|  |  |
| --- | --- |
| **Committee:** | Northern A Health and Disability Ethics Committee |
| **Meeting date:** | 15 December 2016 |
| **Meeting venue:** | Ministry Of Heath - Via Teleconference |

|  |  |
| --- | --- |
| **Time** | **Item of business** |
| 12.00pm | Welcome |
|  | New applications (see over for details) |
| 12.00pm | i 16/NTA/227  ii 16/NTA/228  iii 16/NTA/229  iv 16/NTA/230  v 16/NTA/231  vi 16/NTA/232  vii 16/NTA/233  viii 16/NTA/234  ix 16/NTA/235  x 16/NTA/236  xi 16/NTA/237  xii 16/NTA/238 |
| 4.30pm | General business:   * Noting section of agenda |
| 4.45pm | Meeting ends |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Member Name** | **Member Category** | **Appointed** | **Term Expires** | **Apologies?** |
| Dr Brian Fergus | Lay (consumer/community perspectives) | 11/11/2015 | 11/11/2018 | Present |
| Dr Paties Herst | Non-lay (Intervention studies) | Co-opt | Co-opt | Present |
| Dr Charis Brown | Non-lay (observational studies) | 11/11/2015 | 11/11/2018 | Present |
| Ms Raewyn Idoine | Lay (consumer/community perspectives) | Co-opt | Co-opt | Present |
| Dr Nicola Swain | Non-lay (Intervention studies) | Co-opt | Co-opt | Present |
| Dr Nora Lynch | Non-lay (Intervention studies) | Co-opt | Co-opt | Present |
| Dr Cordelia Thomas | Lay (legal moral reasoning) | Co-opt | Co-opt | Present |
| Dr Peter Gallagher | Non-lay (observational studies) | Co-opt | Co-opt | Present |

## Welcome

The Chair opened the meeting at 12.00pm and welcomed Committee members. The Chair noted this was an exceptional teleconference meeting to facilitate the high demand of applications towards the end of 2016.

The Chair noted that fewer than five appointed members of the Committee were present, and that it would be necessary to co-opt members of other HDECs in accordance with the SOPs.

Dr Nicola Swain, Ms Raewyn Idoine, Dr Nora Lynch, Dr Peter Gallagher, Dr Cordelia Thomas and Dr Patries Herst confirmed their eligibility, and were co-opted by the Chair as members 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.

## New applications

|  |  |  |
| --- | --- | --- |
| **1** | **Ethics ref:** | **16/NTA/227** |
|  | Title: | Nasal high flow in acute respiratory failure in AECOPD – A feasibility study |
|  | Principal Investigator: | Dr James Fingleton |
|  | Sponsor: | Medical Research Institute of New Zealand |
|  | Clock Start Date: | 16 January 2017 |

Steve McKinstry and James Fingleton 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 current feasibility study aims to determine whether the planned full randomised controlled trial is feasible with the current design, timescale and number of sites. The feasibility study will not directly use the NHF device but instead test parts of the full study design.
2. In a future, full study, The Researcher(s) propose to conduct a randomised controlled trial (RCT) in 726 patients with an acute exacerbation of COPD (AECOPD) who present to the Emergency Department (ED) at one of seven sites in New Zealand and are found to have acute hypercapnic respiratory failure (AHRF) with acidosis. The trial will directly compare usual care plus controlled oxygen via NHF therapy with usual care plus controlled oxygen through standard nasal cannulae, in line with current best practice.
3. This feasibility study has 2 components. Agreeing on a protocol between Wellington, Waikato and Christchurch Emergency Departments on how to treat patients with AECOPD and AHRF with acidosis, in accordance with International guidelines, and Following 40 patients, to test feasibility issues with the full study.

Summary of ethical issues (resolved)

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

1. The Committee queried why additional venous blood gas (VBG) sample is required for the study. The Researcher(s) explained it allows increased accuracy due to the ability to compare the two tests. The Researcher(s) explained it determines whether individuals should be treated with a mask or nasal prongs. The Committee noted there was a benefit for the individual participant to have this additional test due to the potential for it to provide clinical information that could lead to less invasive treatments both for the participant during future admissions and for others..
2. The Committee accepted best interest argument made for this study and was satisfied that the study was lawful.
3. The Committee and The Researcher(s) discussed the use of data in the event of death or loss to follow up.

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

1. The Committee noted there should be one Participant Information Sheet for patient and another one for family members/suitable persons to give their views, rather than a dual purpose Participant Information Sheet.

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 Nicola Swain and Mrs Raewyn Idoine.

|  |  |  |
| --- | --- | --- |
| **2** | **Ethics ref:** | **16/NTA/228** |
|  | Title: | A Treatment Study of ACH-0144471 in Patients with Paroxysmal Nocturnal Hemoglobinuria |
|  | Principal Investigator: | Dr Peter Browett |
|  | Sponsor: | Clinical Network Services Ltd |
|  | Clock Start Date: | 16 January 2017 |

