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| **Committee:** | Southern Health and Disability Ethics Committee |
| **Meeting date:** | 18 November 2014 |
| **Meeting venue:** | Sudima Hotel, Christchurch Airport, 550 Memorial Avenue, Christchurch |

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| **Time** | **Item of business** |
| 12.00pm | Welcome |
| 12.15pm | Confirmation of minutes of meeting of 14 October 2014 |
| 12.30pm | New applications (see over for details) |
|  | i 14/STH/170  ii 14/STH/175  iii 14/STH/176  iv 14/STH/177  v 14/STH/178  vi 14/STH/179  vii 14/STH/180 |
| 2.50pm | General business:   * Noting section of agenda |
| 3.15pm | Meeting ends |

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| **Member Name** | **Member Category** | **Appointed** | **Term Expires** | **Apologies?** |
| Ms Raewyn Idoine | Lay (consumer/community perspectives) | 01/07/2012 | 01/07/2015 | Present |
| Mrs Angelika Frank-Alexander | Lay (consumer/community perspectives) | 01/07/2012 | 01/07/2015 | Present |
| Dr Sarah Gunningham | Non-lay (intervention studies) | 01/07/2012 | 01/07/2015 | Present |
| Dr Nicola Swain | Non-lay (observational studies) | 01/07/2012 | 01/07/2015 | Present |
| Dr Mathew Zacharias | Non-lay (health/disability service provision) | 01/07/2012 | 01/07/2015 | Apologies |
| Dr Devonie Waaka | Non-lay (intervention studies) | 01/07/2013 | 01/07/2016 | Present |
| Assc Prof Mira Harrison-Woolrych | Non-lay (intervention studies) | 01/09/2014 | 01/09/2015 | Present |
| Dr Fiona McCrimmon | Lay (the law) | 01/09/2014 | 01/09/2015 | Apologies |

## Welcome

The Chair opened the meeting at 12.00pm and welcomed Committee members, noting that apologies had been received from Dr Mathew Zacharias and Dr Fiona McCrimmon.

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 14 October 2014 were confirmed.

## New applications

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| **1** | **Ethics ref:** | **14/STH/170** |
|  | Title: | Investigating the high incidence of Maori and Polynesian children with autoimmune neurological disease in New Zealand |
|  | Principal Investigator: | Dr Hannah Jones |
|  | Sponsor: |  |
|  | Clock Start Date: | 06 November 2014 |

Dr Hannah Jones 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

* The study aims to investigate autoimmune neurological disease in Australasian children.
* The study involves accessing health information, questionnaires and HLA tissue testing.
* The Committee noted the application was confusing due to each disease (Sydenham’s chorea and anti-NMDAR encephalitis) being addressed at different stages of the application. In future applications the Committee suggest separating the application into two in order to fully answer the questions as they relate to each part of the study.
* Committee noted title is actually a hypothesis and is misleading. The Committee suggested ‘HLA typing and ethnicity of children with autoimmune disease in Australasia.

Summary of ethical issues (resolved)

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

* The Committee queried how participants in New Zealand would be identified. Dr Jones said that 15 participants will be identified through laboratory clinical notes.
* The Committee queried why participants from Australia were recruited, noting that the title suggests the study relates to New Zealand? Dr Jones acknowledged that the title was misleading and that they were conducting testing and accessing data in New Zealand and Australia.
* The Committee queried what ethnicities are expected from the Australian participant group? Dr Jones stated most are European but there may be some Pacific Islanders.
* Dr Jones explained that the study will assess ethnicities with the hypothesis that Maori and Pacific Islanders will be over represented. The study then aims to identify a genetic disposition which explains the prevalence.

