revised protocol on tissue banking from Middlemore Hospital.

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 13 May 2014 were confirmed.

## New applications

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| **1** | **Ethics ref:** | **14/NTA/76** |
|  | Title: | GS-US-337-1118 |
|  | Principal Investigator: | Professor Ed Gane |
|  | Sponsor: | Gilead Sciences, Australia & New Zealand |
|  | Clock Start Date: | 27 May 2014 |

No researchers 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.

Dr Christine Crooks declared a potential conflict of interest, and the Committee decided that she would take full part in the discussions.

Summary of ethical issues

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

* The Committee noted that this was a continuation of one of Professor Gane’s Hepatitis studies and this was an opportunity for people who had not received benefit from a previous trial to take part in this study.
* The Committee noted that this was Phase II study which was looking at the safety of the drug, rather than the efficacy. The Committee were concerned that this was not clear in the PIS and asked that wording to the effect of “this is a Phase II study, looking at the safety of the study drug” was added to the end of the first paragraph of the PIS.
* The Committee noted that there was no evidence of a DSMB and asked for justification on this and how adverse events will be monitored.
* The Committee noted that it is not clear in the PIS that this study will involve future unspecified research. Please include information on future unspecified research in the PIS under a separate heading. This should include the following information:
  + Whether future studies will be reviewed by a New Zealand Ethics Committee
  + Whether patients’ data will be de-linked or linked. If the data will be de-linked, the patient needs to know that they have no right to the information in the future and they can’t withdraw from the study.
  + Please acknowledge that if participants do not want to participate in the future unspecified research, it will not affect their care,
  + Where the sample will be stored, for how long and the governance procedures of storage.
  + Please review further information for participants providing samples for unspecified future use included in the *Guidelines for the Use of Human Tissue for Future Unspecified Research Purposes* at <http://www.health.govt.nz/publication/guidelines-use-human-tissue-future-unspecified-research-purposes-0>
* The Committee asked for confirmation on what will happen if there are incidental findings from the genetic testing.
* The Committee requested the following changes to the PIS and consent form:
  + Please provide information on future unspecified research.

Decision

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

* Please amend the PIS 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, Ms Susan Buckland and Ms Michele Stanton.

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| **2** | **Ethics ref:** | **14/NTA/77** |
|  | Title: | PRINCE Study |
|  | Principal Investigator: | Dr Colin McArthur |
|  | Sponsor: |  |
|  | Clock Start Date: | 29 May 2014 |

Dr Colin McArthur and Ms Rachel McConachy 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.

Dr Christine Crooks declared a potential conflict of interest, and the Committee decided that she would take full part in the discussions.

Summary of ethical issues

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

* Dr McArthur explained that this was a small cohort observational study of patients admitted to ICUs as a result of neurological disease. This will contribute to a worldwide study of 150 ICUs, comparing New Zealand treatment of neurological conditions with other ICUs.
* The Committee advised the researcher to ensure that the Health Information Privacy Code is complied with. Dr McArthur confirmed that only age, sex, ethnicity and diagnosis will be collected and this will not be able to be linked back to the individual.
* The Committee asked whether cultural consultation would have been helpful. Dr McArthur explained that they had no influence on the protocol as the study originated in the US and that as the number of patients is likely to be small (between two and ten) there was benefit in seeking cultural consultation. Dr McArthur confirmed that the information collected will be from an existing case record and will be retrospectively collected by the ICU nurses.
* The Committee asked whether Baylor College of Medicine Ethics Committee who had provided the peer review had any comments or changes. Dr McArthur confirmed that it had been approved outright with no comments. The study has also been approved by the Auckland DHB Review Committee.
* The Committee asked if Dr Helen Wihongi had approved the study. Dr McArthur was unsure but advised that it would be going through the review process.
* The Committee asked if patients’ NHI number would be collected. Dr McArthur explained that as the focus is on diagnosis and treatment, this will not be collected.
* Dr McArthur noted that Baylor College of Medicine is a highly reputable, well regarded neurocritical care centre. Auckland DHB had become involved in the study as Baylor had contacted intensive care collaborative research groups. Dr McArthur confirmed that Auckland was the only ICU involved in New Zealand, with an additional six coming from Australia.

