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| **Committee:** | Southern Health and Disability Ethics Committee |
| **Meeting date:** | 13 December 2016 |
| **Meeting venue:** | Sudima Hotel, Christchurch Airport, 550 Memorial Drive, Christchurch |

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| **Time** | **Item of business** |
| 12:15pm | Welcome |
| 12:20pm | Confirmation of minutes of meeting of 22 November 2016 |
| 12:30pm | New applications (see over for details) |
|  | i 16/STH/194  ii 16/STH/195  iii 16/STH/201  iv 16/STH/203  v 16/STH/206  vi 16/STH/207  vii 16/STH/208  viii 16/STH/209  ix 16/STH/211  x 16/STH/212  xi 16/STH/213  xii 16/STH/216 |
| 5:00pm | General business:   * Noting section of agenda |
| 5:05pm | Meeting ends |

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| **Member Name** | **Member Category** | **Appointed** | **Term Expires** | **Apologies?** |
| Ms Raewyn Idoine | Lay (consumer/community perspectives) | 27/10/2015 | 27/10/2018 | Present |
| Mrs Angelika Frank-Alexander | Lay (consumer/community perspectives) | 27/10/2015 | 27/10/2018 | Apologies |
| Dr Sarah Gunningham | Non-lay (intervention studies) | 27/10/2015 | 27/10/2018 | Present |
| Dr Nicola Swain | Non-lay (observational studies) | 27/10/2015 | 27/10/2018 | Present |
| Dr Mathew Zacharias | Non-lay (health/disability service provision) | 27/10/2015 | 27/10/2018 | Present |
| Dr Devonie Eglinton | Non-lay (intervention studies) | 13/05/2016 | 13/05/2019 | Present |
| Assc Prof Mira Harrison-Woolrych | Non-lay (intervention studies) | 27/10/2015 | 27/10/2018 | Apologies |
| Dr Fiona McCrimmon | Lay (the law) | 27/10/2015 | 27/10/2018 | Present |
| Dr Angela Ballantyne | Ethical and Moral Reasoning (lay) | Co-opt CEN | Co-opt CEN | Present |

## Welcome

The Chair opened the meeting at 12:15pm and welcomed Committee members, noting that apologies had been received from Assc Prof Mira Harrison-Woolrych and Mrs Angelika Frank-Alexander.

The Chair noted that fewer than five appointed members of the Committee were present, and that it would be necessary to co-opt a member of other HDECs in accordance with the SOPs. Dr Angela Ballantyne confirmed her eligibility, and was co-opted by the Chair as a member of the Committee for the duration of the meeting.

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 22 November 2016 were confirmed.

## New applications

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| **1** | **Ethics ref:** | **16/STH/201** |
|  | Title: | Observational Management of young women under the age of 25 with CIN3 (CIN3MA) |
|  | Principal Investigator: | Associate Professor Peter Sykes |
|  | Sponsor: |  |
|  | Clock Start Date: | 01 December 2016 |

Associate Professor Peter Sykes was present by teleconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. This research involves taking a conservative management approach for young women (under 25) who have high grade cervical abnormalities.
2. This study is being undertaken because little is understood about the natural history of high grade abnormalities in young women. It appears that when screening is changed to start after women turn 25 higher rates of cancer are not found.
3. Many countries, including New Zealand, are changing their cervical screening programmes to only screen women over 25 years. This study will lend evidence to the safety of this approach in the New Zealand context.
4. This study follows a successful earlier study that investigated a conservative management approach for lower grade abnormalities.
5. The Researchers believe that a significant portion of women’s abnormalities will regress and not require treatment.
6. All participants in this study will provide fully informed consent.

Summary of ethical issues (resolved)

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

1. The Committee questioned how many participants in the earlier study progressed to a higher grade abnormality during the study. The Researcher explained that they do not know the rates as the HRC monitoring group will not let them know before the end of the study, however, they believe that a significant proportion did progress to CIN3 but it is unable to be known whether they already had CIN3 that was not diagnosed previously or whether it was a new development. In the previous study women with CIN3 would be treated, however, in this study they would not be.
2. The Committee questioned the rate of expected drop out, considering that the study lasts for 2 years. The Researcher stated that they believe 9% of participants had delayed follow up and 2% were completely lost to follow up. The Committee questioned the risk to the women who were completely lost to follow up. The Researcher stated that it would be 11 women and that they do not anticipate any significantly increased risk of cancer for these women as from 2018 they would not have any cervical screening in New Zealand, and not screening any women under 25 does not seem to be associated with higher rates of cancer.
3. The Researcher explained that they believe that not screening or treating women under 25 for CIN3 abnormalities is safe but want to do this study to add evidence behind this approach as treatment in this area has historically been lacking in evidence.
4. The Committee questioned whether the researchers believe they will be able to complete the study before the screening age change in 2018. The Researcher agreed that they need to start quickly and expect that they will have some overlap with the 2018 change, but that they believe they will still be able to screen women under 25 for a period of time following the change. The Researcher stated that even if they are unable to recruit their intended 200 participants they expect that the results will still be useful.
5. The Committee questioned whether the change to the screening age in New Zealand has been announced already. The Researcher confirmed that it has been announced, although the logistics of the change are yet to be finalised.
6. The Committee questioned for how long treating CIN3 abnormalities has been standard of care. The Researcher confirmed that this has been standard for a long time, but it may be that women are being over treated. The Committee noted that they are partially relying on the fact there is sufficient evidence that it is safe to not screen (and, therefore, find and treat abnormalities) in women under 25 as a number of countries are making this change to their screening programmes.
7. The Committee questioned how enrolment would work in a practical way. The Researcher explained that at the time of having their biopsy the women will be introduced to the concept of conservative management as part of a study as a treatment option, and if their biopsy result shows a high grade abnormality they will be formally offered enrolment in the study as a treatment option.
8. The Committee questioned whether selection bias is a concern. The Researcher explained that although they are concerned about selection bias in their study they cannot control for this any further and will do their best to report on this and account for it in the results.