Summary of ethical issues (outstanding)

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

* Dr Jones stated that the study will involve 0-18 year olds. The Committee requested the age group is limited to 6-18 year olds.
* The Committee noted that there must be age appropriate patient information sheets. The age groups are 6-11, 12-15, 15-16 year olds (and then the current ‘adult’ form). Any participants who are 16 may consent on their own and the research team is responsible for identifying those younger participants who may be competent to provide consent. In cases where children cannot consent they should assent by signing an assent form. Examples of PIS for children are here: <http://ethics.health.govt.nz/guidance-materials/example-templates-assent-forms>
* The study should also have a PIS for parents of children who are participating and this should be labelled as such.
* The Committee queried what happens to HLA tissue after the study tests have been conducted. Dr Jones explained that the tissue would be stored for 20 years. The Committee noted that the PIS states that samples can be returned or destroyed.
* The Committee asked how long the study related tests will take. Dr Jones stated one year, but there may be future tests. The Committee explained that any future tests must be consented to by using a separate, optional consent form as they are not specifically part of the study. Please see <http://www.health.govt.nz/publication/guidelines-use-human-tissue-future-unspecified-research-purposes-0> and <http://ethics.health.govt.nz/system/files/documents/pages/features_of_informed_consent_-_hdec_checklist_template_-_research.doc> and <http://ethics.health.govt.nz/system/files/documents/pages/piscf_template-17oct2014.doc> for examples.
* Please submit the evidence of peer review outlined in your application.

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

* Add page numbers, add footer.
* Add an appropriate lay title.
* Review HDEC template for guidance on what information to include for participants.
* Add information on cultural considerations for Maori, particularly relating to tissue analysis and for genetic testing. Please view the Te Ara Tika document available from the Health Research Council website.

Decision

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

* Please amend the information sheet and consent form, and assent forms, taking into account the suggestions made by the Committee (*Ethical Guidelines for Observation Studies* *para 6.11*).
* Please provide an assent form for non-consenting participants to sign (*Ethical Guidelines for Observation Studies 6.21)*
* Please provide evidence of favourable independent peer review of the study protocol (*Ethical Guidelines for Observational Studies* Appendix 1).
* Address the outstanding ethical issues in a cover letter.

This following information will be reviewed, and a final decision made on the application, by Ms Raewyn Idoine and Dr Sarah Gunningham.

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| **2** | **Ethics ref:** | **14/STH/175** |
|  | Title: | KCP-330-501-Selinexor in Diabetic Foot Ulcer Patients |
|  | Principal Investigator: | Dr Edward Watson |
|  | Sponsor: | Karyopharm Therapeutics, Inc. |
|  | Clock Start Date: | 06 November 2014 |

Dr Edward Watson 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

* A Phase 1/2, Multi Dose, Evaluator Blinded, Randomized, Vehicle and Standard of Care Controlled Dose Escalation Study to Assess Safety, Tolerability, and Pharmacokinetics of Topical Selinexor (KPT330) in Subjects with Diabetic Foot Ulcers (DFU).
* The compound has been used to treat tumours but it is novel as a treatment for DFU.
* The Committee commended the completion of section R.1.1.
* The committee queried why only two ulcers would be selected for treatment? Dr Watson explained that this was a Sponsor request and confirmed it was a pragmatic option, adding standard of care is what will occur for any other ulcers.
* Committee queried if there is a risk of cancer from study drug? Researcher stated no, not at this dose. Acknowledged the risk in animal studies but this was minor and not expected in this study / dose.

Summary of ethical issues (resolved)

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

* Dr Watson confirmed study has gone to SCOTT.
* The Committee queried what adverse reactions (side effects) are possible as the dosage for topical is reportedly much lower than for oral treatment for which adverse reactions are listed. The Committee noted that topical treatments can be absorbed at high levels so it was appropriate to list possible adverse reactions, but ensure it is clear that these reactions have generally occurred at much higher oral doses.
* The Committee queried whether it is mandatory for the GP to be informed of study participation. Dr Watson stated he felt it should be. The Committee agreed and requested that the GP is informed, and that participants are made aware of this by having a statement on the CF stating: ‘by participating in this study you are informing your GP’. By signing the consent they are therefore consenting to GP being informed.