Decision

This application was *approved* by consensus.

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| **3** | **Ethics ref:** | **14/NTA/81** |
|  | Title: | G.I.F.T.The Goal dIrected perFusion Trial |
|  | Principal Investigator: | Mr Tim Willcox |
|  | Sponsor: |  |
|  | Clock Start Date: | 29 May 2014 |

Mr Tim Willcox was present in person for discussion of this application.

Potential conflicts of interest

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

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

Summary of ethical issues

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

* Mr Willcox explained that a heart and lung machine is used during cardiac surgery and the normal practice to manage blood flow rates is based on a patient’s body surface area. Recent research has provided an alternative blood flow strategy based on oxygen delivery measures, known as the Goal Directed Perfusion (GDP). This tailors oxygen flows to what the body needs rather than just using a formula. These measures are obtained from the computers in heart lung machines, which deliver real time data and can process instant measures of oxygen delivery. Mr Willcox noted that rates of acute kidney injury after surgery are not uncommon, with international literature estimating rates of around 40%. A few small studies have shown that if oxygen levels are maintained above a certain level, there is a reduction in post-operative kidney injury. At present there has been no decent sized randomised, controlled trial to demonstrate this.
* Mr Willcox advised that this trial has been organised by Marco Ranucci in Italy who invited New Zealand to be part of it.
* The Committee asked if the researcher was satisfied that this study met the equipoise standard. Mr Willcox explained that he was satisfied as the body surface area management strategy has been used long term and while the GDP is used variably, it is not a new technique.
* Mr Willcox noted that a secondary hypothesis is to investigate blood transfusion triggers.
* The Committee asked if cardiac staff supported this study. Mr Willcox advised that he had done a presentation to the cardiac and anaesthesia departments to ensure that they were in support of the study. Dr Paget Milsom, Clinical Director of Cardiac Surgery at Auckland City Hospital is also a co-investigator on the study.
* The Committee were concerned that some of the PIS was not in lay language. Mr Willcox explained that the CVICU nurses would be available during the consent process to answer participants’ questions.
* The Committee asked how this study would be recruited. Mr Willcox explained that the CVICU nurses will approach potential participants.
* The Committee asked whether the researchers had considered obtaining peer review from outside of Auckland DHB, for example from another cardiac centre in Australasia. Mr Willcox agreed to obtain further peer review.
* The Committee asked whether there was a data safety monitoring board for the study. Mr Willcox advised that the advisory board will analyse the data after 25%, 50% and 75% of the patients are enrolled.
* The Committee requested the following changes to the PIS and consent form:
  + Please amend “Injury Prevention, Rehabilitation and Compensation Act” to “Accident Compensation Act” on page 2 of the PIS.
  + Please include in the PIS that this study has received ethical approval from the Northern A Health and Disability Ethics Committee.
  + Please remove the sentence “if you feel there is a problem, you should alert the staff caring for you” from the risks section of the PIS.
  + Please include in the risks section of the PIS that data will be analysed at 25%, 50% and 75% of enrolment.

Decision

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

* Please amend the PIS and consent form, taking into account the suggestions made by the Committee *(Ethical Guidelines for Intervention Studies, para 6.22).*
* Please provide additional peer review of the study *(Ethical Guidelines for Intervention Studies, para 5.11).*

This information received will be reviewed, and a final decision made on the application, by Mr Kerry Hiini, Ms Shamim Chagani and Dr Brian Fergus.

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| **4** | **Ethics ref:** | **14/NTA/82** |
|  | Title: | Dent's disease in New Zealand |
|  | Principal Investigator: | Dr William Wong |
|  | Sponsor: |  |
|  | Clock Start Date: | 29 May 2014 |

Dr William Wong was present in person for discussion of this application.