Dr Peter Browett and Margaret Joppa were present by teleconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. This is a treatment proof-of-concept study designed to evaluate the efficacy of 28 days of treatment, based on reduction of lactate dehydrogenase (LDH) levels. Patients will be evaluated over time with regards to their transfusion history, levels of ongoing hemolysis (i.e., LDH and Hgb), Quality of Life (QoL) assessments, and measures of what the drug does to the body, and what the body does to the drug.
2. Only conducted in healthy volunteers. Other related studies are on-going.
3. Patients will have an initial visit and procedures to confirm their eligibility for this study. The status of their vaccinations against N. meningitidis, H. influenzae, and S. pneumoniae will be determined. Patients may require up to 4 vaccinations depending on their history. Vaccinations may be provided to patients who are eligible but who do not have an adequate vaccination history to qualify for this study (one being Bexsero which is not approved in New Zealand; however, the vaccination is approved in other countries including Australia).
4. Participants may be currently participating in the screening protocol (ACH471-102), which is to collect baseline data and provide vaccination in preparation for this treatment study. Treatment Part 1 consists of 28-day oral dosing with regular clinical assessment to measure pharmacokinetics (PK), pharmacodynamics (PD), efficacy, and safety. A possible dose escalation can take place on either day 7 or 14.
5. Each patient may be offered continued dosing beyond Day 28 in an extension study of up to 60 days (Part 2). Participation in Part 2 will be based on Day 20 data, and will consist of further clinic visits to evaluate safety, efficacy, and PK and PD. In both parts, subjects will be instructed to slowly reduce the dose before stopping.

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 the risk of harm from the study drug, adding there was no formal DMC. The Committee noted they are only proposing to treat 4 patients so should be able to monitor safety adequately.
2. The Committee noted the blood samples are 400-500 ml over ~ 4 weeks. This is more than the usual blood donation volume. The Committee discussed the safety with investigator, given PNH causes anaemia. The Researcher(s) stated the participants will be maintaining an adequate haemoglobin. At the time it will be around 100mls every 7-10 days. The Researcher(s) stated this was a safe amount.
3. The Committee asked whether, if study drug available post study, would this be paid for by the sponsor. The Researcher(s) stated they would.

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

1. Pg. 2 Correct to NTA.
2. Explain what a factor D inhibitor is or leave it out. Currently unclear for participants as to what this means.
3. Pg. 3 Exclusion criteria are vague.
4. Pg. 4 Is alcohol avoidance mandatory. If so make it clear for participants.
5. Labs drawn, please amend to blood drawn. Pg.4.
6. The Committee queried whether prescription drugs are being construed as drugs of abuse. Please amend to just state ‘drugs’.
7. Please remove the option for GP notified as this is not truly optional.
8. Pg. 16. Should read "first study in patients" not "humans".
9. The clinic stay on days 3,6,13,20,28 seems like it will be ~ 8-12 hours. Please make the length of the clinic visits clear.
10. The Committee recommends the researchers add lay language title.
11. The Committee recommends they replace ACH-0144471 with study drug, after defining it first time.
12. Increase the margins so the document is easier to read.
13. Clarify where the visits are located in the Participant Information Sheet.
14. Page 10, additional blood samples. The Committee queried whether these genetic samples are the same genetic samples as optional Participant Information Sheet ones, or whether some are mandatory. The Researcher(s) explained only one sample is optional. Make this clear for participants.
15. Page 15. Regarding health information – you can withdraw verbally. No requirement to withdraw in writing. This is on page 18 of the consent form too.
16. Remove ‘legal representative’.

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 Secretariat.

|  |  |  |
| --- | --- | --- |
| **3** | **Ethics ref:** | **16/NTA/229** |
|  | Title: | A study comparing Filgotinib and placebo in Subjects with Moderately to Severely Active Crohn's Disease |
|  | Principal Investigator: | Dr Ben Griffiths |
|  | Sponsor: | Gilead Sciences, Australia and New Zealand |
|  | Clock Start Date: | 16 January 2017 |

Jonathan Barrett was present by teleconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. The purpose of this study is to see if filgotinib is effective and safe in treating people with moderate to severe Crohn’s Disease (CD). Participants who are biologic naïve and biologic experienced will be enrolled in Cohorts A and B respectively. Treatment assignments will be randomised within each Cohort.
2. Approximately 1320 participants across 400 centres worldwide will take part in this study. This study is open to men and women with Crohns aged between 18 to 75 years.
3. Participation in this study will last about 58 weeks, not including the screening visit or the post ­treatment visit (30 days after last dose).

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 an ethical issue is the use of a placebo in 1/3 of cohort who all have very active disease when there is an untried TNF inhibitor option for Cohort A and a second TNF option for many of Cohort B.
2. The Committee noted additionally, those who are in remission by 10 weeks then have a 1/3 chance of going onto placebo through re-randomisation with flare risk. The Researcher(s) explained that they are recruiting people who have moderate to severe Crohn’s. If they don’t respond to the treatment arm they are assigned to they will have opportunity to go to the OLE.
3. The Researcher(s) explained if patients need treatment they will always be offered it. The Researcher(s) explained the rescue therapies available.
4. The Committee noted the chance of permanent male infertility, based on animal studies. Consider excluding heterosexual men who have yet to complete a family. The Researcher(s) explained they explain the risks in full and leave it up to the individual to decide. There are other options too, such as sperm banking as a precaution which will be explained.
5. The Researcher(s) confirmed placebo arm participants are allowed people to stay on standard of care options.

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

1. Change title of consent form to consent form.
2. A.1.6 – add this information to the Participant Information Sheet.
3. Add statement that participation won’t affect your care on the first page. Send from HDEC template.
4. Questionnaires pg.15 – give an example of personal question.
5. Explain what a placebo is.
6. Pg. 10 reads as through there is compulsory retention of samples for Future Unspecified Research even though there is a separate Participant Information Sheet for this.
7. Pg. 19. Cannot stop access to personal information until the end of the study in 2020. Reword to indicate obtaining information will censor you from the trial.
8. Pg. 19. Don't have to withdraw in writing.
9. Pg. 20 – remove legally authorised.
10. Baby must be born alive before seeking consent to collect data on the child, so please re-contact either in person or via phone to re-consent once baby born to continue data collection.
11. Remove US statements and all cases of representative signatures, this is not valid in New Zealand.
12. Add contact details at the end. This is a suggestion not a requirement.
13. The Committee asked whether page 2 of 7 optional Future Unspecified Research sub study. What is the purpose, outline about biomarkers.