Summary of ethical issues (outstanding)

* The Committee recommended revision of the information about appropriate contraceptive methods in the PIS. They suggested that total abstinence should not be listed as the first method of contraception (suggest it is placed last). Please describe male sterilisation as vasectomy (male sterilisation). Also please simply the information on diaphragms etc. to state ‘barrier methods’ and list those available in NZ

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

* Please insert a lay study title
* The Committee noted the PIS could be simplified and reduced to reflect the nature of the study design. .
* The Committee suggested consolidating the treatment visit procedures listed on the PIS as it is currently repeated several times. The Committee suggested using a table or grid to summarise this information on the PIS
* The committee requested that the need to not have alcohol during the course of this study should be stated earlier in the PIS (currently page 9) and possibly bolded.

Decision

This application was *approved* by consensus.

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| **3** | **Ethics ref:** | **14/STH/176** |
|  | Title: | Functional outcomes after Fontan surgery |
|  | Principal Investigator: | Dr Tom Gentles |
|  | Sponsor: |  |
|  | Clock Start Date: | 06 November 2014 |

Dr Katheryn Rice 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

* The study involves observing outcomes of Fontan patients, focusing on circuit fenestration and on anticoagulation.
* For anticoagulation the study will observe outcomes from use of warfarin vs aspirin and in particular the bone density outcomes.
* Committee noted the amended information that was emailed through prior to the meeting.
* The Committee noted the research relationship with the Australasian Fontan Registry.

Summary of ethical issues (resolved)

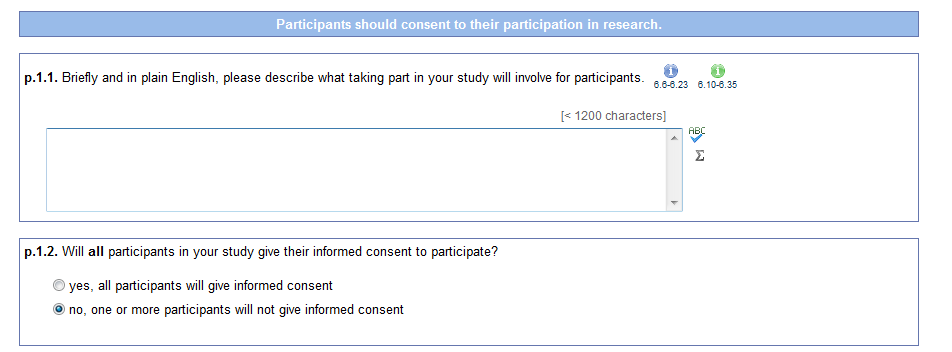
The main ethical issues considered by the Committee and addressed by the Researcher were as follows.

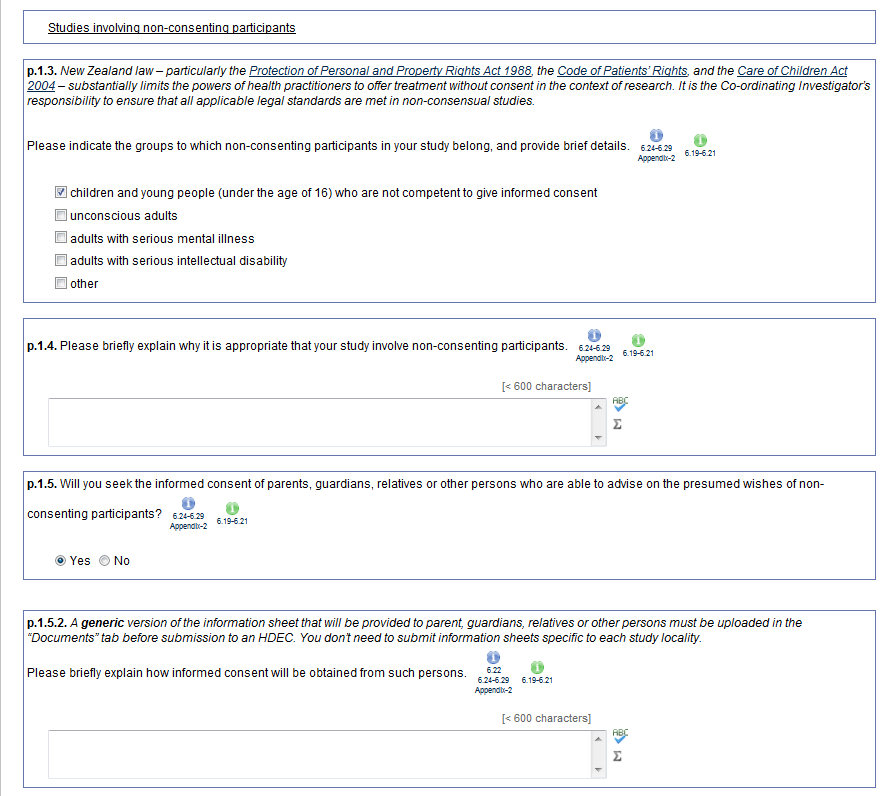
* The Committee queried if the aim was to recruit 25 patients in each anticoagulant group (warfarin vs aspirin). Dr Rice confirmed this was the intention but they did not yet know if this would be possible.
* Dr Rice explained that in New Zealand the standard treatment is generally warfarin until adulthood and then it is a clinician’s call to change from warfarin to aspirin, or to stay on warfarin. , However in Australia it is more common to have aspirin following a Fontan procedure. The number of participants on aspirin in New Zealand will be fairly low compared to warfarin.
* The Committee queried if age had been taken into account in relation to differences in bone density? Dr Rice explained that the age range starts at 13 years old which means there will not be a significant difference between adolescent and adult bone density, in terms of the middle limit.