Summary of ethical issues (outstanding)

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

1. The Committee questioned whether the HRC funding process has been completed. The Researcher said that they have only made it through the first round so far but expect that they will receive HRC funding. The Committee explained that although a study being HRC funded is suitable evidence of scientific review as this study is not yet HRC funded they require further evidence of the scientific validity of the study. Please either provide evidence that the study is fully HRC funded following the completion of this funding process, including the notes from the peer review process for this funding, or provide an alternative independent peer review.
2. The Committee questioned the data safety monitoring arrangements for this study. The Researcher stated that as they expect this study to be HRC funded they expect that HRC will also provide data safety monitoring. The Committee stated that they need to be sure of the data safety monitoring arrangements for this study, please provide more information on what the arrangements will be. Please note that if the study is approved on the grounds that data safety monitoring will be provided by the HRC and this does not eventuate, an amendment will need to be submitted to change the approved data safety monitoring arrangements before the study can begin.

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

1. The Participant Information Sheet indicates that if women change their mind they can withdraw from the study at any time and if they have biopsy results at this time they will receive treatment. Please clarify this as all participants will have biopsy results (as this is an inclusion criteria), the Participant Information Sheet should clearly state that if women have had a high grade abnormality found and wish to withdraw from the study that it is suggested that they have treatment as per standard care.
2. The first page of the Participant Information Sheet indicates that any women with an adverse biopsy result should get treatment, however this is only meant to apply to women who withdraw from the study as all women in the study will have an adverse biopsy result and study participation involves not having treatment. The tense of this section should be revised for clarity.
3. Please explain in the Participant Information Sheet what CIN1/2/3 refers to as it is unclear whether CIN3 is worse than CIN1.
4. Please remove ‘MA’ from the title ‘CIN3MA’ as it is not clear what this ‘MA’ refers to, such as a subtype or CIN3.
5. Please remove the spaces for yes/no tick boxes from all statements in the Consent Form that are not optional, meaning that a participant could select ‘no’ and still participate in the study. Please remove the yes/no tick box from the statement ‘I understand the study involves study visits every 6 months’ and use another method (such as bold) to emphasise this statement as it is not optional.
6. Please add to the Participant Information Sheet the potential risks associated with standard of care (such as ruptured membranes and preterm birth) to help fully inform participants of their treatment options.

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 plans *(Ethical Guidelines for Intervention Studies para 6.50).*
* Please provide evidence of favourable independent peer review of the study protocol (*Ethical Guidelines for Intervention Studies* Appendix 1).

This following information will be reviewed, and a final decision made on the application, by Dr Nicola Swain and Dr Fiona McCrimmon.

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| **2** | **Ethics ref:** | **16/STH/195** |
|  | Title: | USING BRAIN RHYTHMS TO ASSESS ANTI-ANXIETY DRUG ACTION |
|  | Principal Investigator: | Professor Neil McNaughton |
|  | Sponsor: |  |
|  | Clock Start Date: | 01 December 2016 |

Professor Neil McNaughton and Professor Paul Glue 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 (resolved)

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

1. The Committee questioned how participants will be recruited for this study. The Researcher explained that they will advertise the study through Student Job Search and then when approached by potential participants will discuss the study via phone or email, depending on the means the participant used to contact them.
2. The Committee questioned when the Researchers would go over the exclusion criteria. The Researcher explained that if the participants approached by phone they would go over the exclusion criteria on the phone but if approached by email would instead send that Participant Information Sheet that includes the inclusion/exclusion criteria. The Committee questioned whether the inclusion and exclusion criteria would also be covered in person. The Researcher confirmed it would be at the time of obtaining informed consent.
3. The Committee questioned whether the informed consent process would be undertaken individually or in groups. The Researcher stated that they would do it in groups at the time of testing to allow the researchers to give an overview of the nature of the study drugs and possible side effects for all participants. The Committee stated that each participant must meet with a researcher in private to sign the consent form and be given the opportunity to ask any questions that they may be uncomfortable asking in front of the group. The Researcher stated that they would alter their consent process to account for this.
4. The Committee questioned how the sections of the Participant Information Sheet that will be altered for each participant group, depending on the drug they will receive, will be managed in reality. The Researcher explained that each study group would be recruited separately and attend study sessions at separate times so the relevant Participant Information Sheet would be given to each group. The Researcher explained that they only want to discuss the drug(s) that each group may get, not the drugs other groups may get, to avoid a nocebo effect.
5. The Committee noted that some participants receive additional money that they can win during the testing, they questioned how much that may be. The Researcher clarified that participants could win up to approximately $7, with an average of $5 expected. The Committee agreed this amount was insignificant enough to not cause them concern.
6. The Committee questioned whether a breath alcohol test would be conducted prior to dosing participants. The Researcher stated that they had not intended to do this. The Committee suggest it may be beneficial; although participants may state that they have not been drinking, they may have been drinking the night before and still have detectable alcohol in their systems, which may interact with the study drugs and / or assessments. The researchers will consider this option.