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 Peter Gallagher and Dr Cordelia Thomas.

|  |  |  |
| --- | --- | --- |
| **4** | **Ethics ref:** | **16/NTA/230** |
|  | Title: | A Long-Term Extension Study to Evaluate Filgotinib in Subjects with Crohn's Disease |
|  | Principal Investigator: | Dr Ben Griffiths |
|  | Sponsor: | Gilead Sciences, Australia and New Zealand |
|  | Clock Start Date: | 16 January 2017 |

Jonathan Barrett was present by teleconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. The proposed study, GS-US-419-3896, is an extension study to evaluate the safety of filgotinib administered to participants with Crohn’s Disease (CD). Approximately 1000 subjects with CD who have completed or met protocol specified efficacy discontinuation criteria in a prior Gilead sponsored filgotinib treatment study in CD will be enrolled to this study.
2. It is planned to conduct the trial at approximately 350 centers worldwide.
3. Subjects who fully complete the parent study blinded will continue blinded dosing at the same regimen in the LTE study. Subjects who exit a parent study due to disease worsening or failure to meet response will receive OL 200 mg filgotinib.
4. During this time participants will be required to visit the clinic at least 26 times.

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

1. Change title of consent form to consent form.
2. A.1.6 – add this information to the Participant Information Sheet.
3. Add statement that participation won’t affect your care on the first page. Send from HDEC template.
4. Questionnaires pg.15 – give an example of personal question.
5. Pg. 10 reads as through there is compulsory retention of samples for Future Unspecified Research even though there is a separate Participant Information Sheet for this.
6. Pg. 19. Cannot stop access to personal information until the end of the study in 2020. Reword to indicate obtaining information will censor you from the trial.
7. Pg. 19. Don't have to withdraw in writing.
8. Pg. 20 – remove legally authorised.
9. Baby must be born alive before seeking consent to collect data on the child, so please re-contact in person or via phone to re-consent once baby born to continue data collection.
10. Remove US statements and all cases of representative signatures, this is not valid in New Zealand.
11. Add contact details at the end. This is a suggestion not a requirement.
12. The Committee asked whether page 2 of 7 optional Future Unspecified Research sub study. What is the purpose, outline about biomarkers.

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 Cordelia Thomas and Dr Peter Gallagher.

|  |  |  |
| --- | --- | --- |
| **5** | **Ethics ref:** | **16/NTA/231** |
|  | Title: | REDUCCTION |
|  | Principal Investigator: | Dr David Semple |
|  | Sponsor: | The George Institute |
|  | Clock Start Date: | 16 January 2017 |

A/Prof Martin Gallagher was present by teleconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. The REDUCCTION Project is an evidence implementation study that will collect data on at least 75% of all central venous dialysis catheters inserted across Australia and New Zealand. The project will involve a minimum of 35 renal units across the two countries, measuring central venous dialysis catheter exposure and complications.
2. The evidence-based intervention (suite of interventions) will incorporate multiple components of care throughout dialysis catheter use. Using a stepped wedge cluster design, the complete suite of interventions will be implemented at a unit level, with the introduction of the study intervention determined through a randomisation schema. The study will analyse the effect of this intervention upon the primary outcome of the rate of dialysis catheter associated bacteraemia.
3. For New Zealand, the study will be implemented at one site, with an intent to expand to approximately 6-8 over the study duration.
4. 2000 participants in New Zealand. 9000 total participants.

Summary of ethical issues (outstanding)

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

1. The Committee noted the central ethical issue is around proposed consent processes which need to meet New Zealand regulations. The Committee noted there are requirements for non-consented observational research and the researchers will need to justify it on this basis. The requirements also depended upon whether the data was standardly collected or whether it was collected for this research protocol.
2. The Researcher(s) explained that the initial approach to ethics in Australia involved an opt-out process. After speaking with many sites in the Northern Territories they suggested we go for a waiver of consent. This has been approved by other ethics committees in Australia. The Researcher(s) believes it is justified because this data is collected already and is reported in New Zealand. The Researcher(s) believed that patients believe that patient data would be used to improve healthcare. The Researcher(s) stated data comparisons (scientific value) required complete data collection through a waiver.
3. The Committee asked if all data is collected in New Zealand regardless of the study protocol being implemented at the site. The Researcher(s) stated that most data is already collected, but the data collection (from the protocol) goes into more detail, and includes patients who have acute kidney injury. The Researcher(s) clarified that there may be varied data recorded at different sites.
4. The Committee noted informed consent should be sought unless there is a strong reason why it could not be, adding that if data is already collected there are clear regulatory pathways to use data without consent however collecting new information without consent was generally restricted. The Committee noted if any new data is collected for the study then consent must be sought.
5. The Committee noted if data is already collected then retrospective access without consent falls under the Health Information Privacy Code, Rule 11. The National Ethics Advisory Committee Guidelines require a case to be made with reference to the following requirements:

*a) the procedures required to obtain consent are likely to cause unnecessary anxiety for those whose consent would be sought; or the requirement for consent would prejudice the scientific value of the study; or it is impossible in practice to obtain consent due to the quantity or age of the records;* ***and***

*b) there would be no disadvantage to the participants or their relatives or to any collectivities involved;* ***and***

*c) the public interest in the study outweighs the public interest in privacy.*

1. The Committee asked what percentage will be unable to provide consent due to their illness. The Researcher(s) explained there would be some participants unable to provide their own consent but was not sure how many this would be in New Zealand contexts.
2. The Committee was unclear as to whether this protocol involved any new data collection. The Committee stated that as the researcher that was present for the study was not from New Zealand they could not be assured that this study was a retrospective data study or a prospective study involving data collection from participants who could not consent. The two types of studies have different legal and regulatory requirements to be met, which meant the Committee could not make a ruling at this time.
3. The Committee noted the need to ensure the study complies with New Zealand regulations.
4. The Committee suggested resubmitting, taking into account whether the data is standardly collected data or not. If it is not, consent is required to collect this data for research. If it were collected as standard of care an argument could be made to access records without consent, based on argument the guidance provided above.