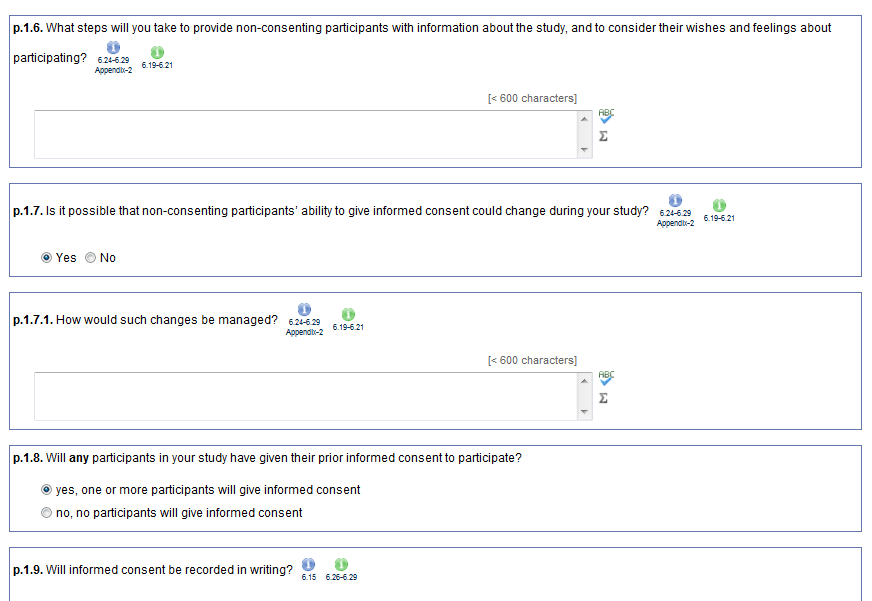
Summary of ethical issues (outstanding)

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

* The committee queried if the study can get enough aspirin participants? Researcher explained yes – due to Australian arm. Perhaps not in NZ but with both countries they are hoping there will be enough to create enough statistical power to provide comparison between the two.
* Please explain how conflict of interests will be managed if the recruiting researcher is also the treatment provider.
* Please explain in a cover letter addressing the following:







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

* (Young person PIS): discrepancy as it asks the child to sign a copy, given by the parents. Please take this statement off the young person PIS and ask the children to sign the parent’s consent form to indicate assent.
* (Young person PIS): please add time frames to the study related procedures.
* Please include how my visits are required, and general expectation of time per visit.
* The Committee asked what ‘functional outcomes’ means? Dr Rice explained this meant quality of life. The Committee requested that the title is amended, for example ‘quality of life after the Fontan procedure’.
* (Guardian PIS): ‘your overall bone health’ please amend to ‘your child’s…’. As a general note, please review all PIS for consistent use of ‘your child’ rather than ‘you’.
* Please proof read both PIS.
* The Committee noted formatting is quite wide on the PIS. On CF the consent form bullet points are small font – please review for consistency and readability.
* Please add more space to sign the CF.
* Amend PIS to state ‘we are comparing aspirin and warfarin’ etc. rather than stating warfarin is suggested to weaken bones.