Summary of ethical issues (outstanding)

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

1. The Committee questioned whether study data will be linked to individual participants, for example to allow their GP to be informed of any adverse events. The Researcher stated that they do not intend to have any link between study results and individual participant identities but they do intend to follow up with participants who have adverse events and the GPs. The Committee requested further information (such as a specific timeline) regarding how this will be managed as participants may have an adverse event at time of testing or approach the researchers later regarding an adverse event and if there is no link with their study data it will not be able to be shared with their GP.
2. The Committee noted that although the application included 2 peer review forms these are very brief and do not provide sufficient information on what was considered by the peer reviewers. Please provide additional evidence of independent peer review for this study that includes commentary regarding what was considered.
3. The Committee raised concerns about whether there are suitable safety measures in place at the study site, considering that participants will be given sedatives. The Researcher explained that Psychology students with first aid certificates will monitor participants. The Committee were not convinced this would be sufficient as participants may have an allergic reaction. The Researcher stated that the study drugs are routinely prescribed in clinical practice (at higher doses than will be used for the study) without safety monitoring. The Committee stated that in the clinical context, the drugs are proscribed for the therapeutic benefit of the patients. In the research context, healthy volunteers are asked to take drugs for the benefit of the study and therefore it is the ethical responsibility of the researchers to ensure their safety. As there is a risk (although it may be small) of allergic reactions suitable processes and personnel must be in place at study sites to respond to these events if they do occur. Please provide further information about the safety monitoring processes that will be in place at all study sites and how these are suitable to respond to adverse events if they do occur.
4. The Committee questioned who will be responsible for determining whether participants are safe to go home after 2 hours. The Researcher stated that this would also be the Psychology students. The Committee felt that this may be inappropriate and requested further information about the suitability of this arrangement and how it will be determined if participants are safe to go home.
5. The Committee questioned whether transport would be provided for participants, as although many participants may live within walking distance some may need to drive and will be unable to drive home following the testing so taxi vouchers should be provided. Please confirm the arrangements for this.

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

1. The Participant Information Sheet states that if participants withdraw post dosing they would be required to stay at the study site for safety monitoring, however, participants cannot be detained against their will and this section should be revised to stated that participants are ‘strongly advised for the own safety’ to remain at the study site.
2. Please remove the yes/no tick boxes from the consent form for all statements that are not truly optional, meaning that participants could select ‘no’ and still participate in the study.
3. Please bold, or otherwise emphasise, the information in the Participant Information Sheet about not driving or drinking alcohol following the study.
4. Please clarify on the first page of the Participant Information Sheet that this is a healthy volunteer study.
5. Please replace ‘advertising’ with ‘seeking’ on page 2 of the Participant Information Sheet.
6. Please remove the statement regarding most females not being pregnant from the Participant Information Sheet as you cannot know this.
7. Please revise the statements regarding the purpose of the study from the first page of the Participant Information Sheet as they are currently overly complicated.

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 confirm the safety arrangements for the study, as detailed in the outstanding ethical concerns detailed above. A mechanism should be in place for responding to any potential safety concerns (Ethical Guidelines for Intervention Studies para 6.62)
* Please provide evidence of favourable independent peer review of the study protocol (Ethical Guidelines for Intervention Studies Appendix 1).

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

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| **3** | **Ethics ref:** | **16/STH/206** |
|  | Title: | TheSafety,TolerabilityandEfficacyofGS-­9674inPatientswithNon­alcoholicSteatohepatitis(NASH) |
|  | Principal Investigator: | Prof Edward Gane |
|  | Sponsor: | Gilead Sciences, Australia and New Zealand |
|  | Clock Start Date: | 01 December 2016 |

Prof Edward Gane 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 (resolved)

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

1. The Committee noted that the Participant Information Sheet listed the risks of the study drug, which is appropriate, but these were not also included in the application form. In future please ensure all risks associated with the study (including risks of the study drug) are listed in the application form.
2. The Committee questioned how unexpected findings would be dealt with. The Researcher explained that participants would be referred to the appropriate services and their GP would be informed.
3. The Committee questioned what the expectation of Māori involvement would be in the study. The Researcher explained that this is their first trial of NASH, and that this condition is associated with obesity and diabetes. Because Māori are overrepresented in obesity and diabetes statistics the Researchers expect that they may also be overrepresented in NASH statistics, and, therefore, they should have a number of Māori and Pacifica participants.
4. The Committee stated that for future applications they would appreciate if more attention was paid to providing suitable responses to the cultural questions in the application form.

Summary of ethical issues (outstanding)

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

1. The Participant Information Sheet states that Māori participants should discuss study participation with their family and friends, the Committee noted that this applies for all participants, not just Māori participants, and requested that the Participant Information Sheet is revised to reflect this.
2. Please remove the ‘<’ and ‘>’ symbols and replace with ‘more than’ and ‘less than’ as appropriate in the Participant Information Sheet to ensure readability for lay participants.

Decision

This application was *approved* by consensus, subject to the following non-standard conditions.

* 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).

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| **4** | **Ethics ref:** | **16/STH/203** |
|  | Title: | Phase 3, randomized, double-blind, placebo-controlled, multicenter study evaluating acalabrutinib plus BR compared with placebo plus BR in subjects with previously untreated MCL. |
|  | Principal Investigator: | Dr David Simpson |
|  | Sponsor: | IncResearch |
|  | Clock Start Date: | 24 November 2016 |

Dr David Simpson was present by teleconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. This study involves participants with an uncommon form of lymphoma that is aggressive and generally found in older adults.
2. One of the main treatments for this lymphoma is not currently funded in New Zealand and all participants in this study will receive this treatment free of charge. One arm of participants will also receive an active study drug and the other study arm will receive a placebo.
3. After completion of the standard cycles of treatment participants will be able to have ongoing treatment free of charge if it is beneficial as it is not currently funded.
4. If participants in the placebo arm of the study have worsening cancer they will be crossed over to the active treatment arm.