Potential conflicts of interest

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

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

Summary of ethical issues

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

* Dr Wong explained that Dent’s Disease is a rare form of kidney disease, characterised by kidney stones. It affects several hundred families around the world, with males being affected and females carrying the gene.
* Researchers at Starship Hospital have found a large extended family in New Zealand who have the gene. This family includes four generations, with around 44 extended family members.
* This study is an opportunity to characterise the genetics and clinical features of this condition mutation. Dr Wong advised that some of the families have their own genetic mutation of the condition and this study will characterise this specific family’s genetic mutation.
* The Committee asked if there is there any treatment that can be offered based on knowledge gained from this study. Dr Wong explained that there is no cure for the condition but preventative treatment can be offered. Kidney failure may be able to be reduced if calcification of the kidney can be prevented.
* Dr Wong advised that an international collaborative study is also being done at the Mayo Clinic in the United States. This study is trying to collect information and genetic samples from as many families as possible to characterise their genetic features. He said that the family involved in his study is also welcome to join this collaborative study if they wish.
* The Committee asked if the family were worried about the risk of stigmatisation. Dr Wong explained that the family have had extensive discussions amongst themselves and seem keen to participate in this study. He said they do not appear to be worried about stigmatisation.
* Dr Wong advised that the results of this study will be analysed and eventually published. This study is an opportunity to increase knowledge of Dent’s Disease.
* Dr Wong confirmed that this is a European family and that there are no Māori members in the family. He consulted with Auckland DHB who advised that if he is sure of this, Māori consultation is not required.
* The Committee asked if there is any chance of incidental findings from the genetic testing. Dr Wong advised that this is unlikely as only the gene particular to this condition will be looked at
* The Committee asked whether there would be any sample left over after the testing. Dr Wong confirmed that there would be a small sample. The Committee noted that point 7 on the consent form gives an option for participants to have their sample destroyed. Dr Wong agreed to remove the option and note that all samples would be destroyed.
* The Committee asked how a positive result would be managed. Dr Wong advised that counselling would be provided from Genetic Health Service New Zealand, along with a local regional kidney service.
* The Committee asked whether this would be part of a patient’s health record. Dr Wong confirmed that it would be as participants would have a kidney disease which would need to be treated.
* Dr Wong noted that this study would only be testing males and that testing females to see if they are carriers of the gene may be done at a later stage.
* The Committee requested the following changes to the PIS and consent form:
  + Please create an age appropriate PIS for children, with an assent form.
  + Please include in the PIS that this study has been approved by the Northern A Ethics Committee.
  + Please amend “Injury Prevention, Rehabilitation and Compensation Act” to “Accident Compensation Act” on page 3 of the PIS.

Decision

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

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

This information received will be reviewed, and a final decision made on the application, by Dr Brian Fergus and Dr Christine Crooks.

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| **5** | **Ethics ref:** | **14/NTA/83** |
|  | Title: | Wheeze And Steroids in Preschoolers (WASP) study |
|  | Principal Investigator: | Dr Stuart Dalziel |
|  | Sponsor: |  |
|  | Clock Start Date: | 29 May 2014 |

Dr Stuart Dalziel 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 ethical issues

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

* Dr Dalziel explained that this study was very similar to a pilot study which was approved in 2012. The original study was a randomised, controlled trial of prednisolone vs placebo, in one, two, three and four year olds. This study does not involve one year olds as evidence suggests that steroids have no benefit for them and this could skew the results. The sample size for this study has also been increased.
* The Committee asked for clarification on the peer review process. Dr Dalziel explained that he did not receive the comments of the HRC peer review process but had received funding. He said that the Auckland Research Review Committee did not have any concerns and thought that it was a worthwhile study. The Committee accepted this.
* Dr Dalziel advised that he is currently going through the Māori review process at Auckland DHB and Counties Manukau District Health Board. He said that in the past the Māori review committees were supportive due to the number of Māori children seen in emergency departments and the rates of respiratory illness in Māori.
* The Committee asked why there was no DSMB for the study. Dr Dalziel advised that he does not expect there to be any safety issues as the children are receiving standard care, which they would still be receiving even if they did not take part in the study. He noted that the steering committee would look at serious adverse events that colleagues may notify him of.
* The Committee noted that there were patient labels on the CRFs and questionnaires and asked whether it was possible to include study IDs. Dr Dalziel explained that some of the CRFs will be completed by doctors and nurses in the emergency department. To avoid confusion patient labels will be applied. These will be removed by the study nurses and study ID applied before study documents are filed.
* The Committee asked if there would be interpreters available for participants. Dr Dalziel explained that this was as part of standard emergency care. He said that there is usually a family member who can translate.
* The Committee requested the following changes to the PIS and consent form:
  + Please add “for parents and guardians” to the PIS title.