Decision

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

* Please address all potential conflicts of interest and explain how these conflicts will be managed or mitigated *(Ethical Guidelines for Observation Studies 4.18)*
* Please amend the information sheet and consent form, and assent forms, taking into account the suggestions made by the Committee (*Ethical Guidelines for Observation Studies* *para 6.11*).
* Please address outstanding ethical issues.

This following information will be reviewed, and a final decision made on the application, by Ms Raewyn Idoine and Dr Devonie Waaka.

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| **4** | **Ethics ref:** | **14/STH/177** |
|  | Title: | MLN9708PlusLenalidomideandDexamethasoneVersusPlaceboPlusLenalidomideandDexamethasoneinAdultPatientsWithNewlyDiagnosedMultipleMyeloma |
|  | Principal Investigator: | Dr Stephen Gibbons |
|  | Sponsor: | PPD |
|  | Clock Start Date: | 06 November 2014 |

Dr David Simpson and Dr Stephen Gibbons 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 study will treat patients who have multiple myeloma who are too old for a bone marrow transplant. Standard practice is enalidomide and dexamethasone, but adding MLN9708 may improve response rate and survival in elderly patients with multiple myeloma.
* The study uses the same drug combination as a previously approved study (MEC/12/05.056) but this protocol is for relapsed multiple myeloma patients.

Summary of ethical issues (resolved)

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

* The Committee asked for clarification on the bone marrow sample. Dr Simpson explained that reasoning was that patients have a bone marrow biopsy for their standard treatment, and to take an additional sample at this time point meant that the potential participant could determine study eligibility without committing to the full study, while avoiding a second biopsy if deciding to participate.
* Dr Simpson explained the scientific basis behind genetic analysis and future unspecified research. The Committee acknowledged the reasoning behind the future unspecified research but requested that all optional parts of the study are removed from the main PIS. It is currently confusing and unclear what parts of the study are mandatory and which are optional.
* Please clarify if the future unspecified samples are ‘additional’ or ‘leftover’ samples. Dr Simpson stated leftover.
* The Committee noted the pregnancy information met the conditions set out in the Decline letter.

Summary of ethical issues (outstanding)

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

* (Pre-screen PIS) The Committee noted that this PIS concerns a small amount of bone marrow collected from a routine bone marrow biopsy. Please remove the statement ‘2’ samples as it suggests there is a study related procedure occurring to collect an additional sample where as it is really just a small increase in the tissue taken during a standard practice procedure.
* (Pre-screen PIS) On page 2 of 8 – states collecting blood samples – should this be bone marrow? Pg. 5 there is a heading ‘what happens to my blood samples or tissue’? Please amend to be consistent about ‘bone marrow’ and remove all info on blood.
* (for all) Remove interpreter box. Review the tick-boxes on the consent form and reduce the number if possible.
* (Pre-screen PIS) Please review the page numbers – currently states 1 of 9 then page 1 of 8.
* Please explain ‘you may want to discuss with your doctor’ – please clarify which doctor - perhaps change to GP or family doctor.
* (Genetic testing PIS) Subheading ‘what happens to my samples’: currently states ‘stored for maximum period of 15 years’ but then goes to say samples will be sent to a laboratory. Please rewrite so it is clear that they are sent to laboratory first and then include info on length of storage.
* General note that the PIS’s require a review for consistency in formatting, spelling, name of study drug.
* Please review study drug names as it is inconsistent between PIS and advertising.
* (Genetic testing PIS): add page numbers.
* PISCF main study - please increase the font size
* The Committee queried the statement about avoiding things containing boron. Please explain what contains boron (pg.11)
* Sub header: potential discomforts and risks – please add frequency information. Please revise technical language, particularly for the simple risks.
* Remove any optional information from the main PIS/CF – only include information on the optional PIS.
* Add lay study title, for example: ‘comparing treatments for multiple myelomas’ or ‘study comparing ML909 verses standard of care’. Remove ‘phase III’ as this means little for participants.
* Lenalidamide and risks to unborn child (P18) suggests the use of spermicidal agents. Please confirm that these are available in NZ and if not, change the recommendation.
* Posters refer to study Tournaline MM2, while other documents refer to C16014, please be consistent throughout.