Summary of ethical issues (resolved)

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

1. The Committee questioned whether Māori are expected to participate in the study. The Researcher stated that they understand that Māori get this form of lymphoma as frequently as other ethnicities and may participate.

Summary of ethical issues (outstanding)

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

1. The biomarkers Participant Information Sheet appears to actually be Future Unspecified Use of Tissue but does not contain all of the necessary information, such as that overseas studies using this tissue are unlikely to have New Zealand ethics approval. Please see the Future Unspecified Use of Tissue Participant Information Sheet template and revise this form to be ensure that all necessary points are covered.
2. Please remove references to the optional studies, such as the biomarker study, from the main Participant Information Sheet as this form should only contain information on the main study to be clear what is compulsory.
3. Please add the location of the central site where study data and samples will be stored.
4. Please ensure all relevant contact numbers are on each Participant Information Sheet.
5. Please remove the tick boxes from the main Consent Form that do not relate to the main study.
6. Please remove any reference to a legally authorised representative from the pregnant partner Participant Information Sheet as this is not relevant for New Zealand.
7. The Committee queried the lack of a Māori tissue statement in the Participant Information Sheet. The committee recommended the following statement: “*You may hold beliefs about a sacred and shared value of all or any tissue samples removed. The cultural issues associated with sending your samples overseas and/or storing your tissue should be discussed with your family/whanau as appropriate. There are a range of views held by Māori around these issues; some iwi disagree with storage of samples citing whakapapa and advise their people to consult prior to participation in research where this occurs. However, it is acknowledged that individuals have the right to choose.”*

Decision

This application was *approved* by consensus, subject to the following non-standard conditions.

* 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*).

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| **5** | **Ethics ref:** | **16/STH/194** |
|  | Title: | Preventing Muscle Cramps in Individuals on Dialysis |
|  | Principal Investigator: | Professor Robert (Rob) Walker |
|  | Sponsor: |  |
|  | Clock Start Date: | 01 November 2016 |

Professor Rob Walker and Dr Luke Wilson were present by teleconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. This study investigates a product that seems to relieve cramps, this study involves testing it in dialysis patients who suffer more muscle cramps.

Summary of ethical issues (resolved)

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

1. The Committee questioned why the Researchers had requested that this application is considered in a closed session. The Researcher explained that this was at the request of the sponsor due to commercial sensitivity.
2. The Committee questioned whether SCOTT review is required for this study. The Researcher confirmed that SCOTT review is not required.
3. The Committee questioned why, as this is a non-therapeutic study and the researchers intend to induce cramps in the study population, healthy volunteers are not used. The Researcher explained that it is easier to induce cramps in dialysis patients, as they are generally more prone to cramping. The Researcher further explained that the reason to induce cramps is to have more mechanised testing and results for proof of concept.
4. The Committee questioned whether the study product may make people less prone to cramps, or just stop cramps once they have started. The Researcher explained that they expect that it may reduce susceptibility to cramps as well as stopping cramps once they start.
5. The Committee questioned whether the placebo is being provided by the company that makes the product being tested. The Researcher confirmed that the company would provide both; and that the placebo matched the active product in terms of taste, smell and viscocity.
6. The Committee questioned whether there are any known risks associated with the product. The Researcher stated that they do not believe there are any risks with the product. The Committee questioned how risks will be monitored. The Researcher explained that they have an internal data safety monitoring and will have single lead ECT and blood pressure testing.
7. The Committee questioned how participants would be recruited. The Researcher explained that the patient’s clinician, who may be a member of the research team, will ask them if they are interested in hearing more about the study, and if they are interested another member of the research team who is not their treating clinician will complete the informed consent process with them.

Summary of ethical issues (outstanding)

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

1. The Committee questioned whether this study is being conducted primarily for the benefit of the manufacturer of study product being tested. The Committee noted that if the study is being conducted primarily for their benefit then participants would be excluded from compensation from ACC and suitable insurance and indemnity would need to be provided by the study sponsor and the Co-ordinating investigator. The Committee stated that their reason for believing that the study is primarily for the benefit of the manufacturer is because the company requested that this study be considered in a closed session for commercial sensitivity and the researchers have been required to sign a NDA. The Committee requested that suitable insurance and indemnity documents are provided to demonstrate that the researchers and sponsor are able to provide at least ACC equivalent compensation to any participant who may be injured during the study.

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

1. The Committee stated that the Participant Information Sheet is not lay friendly and should be revised to ensure it is easily understood by participants.
2. Please revise the Participant Information Sheet to remove the ‘Cramps Away’ name of the product as the Participant Information Sheet should not make therapeutic claims about the product being tested as any therapeutic benefit is not yet know. The Committee suggested that it could be called an ‘investigational product’ or ‘test product’ instead.
3. Please state in the Participant Information Sheet that while there are not any currently known or anticipated risks this is an investigational product and risks of it are not yet known.
4. Please amend the Participant Information Sheet to clearly state that the study is being conducted for the commercial benefit of the manufacturer and participants will not be eligible for compensation from ACC and this will instead be provided by the sponsor (please refer to the text in the Participant Information Sheet template on-line)
5. Please revise the Participant Information Sheet to remove reference to ‘non-pharmaceutical product’ as it is unclear what this means. The Committee suggested that it may be better to call it a ‘natural health product’.
6. Please clarify in the Participant Information Sheet which ‘department of medicine’ has reviewed this study.
7. Please clarify in the Participant Information Sheet, or remove from the consent form, the reference to participants’ medical records being accessed by researchers. Currently this is only in the Consent Form and not mentioned in the Participant Information Sheet.
8. Please remove the statement regarding participants’ GPs from the consent form.

