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| **Committee:** | Central Health and Disability Ethics Committee |
| **Meeting date:** | 27 October 2015 |
| **Meeting venue:** | Freyberg Building, Ground Floor, Room G.04, 20 Aitken Street, Wellington |

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| **Time** | **Item of business** |
| 12.00pm | Welcome |
| 12.05pm | Confirmation of minutes of meeting of 25 September 2015 |
|  | New applications (see over for details) |
|  | i 15/CEN/157  ii 15/CEN/166  iii 15/CEN/167  iv 15/CEN/169  v 15/CEN/170  vi 15/CEN/171  vii 15/CEN/172  viii 15/CEN/173  ix 15/CEN/175  x 15/CEN/179  xi 15/CEN/181  xii 15/CEN/182 |
| 4.45pm | General business:   * Noting section of agenda |
| 5.00pm | Meeting ends |

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| **Member Name** | **Member Category** | **Appointed** | **Term Expires** | **Apologies?** |
| Mrs Helen Walker | Lay (consumer/community perspectives) | 01/07/2012 | 01/07/2015 | Present |
| Dr Angela Ballantyne | Lay (ethical/moral reasoning) | 01/07/2015 | 01/07/2018 | Present |
| Mrs Sandy Gill | Lay (consumer/community perspectives) | 01/07/2015 | 01/07/2018 | Present |
| Dr Patries Herst | Non-lay (intervention studies) | 01/07/2012 | 01/07/2015 | Present |
| Dr Dean Quinn | Non-lay (intervention studies) | 01/07/2012 | 01/07/2015 | Apologies |
| Dr Cordelia Thomas | Lay (ethical/moral reasoning) | 19/05/2014 | 19/05/2017 | Present |
| Dr Melissa Cragg | Non-lay (observational studies) | 01/07/2015 | 01/07/2018 | Present |
| Dr Peter Gallagher | Non-lay (health/disability service provision) | 01/07/2015 | 01/07/2018 | Apologies |

## Welcome

The Chair opened the meeting at 12.00pm and welcomed Committee members, noting that apologies had been received from Dr Peter Gallagher and Dr Dean Quinn.

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 25 September were confirmed.

## New applications

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| **1** | **Ethics ref:** | **15/CEN/157** |
|  | Title: | COG AALL1231: Phase III Randomised Trial of Bortezomib in Newly Diagnosed T-ALL and T-LLy. |
|  | Principal Investigator: | Dr Siobhan Cross |
|  | Sponsor: | Children's Oncology Group |
|  | Clock Start Date: | 15 October 2015 |

Sara Parkin 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 study investigates a standard treatment regime (combination chemotherapy), with or without Bortezomid in patients with newly diagnosed T-cell acute lymphoblastic leukaemia or stage III-V T-cell lymphoblastic lymphoma.

Summary of ethical issues (resolved)

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

1. The Committee discussed the use and storage of tissue, and questioned which parts of the study were mandatory or optional.
2. The Researcher(s) explained the tissue testing that occurs between the two patient groups, noting that the minimal residual disease for the T-LLY group is optional, however in the T-ALL group it is mandatory - this relates to their treatment.
3. The Committee asked if taking additional blood samples is optional, and if the samples were to be used for specified or unspecified research.
4. The Committee requested that there more clarity about storage of tissue, and in particular what parts are optional, in the Participant Information Sheet.
5. The Researcher(s) confirmed the tissue bank is registered and is part of Children's Oncology Group (COG).
6. The Committee queried the requirement for the full names to be listed on the tissue. The Researcher(s) explained that this was only for therapeutic time point specimens – and that it relates to on-going therapy, adding the practice is required for COG samples as it minimises error. The Committee accepted this explanation.
7. The Committee noted the Participant Information Sheet was very long, yet informative.
8. The Researcher(s) explained the Participant Information Sheet is left with parents overnight, and is then discussed at the next appointment. The Researcher(s) are aware how much information it is to take in.
9. The Committee noted there was no need to justify or explain standard treatments or protocols for example on page 2 – ‘in most of united states…is standard....’ etc. The Committee queried why this information is listed, since it is standard of care. The Researcher(s) explained that this is included because of the extensive COG audit procedures. The Researcher(s) pay heavily if they don’t have the same information as the guides that COG submit to research localities, with their study protocol. The Researcher(s) must therefore mirror the COG template as much as possible. This is for their benefit / requirement, as a research site, so they can continue to conduct this research.