Decision

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

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

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

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| **5** | **Ethics ref:** | **14/STH/178** |
|  | Title: | WB28182: A Study of Lebrikizumab in patients with severe asthma who depend on oral corticosteroids |
|  | Principal Investigator: | Dr Benedict D J Brockway |
|  | Sponsor: | Roche Products(New Zealand) Ltd |
|  | Clock Start Date: | 06 November 2014 |

Dr Benedict D J Brockway and Jan Cowan 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

* This Study is a phase II randomised double blind placebo controlled multicentre trial to assess the oral corticosteroid sparing effect of lebrikizumad in patients with severe corticosteroid dependent asthma.
* The study has a cross over design. Patients in the placebo arm will receive study drug at week 44.
* The participants have severe but stable asthma.
* Lebrikizumab has already been used in some asthma studies, however this study is using it for patients with much more severe asthma (those needing significant doses of oral corticosteroids).
* The Committee commended the researchers on the high quality of the PIS and appreciated the editing for New Zealand participants.

Summary of ethical issues (resolved)

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

* The Committee queried if there was evidence of benefit from prior studies. The Researcher confirmed there was.
* The Committee asked for more explanation of the risk of gut infections (pg.12 of PIS). The Researchers explained that they are not aware of these bacterial infections occurring in New Zealand patients. Sites overseas have higher rate of these infections, but researchers have not seen this SAE in New Zealand. The SUSAR from phase I and II have identified this as a risk, so patients who have existing infections are excluded.
* Please bold information on proper cooking and food techniques to reduce the risk of gut infections whilst taking this medicine.
* In future applications please include possible adverse reactions from medicines administered in trials in Section r.1.1 of the application form.

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

* The Committee noted that the electronic diary is first mentioned on page 6. Please explain this aspect of the study earlier.
* Please add more information regarding the frequencies of adverse drug reactions, for example injection site reactions (currently described as ‘very common’ and also information on the severity of these if applicable.
* Typo on page 10 should say withdrawal.
* Pg.12 – Please change ‘throwing up’ to vomiting.
* Pg.7 and 8 – additional samples for RCR. Please be consistent in collection statements concerning DNA and RNA.
* Pg.14 – please list some examples of effective measures of birth control.
* Pg.12 subtitle ‘infections’ – please amend to gut or bowel infections.
* Sub title – immunogenicity – please amend to lay sub title
* .

Decision

This application was *approved* by consensus.

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| **6** | **Ethics ref:** | **14/STH/179** |
|  | Title: | (duplicate) 747-302: Effect of OCA on Outcomes in People with PBC |
|  | Principal Investigator: | Dr David William Orr |
|  | Sponsor: | Intercept Pharmaceuticals, Inc. |
|  | Clock Start Date: | 06 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

* This Study assesses a novel treatment for PBC
* The study will assess Standard care verses OCA.
* The Study has a genetic component to develop future treatments for the patient population.

Summary of ethical issues (resolved)

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

* Dr Biddulph confirmed study has been submitted to SCOTT.
* Dr Biddulph confirmed patients can find out if they are on placebo or active after the study, and that they would not receive the experimental drug after the study.

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

* On page 7 of 13 (PIS) please add subheading ‘reproductive risks’ above the relevant information .
* Please include a lay study title.
* Please reformat tables so they are on their own page.
* Review formatting generally, headings and footers etc.

Decision

This application was *approved* by consensus.

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| **7** | **Ethics ref:** | **14/STH/180** |
|  | Title: | Managing transitions in care for people with advanced progressive illness. |
|  | Principal Investigator: | Professor Maureen Coombs |
|  | Sponsor: | Victoria University of Wellington |
|  | Clock Start Date: | 06 November 2014 |

Professor Maureen Coombs 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

* The study will focus on understanding how organisations work with patients who have advanced progressive illness, and in particular how the patient experience changes during transition between health care settings.
* The study will involve talking, interviewing, observation and questionnaires with staff, patients and their families.