Decision

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

* Please amend the information sheet and consent form, taking into account the suggestions made by the Committee (*Ethical Guidelines for Intervention Studies* *para 6.22*).
* Section 32 (6) of the Accident Compensation Act 2001 specifically excludes from ACC cover any treatment injury from any trial that is conducted ‘principally for the benefit of the manufacturer or distributor of the medicine or item being trialled’. If cover under the Accident Compensation Act 2001 will be excluded for the intervention study, investigators and study sponsors have responsibilities to ensure alternative compensation cover for study participants to at least ACC-equivalent standard. This may include earnings-related compensation. (*Ethical Guidelines for Intervention Studies* *para 8.4).*

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

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| **6** | **Ethics ref:** | **16/STH/207** |
|  | Title: | ZYN2-CL-004: STAR 2 |
|  | Principal Investigator: | Dr Ian Rosemergy |
|  | Sponsor: | Zynerba Pharmaceuticals, Inc |
|  | Clock Start Date: | 01 December 2016 |

Dr Ian Rosemergy was present by teleconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. This study investigates a synthetic product, a transdermal gel, which is being investigated as a treatment for epilepsy.
2. This product is being tested in a gel form as the drug is subject to high first pass metabolism, and when it is taken orally some intestinal issues may arise.

Summary of ethical issues (resolved)

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

1. The Committee questioned why participants will regularly be tested for suicidality, they questioned whether the product may increase suicidality. The Researcher explained that people with epilepsy have increased risk of suicide and sometimes cannabis is associated with suicidality, and although this product is fully synthetic they are taking a cautious approach due to the population group. The Researcher further explained that they frequently talk about suicide with these patients and believe they have a good relationship with their patients, who will be the participants, and can manage any risk well. The Committee questioned whether earlier studies have shown an increased risk of suicidality. The Researcher stated that not that they are aware of.
2. The Committee questioned whether the lowered sperm count that may be caused by the study product is likely to be long term and ongoing. The Researcher stated that they don’t think it will be a long term side effect.
3. The Committee questioned whether the Star 1 related study is meeting recruitment targets. The Researcher stated that it is difficult to recruit for as this form of epilepsy is very specific and many patients are self-medicating and not eligible for participation, but they have recruited 30-40 participants.
4. The Committee questioned whether they expect there to be any local issues or risks for the trial. The Researcher stated that this is a really exciting trial and showing promising results with no reports of ill effects, and compliance is easy as they just need to rub the gel in each day.
5. The Committee questioned whether participants will be unblinded when moving on to the extension study. The Researcher confirmed that they would be.
6. The Committee questioned whether the study product would continue to be available to participants after the end of the extension study. The Committee expressed their strong preference that the study product is not taken away from participants after the study ends if they are experiencing a benefit from this and stated that it should continue to be provided to participants as long as they are receiving a benefit.

Decision

This application was *approved* by consensus, subject to the following non-standard condition.

* Please confirm with the study sponsor, for your records, whether participants getting a benefit from the study product will continue to have access to the product after the end of the extension study.

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| **7** | **Ethics ref:** | **16/STH/216** |
|  | Title: | A STUDY OF MHAA4549A AS MONOTHERAPY FOR ACUTE UNCOMPLICATED SEASONAL INFLUENZA A IN OTHERWISE HEALTHY ADULTS |
|  | Principal Investigator: | Dr DIANE HANFELT-GOADE |
|  | Sponsor: | PPD Global Ltd (New Zealand Branch) |
|  | Clock Start Date: | 01 December 2016 |

Diane Hanfelt-Goade, Olatunji Odumosu, Michelle Raitak, and Charlie Stratton was present by teleconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. This is a continuation of a previous study investigating a treatment for the flu.
2. This study will receive SCOTT approval, includes 15 patients in New Zealand, and involves a treatment being given by infusion.

Summary of ethical issues (resolved)

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

1. The Committee questioned the arrangements for monitoring patients post dosing. The Researcher explained that they would monitor participants before, during, and after dosing for a few hours then daily for 7 days.
2. The Committee questioned whether sites are prepared to deal with any infusion reactions that may occur. The Researcher stated that infusions will be done at a hospital or clinical trial centre and that site initiation involves checking that each site has suitable emergency response ability. The Committee noted that the CI is responsible for this and must be certain that each site has suitable emergency response capabilities.
3. The Committee questioned how long participants would have to decide whether they wanted to participate. The Researcher clarified that they would have less than an hour to decide if they want to be involved in the screening aspect of the study and then overnight to decide whether they would like to be involved in the study.

Summary of ethical issues (outstanding)

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

1. Please fix formatting errors with the Participant Information Sheet as currently the footer and body text are merging on some pages and at times the line spacing changes. Please revise for consistency.
2. Please revise the risk section of the Participant Information Sheet to clearly state how common or not common each risk is, for example 1 in 10.
3. Please clarify in the Participant Information Sheet that blood samples for exploratory research will only be used for testing that is directly related to this study.
4. In the health information section of the Participant Information Sheet please remove the reference to genetic research as this is optional and information regarding it should only be in the optional Participant Information Sheet.
5. Please clarify the level of reimbursement for each study visit and whether participant will be reimbursed for phone calls in the Participant Information Sheet.
6. Please ensure the Participant Information Sheet only has information relevant to New Zealand participants in it.

Decision

This application was *approved* by consensus, subject to the following non-standard conditions.

* 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*).