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

1. Remove legally authorised person signature on the consent form. This is not a valid option in New Zealand.

Decision

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

* In relation to the collection of health information, investigators should provide to observational study participants any information that a reasonable person in their circumstances would expect to receive. This is so whether or not consent to participate in the study is required. The information required (if any) will depend on the design of the observational study in question. The Code of Rights, Right 6(1)(d) states:
* Every consumer has the right to information that a reasonable consumer, in that consumer’s circumstances, would expect to receive, including … notification of any proposed participation in teaching or research, including whether the research requires and has received ethical approval. (See also paragraph 3.2.) Is data standard or new New Zealand law requirements – code and HDC. See the Code of Rights, Right 7(4) for information on research with participants who cannot provide informed consent. *(National Ethics Advisory Committee Guidelines for Observational Studies 6.1)*
* An investigator who proposes not to seek informed consent for use of identified or potentially identifiable data for research must explain to an ethics committee the reasons for not seeking consent, and how the study would be ethical in the absence of consent. *(National Ethics Advisory Committee Guidelines for Observational Studies 6.45)*
* The Committee however notes the importance of this research and suggests that the NZ Principal Investigator take an active role in complying with our regulations. The NZ PI should be well aware of these.

|  |  |  |
| --- | --- | --- |
| **6** | **Ethics ref:** | **16/NTA/232** |
|  | Title: | M16-126: A Study of Glecaprevir/Pibrentasvir in Adults with Chronic Hepatitis C Virus Genotype 5 or 6 |
|  | Principal Investigator: | Prof Edward Gane |
|  | Sponsor: | AbbVie Ltd |
|  | Clock Start Date: | 16 January 2017 |

Prof Edward Gane waspresent 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 Phase 3b, open-label, multicenter study to evaluate the efficacy and safety of Glecaprevir (GLE)/Pibrentasvir (PIB)in HCV treatment-naïve or treatment-experienced (i.e., has failed prior IFN or pegIFN with or without RBV, or SOF plus RBV with or without pegIFN therapy), chronic HCV GT5 or 6 infected subjects, without cirrhosis (F0-F3) for an 8-week treatment duration or with compensated cirrhosis (F4) for a 12-week treatment duration.
2. This study will consist of 2 periods as follows:
3. Treatment Period: Eligible subjects will be enrolled to receive GLE/PIB for an 8 or 12 week treatment duration based on cirrhotic status.
4. Post-Treatment Period: Subjects who complete or prematurely discontinue the
5. Treatment Period will be followed for 24 weeks after their last dose of study drug to evaluate efficacy and to monitor HCV RNA and the emergence and persistence of viral variants.
6. Approximately 80 eligible subjects will be enrolled into one of the following treatment arms:
   * + Arm A: HCV GT 5 or 6 non-cirrhotic subjects will be treated with GLE/PIB 300 mg/120 mg once daily (QD) for 8 weeks.
     + Arm B: HCV GT 5 or 6 subjects with compensated cirrhosis will be treated with GLE/PIB 300 mg/120 mg once daily (QD) for 12 weeks.
7. The study was designed to enrol approximately 80 subjects to meet scientific and regulatory objectives without enrolling an undue number of subjects in alignment with ethical considerations.
8. Therefore, if the target number of subjects has been enrolled, there is a possibility that additional subjects in screening will not be enrolled.
9. The Researcher(s) explained this is a registration study based on the view that the larger study did not involve genotype 5 and 6.

Summary of ethical issues (resolved)

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

1. The Researcher(s) confirmed SCOTT is being sought.
2. The Researcher(s) confirmed participants can remain on standard of care treatments.
3. The Researcher(s) explained why there are no health risks in the event that male participants’ partners became pregnant while on study drug.
4. The Committee stated the insurance certificate expires in 2 months. Please ensure this is updated.

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

1. The Committee noted the Participant Information Sheet is 19 pages not 18.
2. The Committee requested when discussing side effects. Please explain what the last two terms are in lay language.
3. Page 3 – study procedures. Suggested putting in a box or separating it out. This information is important, could get lost in the text.
4. ‘if required by state law’. Please remove US terms. Another example is ‘doctor’s office’.
5. The Committee queried whether consent form could have a statement about receiving information on the outcome of the trial.

Decision

This application was *approved* by consensus.

|  |  |  |
| --- | --- | --- |
| **7** | **Ethics ref:** | **16/NTA/233** |
|  | Title: | Comparison of the blood levels of four forms of isotretinoin 10mg and 25mg capsules in healthy male volunteers under fasting conditions |
|  | Principal Investigator: | Dr Noelyn Hung |
|  | Sponsor: | Douglas Pharmaceuticals America Ltd |
|  | Clock Start Date: | 16 January 2017 |

Dr Noelyn Hung, Dr Tak Hung and Linda Folland 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. The objective of this study is to evaluate the pharmacokinetics of the test formulations of 10 mg and 25 mg isotretinoin capsules (Douglas Pharmaceuticals America Ltd) relative to that of the reference formulations, 10 mg and 25 mg Absorica® capsules, manufactured by Ranbaxy Laboratories, USA following oral administration of a single dose of 10 mg and 25 mg in healthy male subjects under fasting conditions. This pilot study is being conducted to determine the dose proportionality of the pharmacokinetics and will provide valuable information in the design of a pivotal bioequivalence study.
2. During each of the four treatment periods, each of the enrolled and randomised healthy male subjects will receive a single dose of 10 mg or a single dose of 25 mg isotretinoin capsule of the test or reference formulation in a four way cross-over design. There will be at least 1 week washout between each dosing period.
3. Blood samples will be collected at baseline (-10, -2 and 0 hours) and at specified times up to 72 hours after dosing. The plasma will be assayed for isotretinoin by LCMSMS using a fully validated assay as recommended by the US FDA.