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

1. The Committee asked if it is possible to provide some kind of index, or contents that correlates to page numbers to help navigate the lengthy Participant Information Sheet. The Researcher(s) explained that the treating physician talks through the information, and all information is supplemented with verbal information, but noted that a contents page would be helpful and agreed to provide one.
2. Heading, compensation – suggest that participants check with their private medical insurance.
3. The Committee requested that yes/no tick boxes on the consent form are removed, unless the statement is truly optional. For example, to receive a lay language summary of results.
4. Page 3 of the main Participant Information Sheet has a triple negative. People with limited literacy will struggle with this information. Please review and change the document, where possible, to suit a New Zealand audience. The Committee noted the argument made by the Researcher(s) about the lack of flexibility in changing the documents v=because of COG audits.
5. The Committee discussed the 7-11 year old Participant Information Sheet. The Committee suggested that the language is too complex for this age range. Please revise and make more accessible.
6. The Committee noted that the Future Unspecified Research guidelines must be followed if consent is given for tissue to be banked overseas for undefined research. This applies to the specimens’ bio banking Participant Information Sheet. The checklist below can be used to ensure you meet the requirements.

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

Decision

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

* Please amend the information sheet and consent form, assent form and future unspecified research forms, 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 Mrs Sandy Gill.

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| **2** | **Ethics ref:** | **15/CEN/166** |
|  | Title: | D3FEAT |
|  | Principal Investigator: | Professor Ed Gane |
|  | Sponsor: | University of New South Wales Australia |
|  | Clock Start Date: | 08 October 2015 |

Victoria Oliver & Professor Edward Gane 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 study investigates a treatment (direct acting antiviral regimen) that is approved but not funded in New Zealand.
2. There are 12 weeks of treatment with a 90-96% cure rate in standard patient populations (non-chaotic, non-injecting patients)
3. The Researcher(s) explained that in order to know if the drug works in real life settings we need to use it in an injecting drug population (or those receiving opiate substitution therapy).
4. The study drug is best available treatment, but patient population is potentially vulnerable.

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 how the electronic blister pack works. The Researcher(s) explained that each time the blister pack is used it stores a time. When the person comes into the clinic the times are read by a machine and checked. This information doesn’t confirm that they took them but it tells us when they took them out. It is a fairly reliable measure of patient adherence.
2. The Committee asked about the tissue samples and subsequent testing. The Researcher(s) explained that the University of New South Wales Australia wants to look at immunology and how it improves in this study population. The other research area will focus on feasibility of a pinprick method to identify disease, which is desirable due to the poor veins in this patient population.
3. The Researcher(s) explained that in normal population they expect 90-96% cure rate, however they want to also see whether this patient group will relapse, the study will look at relapse, and resistant rates. The Committee suggested that the different sub-studies were separated out, for clarity. The Researcher(s) agreed.
4. (R.3.7) The Committee noted that this question trails off at the end. The Researcher(s) noted this was an error.
5. The Committee queried if the exclusion criteria for being treated for HCV in the last 6 months should be in the Participant Information Sheet as doctors may not be aware of this for their patients. The Researcher(s) noted it should, and stated they would add it.
6. The Committee asked what analysis would occur on the ethnicity data. The Researcher(s) explained all baseline information was assessed, age, gender, ethnicity. There will be a multi-variant analysis, adding most information would refer to ethnicities in the USA.
7. The Committee queried how Maori would be ensured equal access to the study. The Researcher(s) explained that anecdotally, the rate of Hep C in primary or secondary care, the prevalence is the same. The Researcher(s) think that the prevalence is higher in Maori. The Researcher(s) explained Maori engagement in needle exchange is higher than non-Maori. The Researcher(s) will be recruiting from these sites to help address any lack of treatment of Maori in secondary care, due to lack of engagement.
8. The Committee asked about feedback from Maori consultation. The Researcher(s) explained it had been approved and was not aware of any changes requested.
9. The Committee noted that (P.4.1) should include incidence and prevalence of the disorder under study (or treatment indication if a drug trial) in Maori. The Secretariat notes that some disorders are particularly important for Maori health, while others are relatively rare in Maori and may have less of an impact. If the study is an early phase trial, a caveat that no benefit is expected as a direct result of the study. If relevant, please include information on how researchers will ensure that Maori benefit at least equally (and actually how they can disproportionately benefit if they are disproportionately burdened) –for example, what extra measures if any are in place to ensure Maori participation (iwi consultation, Maori researchers, active follow up etc.) as well as interpretation of results and presentation of findings back to those consulted.
10. The Committee noted that (F.1.1 and F.1.2) should outline what could happen if the study generates knowledge that would reduce outcomes, and then how/what extra measures they have in place to ensure equal (or at least population commensurate) Maori **and other populations** participation in order to inform study findings and results, and how those results are interpreted and shared – and how they may be used to reduce inequalities.