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| **8** | **Ethics ref:** | **16/STH/213** |
|  | Title: | ABSORB BTK Study |
|  | Principal Investigator: | Associate Professor Andrew Holden |
|  | Sponsor: |  |
|  | Clock Start Date: | 01 December 2016 |

Associate Professor Andrew Holden and Helen Knight were present by teleconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. This trial is designed to assess the safety and efficacy of a new stent to be used for patients with a narrowing of a leg artery.
2. Permanent stents can cause long term re-narrowing issues but the study stent dissolves and it is hoped that this will avoid these issues.

Summary of ethical issues (resolved)

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

1. The Committee questioned whether this study is being conducted principally for the benefit of the manufacturer of the study drug, and, consequently, whether participants would be excluded from compensation under ACC. The Researcher confirmed that although the manufacturer is covering some study costs the study is initiated by the researchers, and the information will be owned by the researchers rather than the manufacturer and the manufacturer doesn’t have any access to study data or control over publication. The Committee agreed that the study is not being conducted principally for the benefit of the manufacturer and participants would be eligible to apply for compensation from ACC.
2. The Committee questioned whether the Participant Information Sheet needs information about other drugs participants may take, such as Aspirin. The Researcher stated that they did not feel this should be in the Participant Information Sheet as it was standard care whether participants are in the study or not.

Summary of ethical issues (outstanding)

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

1. The Committee questioned the data safety monitoring arrangements for the study. The Researcher confirmed that someone independent from both the manufacturer and the study would be monitoring the data for safety. The Committee stated that they are concerned about this arrangement as the details of it are not included in the protocol, for example what needs to be reported and within what timeframe. Please clarify the exact arrangements for data safety monitoring in the protocol.
2. The Committee discussed whether the peer reviewer is currently associated with the manufacturer. The Researcher explained that their understanding is that even if they were an advisor to the manufacturer in the past they are not currently. The Committee stated that if the peer reviewer is still involved with the manufacturer they expect additional, suitably independent, peer review is provided, please confirm and submit if required.

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

1. Please revise the Participant Information Sheet to reduce formatting issues as currently the footer wording merges with the main body text at times.
2. Please revise the risk section of the Participant Information Sheet to make it more easily understood for lay participants, including what the risks mean and how common they are.
3. Please revise the Participant Information Sheet to reduce bias as currently the expected benefits of the study device are overstated.

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 plans *(Ethical Guidelines for Intervention Studies para 6.50).*
* Please provide evidence of favourable independent peer review of the study protocol or confirm that the peer reviewer is suitably independent (*Ethical Guidelines for Intervention Studies* Appendix 1).

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

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| **9** | **Ethics ref:** | **16/STH/211** |
|  | Title: | ‘What works? Service users' knowledge and experience of suicide prevention interventions in Aotearoa / New Zealand' |
|  | Principal Investigator: | Miss Behiye (Becky) Ali |
|  | Sponsor: |  |
|  | Clock Start Date: | 01 December 2016 |

Miss Becky Ali was present by teleconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. This study is being conducted as part of a PHD and involves speaking with people who have used suicide prevention services in New Zealand, and people who have used suicide prevention services and now work for suicide prevention services.
2. The researcher wants to speak with these people about what worked for them as they are experts in their care.

Summary of ethical issues (outstanding)

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

1. The Committee raised concerns about whether the study would be able to achieve its specified goals, as although the participants may be able to tell the researcher what they liked or felt worked, it would not mean that those things actually worked.
2. Further, the study faces an inherent selection bias as it would seem that suicide prevention services must have worked for all participants, as people who these services did not work for may be dead.
3. The Committee noted that another issue for the study is because participants are self-selecting they are likely to be people who are very happy or very unhappy with the service they have received and it may influence the study results. The Committee noted that as participants may also be referred from services that these services are unlikely to refer any people who were very unhappy with the service.
4. The Committee asked the Researcher for more information regarding how these issues would be accounted for. The Researcher stated that they felt that they would control for the service selection bias by also recruiting through advertising, and that some of the bias would be inherent in this kind of research.
5. The Committee questioned the Researcher on the risks associated with having a number of previously (or possibly currently) suicidal people in the same room together talking about their experiences. The Committee felt that this could be upsetting for the participants, they may share personal information such as current or past abuse, they may feel uncomfortable sharing their experiences in a group setting, it may awaken suicidal thoughts for participants, or their responses may be swayed by the feeling of the group. The Researcher felt that having participants share in a focus group setting may be less confrontational for participants and allow them to avoid answering questions they are uncomfortable with, they stated that the Participant Information Sheet makes it clear that confidentiality cannot be ensured in this setting, participants could bring a support person, and they would have a psychiatrist present at the focus group to help make them feel more comfortable.
6. The Committee requested further information on the psychiatrist who would be present at the focus groups, specifically who they are and their qualifications, what their role during the after the focus group would be, and whether they would be available after the focus group if participants became distressed. The Committee stated that this information must also be added to the Participant Information Sheet. The Researcher explained that they have only recently had this psychiatrist come on board with the study and this is why they are not yet on the Participant Information Sheet.
7. The Committee questioned what would happen if a participant ended up leaving the focus group early because they felt upset and whether someone would be available to speak with them and ensure they were safe. The Committee noted that this probably could not be the psychiatrist as they would still need to attend the focus group.
8. The Committee questioned what would happen if someone in the focus group disclosed suicidal thoughts, current abuse, or other concerning information. The Researcher noted that the Participant Information Sheet had contact information for support services. The Committee stated that a more specific and immediate plan must be in place to deal with this possibility.
9. The Committee questioned whether the Researcher’s supervisors are suitably qualified and experienced to supervise this study. The Researcher explained that both of her supervisors are psychiatrists. The Committee stated that from their University profiles and publication history this did not appear to be correct, and it did not seem that they have specific experience working with suicidal people. The Committee requested further information about the suitability of the supervisors for the study.
10. The Committee emphasised that the participants are very vulnerable and although the study stated participants in active crisis would be excluded it was not clear how this would be determined, who would determine it, or what specifically is meant by ‘active crisis’.
11. The Committee questioned the responses to the cultural questions in the application form, specifically it was indicated that Kaupapa Māori research methodologies would be used but no further information on this was given. The Committee suggested that this may be an error and requested further information.
12. The form indicates that there will be a Māori focus group involving a number of specific cultural practices. The Committee questioned who would be preforming these, indicating that they expect these to take a considerable amount of time at the start of the focus group and require an experienced person to lead. The Committee further questioned whether a Māori cultural support person would be present at the Māori focus group.
13. The Committee noted that the researcher made reference a number of times to a reference group, they indicated that further information about this would be helpful.
14. The Committee raised concerns regarding whether or not the CI is suitably qualified and experienced to take professional responsibility for this study. They explained that if they felt that she was suitably supported and supervised that it would alleviate their concerns, however, the Committee felt that from the information they currently have this was not clear.
15. The Committee expressed strong disappointment that the CI’s supervisors were not present to support the CI and help answer questions and stated that they expect the supervisors to be more involved for all applications from students.
16. The Committee stated that the evidence of scientific review that was provided with this study was not sufficient and requested more evidence to show the scientific validity and suitability of the study. The Committee indicated that this needed to be suitably independent and detailed, they suggested that the HDEC template is used for guidance.