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 this is a nontherapeutic study in healthy male volunteers. Safety systems seem appropriate. Internal DMC appropriate for the dose and drug.
2. Note large blood draw, equivalent to 2 x donations of blood in 30 days. The Researcher(s) noted it is at the upper limit. The Committee queried whether the haemoglobin levels drops. The Researcher(s) stated yes it can drop 10 points. The Researcher(s) explained this is men only, who can handle this drop in blood.

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

1. The Committee noted that Isotretinoin is a teratogen with a 60 day stand down from conceiving. This needs to be clearly explained.
2. The Committee queried why insurance should only be checked for international students, please change to any participant should check their insurance.

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

1. Pg. 1 says double blinded but protocol and HDEC form say open trial. Clarify and correct if necessary.
2. Pg. 2 Correct to NTA from Southern HDEC.
3. Pg. 2 No power or energy drinks within a year. The Committee asked whether this was correct and asked what is defined as an energy drink. Please clarify for participants. The Researcher(s) stated one week for using caffeine but the drug abuse is one year. This was an error that would be fixed.

Decision

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

|  |  |  |
| --- | --- | --- |
| **8** | **Ethics ref:** | **16/NTA/234** |
|  | Title: | Can a new blood test predict dementia |
|  | Principal Investigator: | Dr Joanna Williams |
|  | Sponsor: |  |
|  | Clock Start Date: | 16 January 2017 |

Joanna Williams and Bob 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 study aims to discover molecules (biomarkers) in blood samples that predict Alzheimer’s disease.
2. If the onset of dementia could be predicted from blood tests, it would be possible to inform people of lifestyle changes and future drug interventions that would delay progression of the disease.
3. In prior research we have recruited a sample of persons with a clinical diagnosis of Alzheimer’s disease through clinics in Dunedin Hospital and dementia support groups in the community.
4. The Researcher(s) have confirmed the diagnosis of Alzheimer’s disease from hospital records, and further laboratory and clinical tests including an MRI scans. An age-matched sample of healthy controls had been recruited from the community by advertisement, who have been asked to attend a psychometric testing session to ensure they have normal memory performance for their age.
5. All participants had been asked to supply a blood sample that will be analysed using modern molecular technology to test for candidates’ molecules that may form a blood test of dementia. These molecules include proteins and microRNAs.

Summary of ethical issues (resolved)

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

1. The Committee asked for more details around the original consent process for future unspecified research. In particular, were all of the Alzheimer’s patients deemed able to consent (in terms of capacity). The Researcher(s) explained that initially they recruited people who were able to consent. The Researcher(s) added they also recruited people with relatives consent. The Committee noted this is not a legally valid consent but noted the samples were already stored. The Researcher(s) stated the total figure was 50 participants with dementia and 50 controls, though how many were those with dementia who could not consent themselves may have been around 10-20.
2. The Researcher(s) stated the samples were collected in 2010-12.
3. The Committee noted 7(10) of the Code states that stored samples can be used with ethics committee review. The Committee noted it is unfortunate that a proxy consent was used in 2010 as this is not lawful but the samples are not able to be re-consented for this group and there are important health benefits from this study.
4. The consent for Future Unspecified Research was for up to 5 years from publication of the first trial (see pg. 2 of PIS). The Committee asked when this expires, adding this consideration is particularly relevant to using the samples in this project due to the intent to continue storage by setting up a tissue bank. The Researcher(s) confirmed the study has not been published, so the 5 years has not started.
5. The Researcher(s) stated blood will not go overseas. This was an error in the application.
6. R.4.1 - What will they do if a new Alzheimer’s biomarker is developed and found positive in participants within the normal control group? Will subjects be informed? The Researcher(s) stated currently they only compare between the control groups vs. AD patients. The data that is compared is anonymised and the analysis concerns patterns and data points not individuals. The Researcher(s) confirmed there is no way this study will generate incidental findings.
7. The Committee confirmed approval to store tissue in a HDEC registered tissue bank (which will come as a separate application).

Decision

This application was *approved* by consensus.

|  |  |  |
| --- | --- | --- |
| **9** | **Ethics ref:** | **16/NTA/235** |
|  | Title: | EFC14335\_ICARIA MM |
|  | Principal Investigator: | Dr Hilary Blacklock |
|  | Sponsor: | sanofi-aventis Australia Pty Ltd |
|  | Clock Start Date: | 16 January 2017 |

Hillary Blacklock, Catherine Howie and Smita Charles were present by teleconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. This is a phase 3, multinational, multicentre, open-label,randomised study to evaluate the effectiveness and possible risks of isatuximab in combination with pomalidomide and low-dose dexamethasone (experimental arm) compared to pomalidomide and low-dose dexamethasone (control arm) in the treatment of patients with refractory or relapsed and refractory multiple myeloma multiple myeloma.
2. The study treatment will be randomly assigned to patients who will have an equal chance of receiving either of the 2 arms of the study treatment. Being open-label, both the patient and the study doctor will know which treatment the patient is receiving.
3. Study treatment will be given in 28 day cycles. Participants will receive study treatment unless their disease worsens or they experience unacceptable side effects, or until their study doctor decides to stop the study medication.
4. There will be four study sites in New Zealand aiming to recruit 9 participants.