Decision

This application was *approved* by consensus.

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| **6** | **Ethics ref:** | **14/NTA/85** |
|  | Title: | A psycho-educational intervention for patients with PTSD symptomatology following cardiac intensive care treatment. |
|  | Principal Investigator: | Ms Fleur Bethell |
|  | Sponsor: | Massey University |
|  | Clock Start Date: | 29 May 2014 |

Ms Fleur Bethell 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 ethical issues

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

* The Committee asked whether Ms Bethell’s supervisor was available and noted that it would have been helpful if they were involved in the discussions.
* The Committee asked how the sample size had been calculated. Ms Bethell advised that she had used an online power analysis, which had worked out that 30 participants per group were needed. She had discussed this number with her supervisor as it was quite a large number. She noted that the clinical advisor at Auckland Hospital thought she would only be able to recruit two or three per week which would take six to seven weeks. After discussions with her supervisor, she agreed to reduce the number to around 20 per group and explain this reduction in her thesis.
* The Committee expressed concern that this was a Master’s study and hence should be treated as a pilot study (testing the process) and that consequently her study was overpowered and a smaller sample size would suffice.
* Ms Bethell explained that participants would be recruited from the pre-surgical clinic at Greenlane Hospital.
* The Committee asked whether the researcher would have access to participants’ medical records. Ms Bethell confirmed that she would not be accessing medical records but she has been asked by the Clinical Director at Greenlane Hospital to collect information on the number of days participants were kept in hospital.
* Ms Bethell advised that at recruitment, potential participants who have any previous psychological conditions will be identified and excluded from the study.
* Ms Bethell explained that participants will complete a survey one week before surgery to get a baseline measure. They will also be asked to complete the survey one week and four weeks after the surgery.
* The Committee asked if the questionnaires were validated and developed for this type of study. Ms Bethell advised that both the brief COPE survey and the impact of events scale, which is designed for an older population and assesses the impact of a traumatic event, are widely used and recognised in research.
* The Committee asked whether the researcher could distance herself from recruitment so potential participants do not feel as if they are unable to refuse to take part in the study, for example, a nurse asking them before the researcher. Ms Bethell agreed that this could be done.
* The Committee asked how the researcher will know that participants have done the physical and psychological exercises. Ms Bethell advised that there would be spaces in the manual to complete this but it would be assumed that this was filled out honestly.
* The Committee asked if a letter of support had been provided from the cardiologist involved in the study. Ms Bethell advised that Dr Andrew McKee had signed the Auckland DHB application agreeing that he is happy for the study to be done there. The Committee asked that a letter of support from Dr McKee be provided.
* The Committee asked what experience the researcher had in dealing with psychological tests. Ms Bethell noted that she had no experience but the manual was based on other self-help manuals and her clinical supervisor Ian de Terte had overseen the development of the study.
* The Committee asked if the researcher had any idea of the recovery process for patients undergoing cardiac surgery. Ms Bethell noted that Dr McKee thought that patients would be up to this study as the study is not intensive and mainly involves reading, breathing and relaxation techniques. She said that the reading would only take about 30 to 45 minutes per week.
* The Committee noted that any documents that the participant will see, for example patient diaries and study manuals, should have been uploaded as part of the application.
* The Committee noted that the peer reviewer had questions on the timeframe being too short and asked how this would be addressed.
* The Committee asked whether recruitment would take place before or after the participant had seen their doctor. Ms Bethell advised that she was unsure of this as it would depend on what best suited the participant and the doctor. The Committee advised that this would need to be considered as the outcome may be different depending on whether participants had seen their doctor or not.
* The Committee noted that the questionnaires should have a study ID and not patient names to protect confidentiality.
* The Committee asked about the Māori consultation process. Ms Bethell advised that she had consulted with Trish Young at Massey and had a letter from Dr Helen Wihongi from Auckland DHB. She agreed to send the letter to the Committee.
* The Committee noted that there was a contradiction in the answers to P.4.2 and P.4.3 and recommended that the researcher reviews the Health Research Council’s *Guidelines for Researchers on Health Research Involving Māori.*
* The Committee requested the following changes to the PIS and consent form:
  + Please include more symptoms of PTSD in lay language on page 3 of the PIS.
  + Please include more information in the PIS on what is involved for participants, one week before, one week and four weeks after surgery. The Committee recommended a flowchart.
  + Please change the reference to the Central Region Ethics Committee to Northern A Ethics Committee on page 6 of the PIS.
  + Please notify participants in the consent form if academic supervisors or others will be looking at the data.
  + Please include a version number and page numbers for the PIS and consent form.