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

1. The Committee raised concerns about the suitability of the terms ‘service users’ and ‘key informants’ as the Committee feel that these people are unlikely to refer to themselves with these terms. The Researcher explained that these terms were suggested by their supervisors. The Committee stated that it was fine to use these terms in study documents that weren’t participant facing, but all participant facing documents should be revised to use more participant friendly terms. The Committee suggested that ‘service users’ could be replaced with ‘people who have used suicide prevention services’.
2. Please revise the Participant Information Sheet to remove all jargon, lay participants must be able to understand the Participant Information Sheet. For example, ‘best practice’ should be removed and replaced with a statement such as ‘we want to find out what worked best for you, or helped you the most’. Terms like ‘best practice’ are not used by lay people and participants should not be expected to know what this means.
3. Please add to the Participant Information Sheet information on getting emergency help, specifically that participants should call 111 if they need emergency assistance. This information should be bolded for emphasis.
4. The Participant Information Sheet indicates that the CI has a number of years experience, please clarify how many and the Committee suggests that it may be better to not state this experience is in the UK.
5. The Committee explained that the Participant Information Sheet needs to be a balance of friendly and professional, currently they feel it is not friendly enough for the vulnerable nature of the participants.
6. Please revise the Participant Information Sheet to remove repetition of the research question.
7. The Committee appreciated the inclusion of personal information in the Participant Information Sheet as they expected this would help build trust with participants and make it more relatable.
8. Please remove all yes/no tick boxes from the Consent Form for all statements that aren’t truly optional, meaning that a participant could select ‘no’ and still participate in the study.
9. Please revise the Consent Form to ensure all statements are relevant and applicable to this study as many seem to only apply to clinical trials.
10. The Committee questioned who would transcribe the interviews and conflicting information was provided. The Researcher explained that they had intended to do it themselves but have now been advised to hire a transcriber to do this task. Please revise the Participant Information Sheet to reflect this.
11. Please clarify the Participant Information Sheet to be clear that all health information collected will be stored for a minimum of 10 years.

Decision

This application was *declined* by consensus, as the Committee did not consider that the study would meet the following ethical standards.

* Further information is required to demonstrate that the investigator conducting the focus groups and interviews is suitably qualified and experienced. The lead/principal investigator [should be] suitably qualified, experienced, registered and indemnified to take professional responsibility … for the conduct of the study … (*HDEC Standard Operating* Procedures para 176.1).
* Studies must be conducted or supervised only by investigators with the necessary skills and resources to conduct the study and deal with any contingencies that may affect participants. Necessary skills may include competence in understanding different cultural understandings of knowledge and of how such understandings might impact on the analysis and results of a study. (*Ethical Guidelines for Observational Studies* para 5.9).
* Please amend the information sheet and consent forms, taking into account the suggestions made by the committee *(Ethical Guidelines for Observational Studies para 6.10)*

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| **10** | **Ethics ref:** | **16/STH/212** |
|  | Title: | Knee-Fix study (Cemented vs Uncemented Total Knee Replacement) |
|  | Principal Investigator: | Mr Simon Young |
|  | Sponsor: |  |
|  | Clock Start Date: | 01 December 2016 |

Mr Simon Young and Mr Luke Brunton were present by teleconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. This study investigates whether uncemented total knee replacements are more suitable, or at least non-inferior than the current gold standard of care (cemented total knee replacement).
2. Although both cemented and uncemented are currently used it is believed that uncemented may be better but is used less frequently than cemented.