Summary of ethical issues (resolved)

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

1. The Researcher(s) explained there is no clear standard of care for these patients.

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

1. The main Participant Information Sheet is very long. The Committee noted this is an issue because it puts a group of vulnerable participants, who are effectively out of options, at risk of missing the important information.
2. Although it makes use of headings and bullet points, there is quite a lot of unnecessary verbiage that could be simplified in it.
3. For example, section 3: 'What does participation in this research involve? 'This could be revised and shortened, removing duplicated phrases. The following is a good example of what I mean about excessive verbiage: [What is the cost of participation in the study? There are no additional costs associated with participating in this research project, nor will you be paid. All medication, tests and medical care required as part of the research project will be provided to you free of charge. You will not be paid for taking part in this study. You can be reimbursed for reasonable travel or parking expenses related to your study visits. The study drug and all study related procedures will be supplied at no cost to you.] Consider also putting a lot of the repetitive information on tests at different visits, into a tick-box table
4. Another example: Section 9 'Risks associated with medication' pg. 10-13: this is written like a protocol document rather than a PIS for lay use. Reading it gives no sense of probability or proportion to the various side effects described. The section on the Risk management i-access program for pomalidomide is confusing. The information on pomalidomide also moves from 'Risks' to talk about how to take the drug/ return unused tablets etc. The Committee noted the risk of foetal damage from this drug which is related to thalidomide, is omitted from this section.
5. Another example: 'Risks associated with procedures' The Committee cannot see why you need 21 lines in 5 paragraphs to describe the risks associated with having an MRI. Review this section.
6. Within the Main PIS, attend to the following: -explain 'mitigate' pg. 3,'conglomerate' pg. 4 - replace 'Australia" with 'New Zealand' pg. 2 para 4 - remove all references to 'flip of a coin - remove phrase 'As per regulatory requirement.'
7. pgs. 15 and 16 in relation to providing information on outcome of any inadvertent pregnancy. It is entirely over to the patient to decide whether to provide info and this makes it sounded mandated - highly effective contraception methods: why list birth control pills and then say in the next sentence they are not recommended? List only those which are acceptable to avoid confusion.
8. pg. 15-16 -remove the phrase which indicates the study may be terminated in the commercial interest of the sponsor pg. 18
9. In all PISs, refer to HDEC not MEC (multiregional ethics committee) - remove phrase 'or participants legally acceptable representative' from the signing space of all consent forms
10. The creation of a signed withdrawal form is fine but underscore that verbal notice of withdrawal is adequate.
11. There are optional substudies for genetic studies and biobanking. There are separate PISs for each and in general these are well done. However, in 'Pharmacogenomics': - pg. 2, remove reference to withdrawing in writing. Pg. 3 - is it really reasonable to refer questions on genetic test data back to the GP for interpretation. The Researcher(s) confirmed this would not be the case.
12. In 'Future use of Samples’: - pg. 2, remove the need to withdraw use of samples by writing. Verbal is adequate.
13. ‘Adult providing own consent’ – not relevant for new Zealand as only those who consent will have it
14. Review paragraphs for readability, some are difficult and seem to be missing.
15. Please consider adding a chart or table for procedures, currently takes up a lot of space.
16. Remove legally accepted representative – not relevant for New Zealand context.

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 Nora Lynch.

|  |  |  |
| --- | --- | --- |
| **10** | **Ethics ref:** | **16/NTA/236** |
|  | Title: | An exploratory Safety Study of 480 Biomedical Mometasone Furoate Sinus DrugDepot (MFSDD) in Adult Subjects with Chronic Sinusitis |
|  | Principal Investigator: | A/Prof Richard Douglas |
|  | Sponsor: | 480 Biomedical, Inc |
|  | Clock Start Date: | 16 January 2017 |

James Johnston was present by teleconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. The purpose of this study is to evaluate the safety and possible benefits of an investigational drug called the 480 Biomedical Mometasone Furoate Sinus Drug Depot (MFSDD) in helping to treat those who have been diagnosed with Chronic Sinusitis (CS). Chronic Sinusitis is a common condition that causes inflammation in the nasal passage lasting longer than 12 weeks.
2. The drug being used in this study is Mometasone Furoate, which is an approved corticosteroid medication used for treating CS.
3. Likely to recruit 5 participants from New Zealand.

Summary of ethical issues (resolved)

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

1. The Researcher(s) confirmed pictures are intranasal and will not be identifiable.
2. The Researcher(s) explained the scaffold will be removed, but may also disintegrate over time. If anything is left we will remove any remaining device.
3. The Researcher(s) explained GPs will refer to specialist care. The Committee queried whether it will be an independent person who approaches the person to participate. The Researcher(s) confirmed a research nurse will make the first approach.
4. The Researcher(s) explained the difficulties in nasal delivery of drugs.
5. The Committee noted regarding publication of results, b.4.3, what exactly does the Research Agreement say in relation to being able to block publication of negative results. The Researcher(s) stated no, the clause relates to publication from individual sites.
6. Why do participants need a CT and an MRI? The Researcher(s) stated every patient has a CT regardless as they are not referred without a CT scan. The MRI is so we can correlate the findings at the start of the study and the end. The Researcher(s) explained company wanted to do a CT at the end, but we decided against due to the additional radiation. The MRI is a compromise between the need to scan. The Researcher(s) confirmed we will not conduct any additional CT scans in New Zealand.