Decision

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

* Please amend the PIS and consent form, taking into account the suggestions made by the Committee *(Ethical Guidelines for Intervention Studies, para 6.22).*
* Please provide a letter of support from the Clinical Director at Greenlane Hospital *(Ethical Guidelines for Intervention Studies, para 6.2).*
* Please provide evidence of Māori consultation from Auckland DHB and Massey University *(Ethical Guidelines for Intervention Studies, para 4.7).*
* Please upload all outstanding documents including patient diaries *(Ethical Guidelines for Intervention Studies, para 6.22).*
* Please clarify how the peer reviewers comments that the timeframe is too short will be addressed *(Ethical Guidelines for Intervention Studies, para 5.11)*

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

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| **7** | **Ethics ref:** | **14/NTA/86** |
|  | Title: | Canagliflozin and Renal Events in Diabetes with Established Nephropathy |
|  | Principal Investigator: | Dr John Baker |
|  | Sponsor: | Janssen Cilag (New Zealand) Ltd |
|  | Clock Start Date: | 29 May 2014 |

Dr John Baker 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 ethical issues

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

* Dr Baker explained that this is a Phase 4 study of a drug for glucose control and weight reduction for patients with diabetes. The drug is not yet registered for use in New Zealand but is registered in the US, Europe and Australia.
* Dr Baker noted that in previous studies, the drug was quite well tolerated by patients. As the drug works by promoting glucose secretion through the kidneys, this study is investigating how effective the drug is when kidney function is impaired. Dr Baker said that the current information suggests that the drug does not affect renal outcomes.
* The Committee noted that the term “banking” in section 13 of the optional pharmacogenomic PIS was confusing as it implied that a tissue bank is being set up. Mrs Howie confirmed that the tissue samples will be destroyed after 15 years. Please amend the reference from “banking” to “long term storage”.
* The Committee asked if there was future testing being planned for the stored tissue. Dr Baker confirmed that PK testing is not usually done until after the study has finished. The Committee advised that it needs to be clear in the PIS if the testing will be specified or unspecified and what will happen to the samples. Mrs Howie confirmed that the samples will be de-identified and that patients will not be getting results of the testing. Please refer to the *Guidelines for the Use of Human Tissue for Future Unspecified Research Purposes* at <http://www.health.govt.nz/publication/guidelines-use-human-tissue-future-unspecified-research-purposes-0> for further information.
* The Committee asked for clarification on the withdrawal of consent form. Dr Baker explained that participants can withdraw at any stage and that this form is to ensure that researchers can find out what has happened to participants at the end of the study.
* The Committee asked for clarification on “medical records or public records” on page 15 of the PIS. Dr Baker explained that this was related to patient outcomes and referred to publicly available documents, for example death certificates.
* Dr Baker advised that Māori consultation was being done as part of the locality assessment and that each site would undergo Māori research review. The Committee asked that this is sent to the HDEC Secretariat when it is received.
* The Committee asked if the researchers anticipated any issues with people not wanting to take place in the study as they may be on a placebo for five years. Dr Baker confirmed that the placebo is on top of standard care. Mrs Howie noted that people may want to take part in the study as they will be more closely monitored than those with standard care.
* The Committee asked if eligibility is not confirmed until after the run in phase. Dr Baker confirmed this. The Committee asked that this be made clearer in the PIS.
* The Committee noted that the study is being run in 27 other countries and asked if it has been approved in any other places. To her knowledge, Mrs Howie is not aware that it has received approval in any other country but Dr Baker reiterated that this is a registered medicine in some countries.
* The Committee were concerned about the length and repetition in the PIS and would encourage the researchers to reduce it where possible, for example information on page 9 and page 13 is repeated. Sponsors should be aware that PIS’s should be readable to participants, so reduce unnecessary jargon, duplication and legalese.
* The Committee asked that drug companies are reminded that participants are giving up their ACC rights to take part in clinical studies and to ensure that appropriate insurance provisions are in place for participants.
* The Committee requested the following changes to the PIS and consent form:
  + Please add “New Zealand” to “industry guidelines” under the section on what if something goes wrong on page 15 of the PIS.
  + Please amend the reference to “banking” in section 13 of the optional pharmacogenomic PIS.