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 B.4.5.2 states ‘Additional consent will not be sought for this storage and future use. It is not optional. Participants not wishing to have their samples stored or used in future hepatitis C related research will not be eligible to participate in this study.’ Please confirm for the Committee that the sub-study is optional. The Committee noted that they would not be able to approve the study if it was mandatory.

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

1. The Committee asked if the GP would be notified of study participation. The Researcher(s) stated that it is on the main consent form. Please add it to the Participant Information Sheet.

Decision

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

* Clarify that Future Unspecified Research is optional (*Guidelines for the Use of Human Tissue for Future Unspecified Research Purposes, para 2*).

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

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| **3** | **Ethics ref:** | **15/CEN/167** |
|  | Title: | BH29884:Prophylactic Subcutaneous R05534262 in Haemophilia A with inhibitors |
|  | Principal Investigator: | Dr Paul Ockelford |
|  | Sponsor: | Roche Products (New Zealand Ltd) |
|  | Clock Start Date: | 15 October 2015 |

Dr Paul Ockelford 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 study investigates prophylactic subcutaneous treatment in patients with haemophilia.
2. About 15-30% of people develop inhibitors that are transient however some have more permanent inhibitors.
3. The Researcher(s) will use bypassing agents that contain activated forms of clotting proteins. The Researcher(s) explained the high cost of these bypassing agents and how they are usually only used for major bleeding events.
4. The Researcher(s) explained that the new protein, an antibody (R05534262), is an immunoglobulin. It interacts with two proteins that substitutes in a similar way to the factor 8, catalysing a particular reaction that can prevent bleeding. This new treatment is administered subcutaneously and is not affected by the inhibitors that work against factor 8.

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 whether the tissue bank is accredited. The Researcher(s) confirmed it would be an accredited Roche tissue bank.
2. The Researcher(s) explained that on-going treatment, post study, would include monitoring of the participants, every 3 months.

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

1. The Committee queried what the guidelines that are referred to in the Participant Information sheet are in terms of being eligible for access to the drug post study. The Researcher(s) explained that basically the understanding is that provided the drug is effective it will be made available on an ongoing basis until this product is registered in this country. We will provide patients access. The Committee asked that this is clarified for participants.
2. Be sure to add Maori contact details and general contact information.
3. ‘You or your legally authorised representative’ please take this out, it is not relevant for a New Zealand context.
4. The Committee noted there is no need to withdraw in writing. Participants may verbally withdraw, and this should be formally noted by the study team. Please make this clear to participants.
5. The Committee requested that the optional tissue collection Participant Information Sheet contains all the requirements from the future unspecified tissue guidelines. Please cross reference your participant information sheet with the information below:

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

Decision

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

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| **4** | **Ethics ref:** | **15/CEN/169** |
|  | Title: | MagLev: Increasing magnesium levels and cognition in women with breast cancer receiving adjuvant endocrine treatment |
|  | Principal Investigator: | Dr David Porter |
|  | Sponsor: | The University of Auckland |
|  | Clock Start Date: | 15 October 2015 |

Dr David Porter 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 study investigates whether increased magnesium levels assists with cognition in women with breast cancer who are receiving adjuvant endocrine treatment.
2. The Researcher(s) have recently been able to prove that there are negative cognitive impacts of endocrine treatment. The Researcher(s) have identified the possibility for estrogen to decrease magnesium levels, meaning women become magnesium deficient.
3. The study aims to improve acceptability of treatment, and increase quality of life while on treatment.
4. This study uses an over the counter magnesium product.
5. This is a feasibility study to test hypothesis, with goals to conduct larger randomised controlled trial later on.