Summary of ethical issues (outstanding)

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

1. The Committee noted the peer review is not independent. The Researcher(s) explained the difficulty when it came to expertise and independence, due to the specialist nature of the devices. Please provide another peer review using the HDEC template.

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

1. Add first in human (for the scaffold).
2. There are a few words/phrases which need replacing or explaining or correcting: Pg 2 –depot, pg. 3 demographic makeup, pg. 8 alteration of HPA (endocrine), pg. 10 line 2 "injury" doesn't make sense.
3. Clarify phrase re reimbursement which reads “according to Mauharanui Clinic policy" - explain why sentence re receiving a bill needs to be there. The Researcher(s) explained the initial consultation is a billed visit, once a participant, any related study visits will not be charged. Just state what it is.
4. Do you anticipate charging for some visit as part of standard care? Clarify or remove.
5. Correct Southern to NTA (and also on pg. 11) - remove reference to 'state and federal law’.
6. Maori contacts given twice. Should one of them refer to someone else?
7. Consent form: Add a tick box to agree to videoing.
8. The Committee queried what the statement about the lack of an expiration date means with regards to access to health information. The Researcher(s) stated they meant to say data they do collect will be de-identified but not destroyed.
9. The Committee noted samples that can be linked are ‘potentially identifiable’ and at some point these samples should be de-identified, which means the link is removed.
10. Explain where samples are sent.
11. Can participants remove device if they withdraw earlier? The Researcher(s) confirmed they could. The Committee requested this is made clear for participants.
12. Does not explain what the risks are that one should tell their partner. Please add missing information.

Decision

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

* Please provide evidence of favourable independent peer review of the study protocol (*Ethical Guidelines for Intervention Studies* Appendix 1).
* 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 Charis Brown and Dr Brian Fergus.

|  |  |  |
| --- | --- | --- |
| **11** | **Ethics ref:** | **16/NTA/237** |
|  | Title: | Endoform Dental Membrane - Clinical Feedback Study |
|  | Principal Investigator: | Dr. Warwick Duncan |
|  | Sponsor: | Aroa Biosurgery |
|  | Clock Start Date: | 16 January 2017 |

Christopher Miller, Warwick Duncan, Lisa Avery and Barnaby May 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. The Endoform Dental Membrane (EndoDent) is a collagen based dental membrane intended for use to aid in guided tissue regeneration and guided bone regeneration. The device is placed into the implant site either dry or rehydrated.
2. EndoDent collagen membrane is a new product that the current study shall evaluate in a limited number of case studies, whereby the device shall be used in two commonly performed oral procedures.

Summary of ethical issues (resolved)

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

1. The Committee commended the applicants’ response on Maori and benefit.

Summary of ethical issues (outstanding)

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

1. Please clarify for the Committee whether SCOTT is required. You may email [becci\_slyfield@moh.govt.nz](mailto:becci_slyfield@moh.govt.nz)
2. The Committee noted all peer review and data monitoring will be internal. The Committee stated it seems likely this is related to commercial sensitivity. The Researcher(s) explained the peer review process that has occurred. The Researcher(s) confirmed they can arrange independent peer review.
3. R.1.1 – pg.14. Add some of this information to the Participant Information Sheet.
4. R.3.10 and r.3.2 – this information is also not in the Participant Information Sheet.
5. The Researcher(s) explained what is and is not covered in terms of procedures and payments if someone participates in the study. Please include this information in the Participant Information Sheet.
6. The Researcher(s) explained that the co-ordinating Investigator will recruit. The Researcher(s) explained their patients are referred across Auckland. The Researcher(s) explained to have someone independently to ask prospective patients about the study would be difficult.
7. The Researcher(s) explained the possibility of advertising. The Committee requested a copy of the advertisement if the researchers decided to advertise.

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

1. Add page numbers, contacts for Maori and HDEC advocacy, change all HDEC references to NTA, remove yes/no tick boxes from the compulsory items of the consent.
2. Add that tissue will be taken from some and analysed in New Zealand.
3. Please increase font size.
4. Remove double columns.
5. Remove the interpreter statement.
6. Add information on health information and tissue. See the HDEC checklist for informed consent at http://ethics.health.govt.nz/
7. Remove ‘slight’ risk.
8. The Committee queried whether it was possible that there was a less beneficial outcome. The Researcher(s) explained it will be the same or better, due to the technology used.
9. Compensation heading is missing, currently information under confidentiality.
10. Regarding receiving the results, could they not be given a summary rather than having to go into the dentist surgery. The Researcher(s) confirmed they would post it.
11. Only have yes/no boxes if the option is truly optional.
12. Please reword confidential photograph to non-identifiable photograph.
13. Please add information on tissue analysis.
14. Add information about infusions.
15. Can this device be taken out again if there is harm? The Researcher(s) explained it would be on a case by case basis. For example, is there an adverse event immediately after putting the device in, or whether it occurs later. The Committee noted at some point it can’t be removed, so this should be clear.
16. Add contacting GP to the Participant Information Sheet.