Summary of ethical issues (resolved)

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

1. The Committee questioned whether this study is being conducted principally for the benefit of the manufacturer of the product. The Researcher explained that although the company that manufactures the implants is providing some funding the study is primarily funded internally by the researchers’ organisation and the manufacturer has no control over the study or results.
2. The Committee questioned the data safety monitoring arrangements for the study. The Researcher has confirmed that they have internal data safety monitoring committee (consisting of two consultants and a patient advocate).
3. The Committee questioned how participants will be recruited for the study. The Researcher explained that they will be approached about the study in clinic by their clinician and then informed consent will be obtained by a research assistant if they are interested, participants are given 24 hours to decide whether they would like to be involved. The Committee questioned whether more time could be given if participants are undecided. The Researcher clarified that there will be approximately 3 months between when the trial is mentioned and when they have their surgery and they will be able to consider their participation at this time.
4. The Committee questioned whether the researchers have signed a clinical trial agreement, as indicated in the application form. The Researcher explained that this was a mistake in the application form.
5. The Committee questioned whether the researchers felt that the reading level of their Participant Information Sheet is suitable. The Researcher felt that it is. The Committee agreed, and noted that the formatting made the Participant Information Sheet more readable.
6. The Committee questioned when the surgeon will be unblinded. The Researcher explained that they will be unblinded before surgery as the preparation is slightly different.

Summary of ethical issues (outstanding)

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

1. Please remove the interpreter box from the Consent Form and replace with a statement regarding the availability of interpreters.
2. The Committee suggested that the word ‘fix’ in the study title may mislead participants about the expected benefits of study participation, the Committee assumed that in this case ‘fix’ is intended to refer to ‘fixation’ but they stated that participants are likely to assume it refers to fixing their damaged knee. The Committee suggests that this may be revised on the Participant Information Sheet.
3. The Participant Information Sheet lists benefits of knee replacement as benefits of study participation, however, participants are getting a knee replacement whether or not they are involved in the study. Please revise this section to only include study specific benefits.
4. The Participant Information Sheet currently implies that if participants withdraw from the study they will receive a cemented knee, even if they have already had their knee replacement. Please revise this statement for clarity. The Committee suggested that a statement along the lines of the following may be suitable: ‘If you withdraw from the study before your knee replacement surgery you may or may not have the uncemented knee replacement and will not be followed up by the study team’.

Decision

This application was *approved* by consensus, subject to the following non-standard conditions.

* 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*).

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| 11 | **Ethics ref:** | **16/STH/208** |
|  | Title: | A study comparing Filgotinib and placebo in Subjects with Moderately to Severely Active Ulcerative Colitis |
|  | Principal Investigator: | Dr Benjamin Griffiths |
|  | Sponsor: | Gilead Sciences, Australia & New Zealand |
|  | Clock Start Date: | 24 November 2016 |

No member of the research team was 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 (resolved)

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

1. The Committee noted that the application was confusing regarding whether participants could be taking other standards of care and still be in the study. However, they understood that participants cannot take a number of standard medications while in the study and this is clear in the Participant Information Sheet.

Summary of ethical issues (outstanding)

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

1. Please revise the Participant Information Sheet to make it not optional to inform the participant’s GP for their study participation, all participants’ GPs must be informed of their participation.
2. Please add information to the Participant Information Sheet regarding tissue being sent overseas, including where it will be sent.
3. In the Future Unspecified Use of Tissue Participant Information Sheet please replace the statement ‘samples will be provided at no charge’ with a statement that clearly states participants will not be paid.
4. The Committee queried the lack of a Māori tissue statement in the Participant Information Sheets. The committee recommended the following statement: “*You may hold beliefs about a sacred and shared value of all or any tissue samples removed. The cultural issues associated with sending your samples overseas and/or storing your tissue should be discussed with your family/whanau as appropriate. There are a range of views held by Māori around these issues; some iwi disagree with storage of samples citing whakapapa and advise their people to consult prior to participation in research where this occurs. However, it is acknowledged that individuals have the right to choose.”*

Decision

This application was *approved* by consensus, subject to the following non-standard conditions.

* 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*).

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| **12** | **Ethics ref:** | **16/STH/209** |
|  | Title: | A Long-Term Extension Study to Evaluate the Safety of Filgotinib in Subjects with Ulcerative Colitis |
|  | Principal Investigator: | Dr Benjamin Griffiths |
|  | Sponsor: | Gilead Sciences, Australia & New Zealand |
|  | Clock Start Date: | 24 November 2016 |

No member of the research team was 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 (resolved)

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

1. The Committee noted that the application was confusing regarding whether participants could be taking other standards of care and still be in the study. However, they understood that participants cannot take a number of standard medications while in the study and this is clear in the Participant Information Sheet.
2. There is an open-label alternative at the highest possible dose for participants who had disease worsening or lack of response in the parent study. Have this group been unblinded, it is assumed that these participants will not have already been receiving the maximum dose of Filgotinib.

Summary of ethical issues (outstanding)

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

1. Please revise the Participant Information Sheet to make it not optional to inform the participant’s GP for their study participation, all participants’ GPs must be informed of their participation.
2. Please add information to the Participant Information Sheet regarding tissue being sent overseas, including where it will be sent.
3. In the Future Unspecified Use of Tissue Participant Information Sheet please replace the statement ‘samples will be provided at no charge’ with a statement that clearly states participants will not be paid.
4. The Committee queried the lack of a Māori tissue statement in the Participant Information Sheets. The committee recommended the following statement: “*You may hold beliefs about a sacred and shared value of all or any tissue samples removed. The cultural issues associated with sending your samples overseas and/or storing your tissue should be discussed with your family/whanau as appropriate. There are a range of views held by Māori around these issues; some iwi disagree with storage of samples citing whakapapa and advise their people to consult prior to participation in research where this occurs. However, it is acknowledged that individuals have the right to choose.”*

Decision

This application was *approved* by consensus, subject to the following non-standard conditions.

* 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*).

## 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:** | 24 January 2017, 12:00 PM |
| **Meeting venue:** | Sudima Hotel – Christchurch Airport, 550 Memorial Drive, Christchurch |

1. **Problem with Last Minutes**

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

The meeting closed at 5:05pm.