Decision

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

* Please amend the PIS 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 Mr Kerry Hiini and Dr Christine Crooks.

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| **8** | **Ethics ref:** | **14/NTA/87** |
|  | Title: | IDX-04B-004: A study of Samatasvir and IDX21437 with or without Ribavirin in Subjects with Hepatitis C. |
|  | Principal Investigator: | Professor Edward Gane |
|  | Sponsor: | Idenix Pharmaceuticals, Inc. |
|  | Clock Start Date: | 29 May 2014 |

No researchers were 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 ethical issues

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

* As no researchers were available for interview, the Committee had some difficulty understanding the study.
* The Committee asked for clarification on whether the pharmacokinetic research is optional as page 4 of the main PIS says that this is not optional. If it is not, please remove the word “optional” from the title of the Optional Pharmacokinetic (PK) Research Sub Study PIS.
* The Committee asked for clarification on the sentence “the samples will be shipped from Covance to PRA, located at United States, at Sponsor request, for future pharmacokinetic testing” on page 3 of the PK testing PIS. Does this testing relate to this study?
* The Committee asked for confirmation on whether genetic testing is for a specific gene. This needs to be specified in the PIS.
* The Committee asked for clarification on “sensitive information about your physical or mental health or condition” under what are my rights on page 11 of the PIS. Please clarify what sensitive information will be collected and for what purpose.
* The Committee asked for justification of the inclusion of the sentence “Information about you and your health that might identify you may be given to others to carry out the research study”, on page 12 of the PIS.
* The Committee considered that more peer review might be desirable for such projects where New Zealand is the first site in the world where ethics approval is being sought. We would be interested in the researcher’s views of how this might be addressed.
* In view of the number of other studies being conducted by this researcher, and the specialised nature of the work, the Committee thought it would be helpful if the researcher could prepare a brief synopsis of how all these studies relate to one another. The Committee is not questioning the importance of this work for people with this disease – just how it all relates together. If he prefers, Professor Gane could come to the next meeting to discuss this.
* The Committee requested the following changes to the PIS and consent form:
  + Please clarify whether the pharmacokinetic testing is optional.
  + Please specify what the future pharmacokinetic testing will involve.

Decision

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

* Please amend the PIS and consent form, taking into account the suggestions made by the Committee *(Ethical Guidelines for Intervention Studies, para 6.22).*
* Please provide results of SCOTT review *(Ethical Guidelines for Intervention Studies, para 5.11).*

This information received will be reviewed, and a final decision made on the application, by Dr Brian Fergus, Dr Christine Crooks and Mr Kerry Hiini.

## 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:** | 8 July 2014, 01:00 PM |
| **Meeting venue:** | Novotel Ellerslie, 72-112 Greenlane Rd East, Ellerslie, Auckland |

No members tendered apologies for this meeting.

The meeting closed at 4.51pm