Decision

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

* + Please provide evidence of favourable independent peer review of the study protocol (*Ethical Guidelines for Intervention Studies* Appendix 1).
  + 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 Patries Herst and Dr Cordelia Thomas.

|  |  |  |
| --- | --- | --- |
| **12** | **Ethics ref:** | **16/NTA/238** |
|  | Title: | Vitamin C for Severe Sepsis |
|  | Principal Investigator: | Dr Anitra Carr |
|  | Sponsor: |  |
|  | Clock Start Date: | 16 January 2017 |

Dr Anitra Carr, Steve Chambers and Geoff Shaw 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. Sepsis is a major health problem worldwide and in New Zealand. Despite a massive effort in recent years to develop therapies, none has as yet proven successful in reducing mortality in patients with sepsis, which currently remain the leading cause of death in most intensive care units. Studies indicate that critically ill patients, including those with sepsis, exhibit very low vitamin C levels compared to healthy people. Furthermore, recent pre-clinical trials and clinical studies indicate a potential role for vitamin C in reducing inflammation, multiple organ failure, and vasopressor requirements and improving outcomes in patients with severe sepsis and septic shock.
2. The Researcher(s) propose to carry out a double-blind randomised placebo-controlled trial to test the efficacy of intravenous (IV) vitamin C administration in patients with severe sepsis, with a specific focus on cardiovascular, metabolic and immune function.
3. Participants will be diagnosed with severe sepsis while being admitted to the Christchurch Hospital Intensive Care Unit (ICU). Forty participants will be randomised into two groups: IV vitamin C (50 mg/kg body weight, 6 hourly) or IV saline placebo; 1:1 ratio) for a duration of 96 hours.
4. Blood and urine samples will be collected daily from patients to measure vitamin C levels along with selected biomarkers of inflammation, oxidative stress, cardiovascular function, metabolic function, and immune function. The analyses of these biomarkers, which relate to the severity of sepsis, will determine whether levels are changed in patients who receive the intervention. Clinical outcomes will also be monitored.

Summary of ethical issues (resolved)

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

1. The Researcher(s) confirmed placebo arm receives all standard care treatments.

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 main ethical issue is around consent. Most participants will be unconscious/intubated at the time of proposed enrolment. The applicant has provided a cover letter arguing for consent for the trial from the lead clinician in the best interests of the patients, bookended by family giving up front consent that the patient would consent if able and the recovered patient reviewing this later.
2. The Committee noted the consent materials supplied are different in significant ways: i The clinician is consenting that it is in the best interests of a group of patients of which this person is one. The family member is consenting for the patient to be enrolled. In order to comply with the Code of Rights, the clinician would need to sign that it was in the best interests of this patient and the family member/suitable person would need to state that they believe the patient would have agreed if able. ie rewrite the Family PIS to reflect this.
3. The Committee noted there was a need for retrospective consent for continued use of data Participant Information Sheet.
4. Regarding the protocol: 3/5 reviewers have queried the choice of Vitamin C dose. Only 8/52 of the participants across the 2 small previous studies about vitamin C in severe sepsis have received this dose. The 2014 study showed no definite difference between 200 and 100mg/kg/day so why has The Researcher(s) picked the higher dose. The Researcher(s) discussed the other studies outlined in the protocol.
5. The Committee noted the prior results indicated some positive results but the baseline data about participants in one of two studies (Fowler, 2014) did not allow assessment of confounding factors.
6. The Researcher(s) explained earlier studies indicated better results at higher doses. The Researcher(s) noted they could drop their dose but a few grams either way would not make a difference either way. The Committee noted that the researchers could not be sure of that, hence the research.
7. The Researcher(s) noted in cancer patients the doses can be much higher than the levels outlined in this protocol.
8. The Committee asked for a justification of best interests. The Researcher(s) stated the trials conducted so far indicated better outcomes from those in the trials compared to being outside of them.
9. The Committee and The Researcher(s) explained in full the best interests, including other trials that had met the best interests test and how this trial could be in the best interests.
10. The Committee and The Researcher(s) discussed the difficulty in determining best interests with a placebo arm. They also discussed the option of having Vitamin C in both arms.
11. The Committee requested the researchers provide a legal opinion regarding the legality of the trial, and evidence that the researchers fully understood the legal environment for this kind of research.
12. The DMC is internal. Usually external for a Phase 2b study. Please justify this decision.
13. Regarding the hospital advertising poster: The following statement is too strong for the available evidence: "Recent studies indicate that administration of vitamin C to patients with severe sepsis improves outcomes" Reword to reflect the small number of participants studied so far.
14. Please confirm SCOTT is not required for this research.

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

1. PIS needs to be reworked to reflect it is being signed post hoc. If there are to be some participants who can consent up front then there will need to be 3 PISs.
2. Need page numbers and go through to change HDEC to NTA, not Southern, define placebo( most won't know what normal saline is)
3. Pg 3 Family PIS: samples may not be collected before the patient or clinician certifying "best interest" has been met.
4. Pg 3 Both PISs: Under 'Risks" mention the possibility of unknown risks since there is inadequate safety data particularly long-term, in sepsis patients receiving high dose Vit C.
5. Pg 4 Family PIS: mention that patient will be informed about the study when well enough.

Decision

This application was *provisionally approved*, with 1 of the 8 members abstaining from the decision, subject to the following information being received.

* The Committee stated that it is not possible for HDECs to approve an application unless it is consistent with New Zealand law. Research involving participants who are not competent to consent is inconsistent with New Zealand law, unless undertaken in accordance with Right 7 (4) of the of the Code of Health and Disability Services Consumers’ Rights. In addition to requirements regarding ascertaining the views of the consumer and other suitable persons (forms consistent with this aspect are currently included in this application), Right 7(4) of the Code requires that any health services provided without the informed consent of the consumer must be in the best interests of the consumer. This means that there must be some benefit, or potential benefit, to the participant beyond what they would receive if they were not participating in the research. Please provide a legal view on this research application.
* 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 a justification of the internal Data Safety Monitoring Committee *(Ethical Guidelines for Intervention Studies para 6.50).*

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

## 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:

|  |  |
| --- | --- |
| **Meeting date:** | 21 February 2017, 01:00 PM |
| **Meeting venue:** | TBA |

The following members tendered apologies for this meeting.

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 4.45pm