Summary of ethical issues (resolved)

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

* The Committee asked what would occur if a family member did not consent to participate. Professor Coombs confirmed that the families will only be involved if they provide consent.
* The Committee noted the acute setting and queried if only patients who can provide informed consent will be approached. The researcher confirmed this was the case, and was part of the screening process, as well as being an important part of the consent process.
* The Committee queried how much of the study is listening to the conversations and how much is the answers from the questionnaires? (in relation to all three groups). Professor Coombs stated they will only be there in terms of working beside health professionals, while there is a transition of care provision. The researchers will not be observing clinical care or direct care. The study only focuses on where the patients are for care and where they are going to for care – and the transition between.
* The Committee queried if the presence of the researchers will change the conversations that occur. Professor Coombs acknowledged that this was a consequence of the observation, but they aimed to engage with the people in the study to minimise the impact of observation. This will be increased by ensuring staff are comfortable with the presence of the researchers.
* The Committee noted that decisions relating to changing patient care or setting may be made out of regular hours and asked how the researchers would ensure the observation occurs during the time outside the typical 9-4pm? Professor Coombs explained that the resulting discussions will enable researchers to learn from the health care staff which can direct the future fieldwork and therefore the timeframe put in place for each different site. The different sites may well require different times.
* Please clarify that this observation only looks at staff processes? Professor Coombs confirmed there is no access to patient records, no access to any patient documentation – the only access to patient details is provided by the patient details that are given by patients themselves.
* (B.1.1) – noted hypotheses rather than study objectives. Please explain. Professor Coombs explained that there are no hypotheses as this is the qualitative stage of research. The committee suggested the hypotheses might be that ‘transition is difficult?’. Professor Coombs confirmed this was a possible hypothesis, another being that there is difficulty in communication between staff and patients – the study aims to identify where the deficits are.
* (R.1.2) states that GP will be informed. The Committee asked the researchers to check to see whether informing GP is mandatory, and if so include on PIS – if not then remove.
* The Committee asked Professor Coombes to describe the SPICT tool she explained it is a validated tool to identify people who require supportive care. It has 4 key sections and the researchers have modified it by adding questions. It is a mixture of questions relating to experiences and clinical indications (answered by clinicians).
* Please explain what occurs when patient consents but key staff members do not consent? Then the observations will not involve the staff. If one party does not give consent then we will not gather data when those conversations are going on.

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

* Pg.2 of PIS – please amend the timeframe, as the study will take 9 months rather than 1 month.
* The Committee requested a lay language study title.
* The Committee asked the researchers to consider whether 14 tick boxes are appropriate and/or required on the CF.
* In The paragraph ‘what happens after the study?’ please use four bullet points rather than a long block of text, for instance. .
* The Committee noted the patient information sheet is fairly repetitive. The Committee felt that the researcher described the study very simply during the ethics meeting, whereas the PIS is lengthy. Please review the PIS and reduce repetition where possible.
* Please review all consent forms for repetition and clarity.

Decision

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

* Please amend the information sheet and consent form, and assent forms, taking into account the suggestions made by the Committee (*Ethical Guidelines for Observation Studies* *para 6.11*).

This following information will be reviewed, and a final decision made on the application, by Ms Raewyn Idoine and Dr Sarah Gunningham.

## General business

1. The Committee noted the content of the “noting section” of the agenda.
2. The Committee agreed that a lay title should be added to the header of the template PIS on HDEC website.
3. The Chair reminded the Committee of the date and time of its next scheduled meeting, namely:

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| **Meeting date:** | 16 December 2014, 12:00 PM |
| **Meeting venue:** | Sudima Hotel, Christchurch Airport, 550 Memorial Avenue, Christchurch |

The following members tendered apologies for this meeting.

1. Mrs Angelika Frank-Alexander
2. **Problem with Last Minutes**

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

The meeting closed at 3.15pm