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 (P.4.2) “Maori will only be excluded if they do not fulfil the standard inclusion/exclusion criteria or require an interpreter”, is there an interpreter for Maori at the DHB? The Researcher explained the reason interpretation is an exclusion criteria is because the NIH toolkit only comes in English and Spanish. The Researcher(s) have very little influence over the NIH in USA. To do the study we need people to be able to use the toolkit, in English.
2. The Committee confirmed the Maori research committee review at ADHB is ongoing.
3. (R.4.1) The Committee queried whether participants would be told of any genetic findings from this testing. The Researcher(s) explained that the information on genetics is not relevant clinically, and that the information provided to the lab, is de-identified. The Committee noted this was appropriate.
4. The Committee explained that whakama could apply to participants with breast cancer, which would be a potential cultural issue.
5. The Researcher(s) confirmed that Maori had a higher level of prevalence for breast cancer. The Committee noted that (P.4.1) should include incidence and prevalence of the disorder under study (or treatment indication if a drug trial) in Maori. The Secretariat notes that some disorders are particularly important for Maori health, while others are relatively rare in Maori and may have less of an impact. If the study is an early phase trial, a caveat that no benefit is expected as a direct result of the study. If relevant, please include information on how researchers will ensure that Maori benefit at least equally (and actually how they can disproportionately benefit if they are disproportionately burdened) –for example, what extra measures if any are in place to ensure Maori participation (iwi consultation, Maori researchers, active follow up etc.) as well as interpretation of results and presentation of findings back to those consulted.

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

1. Remove the yes/no tick boxes – only have them if they are truly optional.
2. The Committee noted that it should be clear that participants will be able to access ACC but that their claim may or may not be accepted, as per usual practice. Participation in a trial does not exclude them from ACC but it also does not guarantee payment or compensation.
3. The Committee noted there is future unspecified research and genomic sub studies. The Committee stated there must be a separate Participant Information Sheet for the future unspecified research but that the optional sub study could remain in the consent form, as is. The Researcher(s) clarified that there is no future unspecified research - this was an error. The Committee requested that mention of this was removed from the Consent Form.

Decision

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

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| **5** | **Ethics ref:** | **15/CEN/170** |
|  | Title: | Comparison of the blood levels of two forms of buprenorphine 20 mcg/hr transdermal patch in healthy male and female volunteers |
|  | Principal Investigator: | Dr Noelyn Hung |
|  | Sponsor: | Juno Pharmaceuticals Pty Ltd |
|  | Clock Start Date: | 15 October 2015 |

Linda Folland and Nolene Hung 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 study investigates bioequivalence of study drug in healthy volunteers.

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

1. Amend referred HDEC to CEN from STH.
2. Add information about contacting the GP to the information sheet, it is currently only on the consent form.
3. The Committee asked if time needed to be expressed in hours. Please amend for accessibility.
4. Amend wording ‘you are not permitted to leave’ to ‘we request that you stay at the site for the duration of the study…if you leave you are withdrawn from the study’,’ etc.
5. The Committee noted it is confusing to be asked to report to clinical site, while also saying they will be transported from Zenith to the clinical site.

Decision

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

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| **6** | **Ethics ref:** | **15/CEN/171** |
|  | Title: | Efficacy and safety of finerenone in subjects with chronic heart failure at high risk of recurrent heart failure decompensation |
|  | Principal Investigator: | Prof. Richard Troughton |
|  | Sponsor: | Bayer New Zealand Ltd |
|  | Clock Start Date: | 15 October 2015 |

Prof. Richard Troughton was not 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 (outstanding)

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

1. R.5.4.1 – please clarify who ‘our’ was in this context.
2. The Committee noted that (F.1.1 and F.1.2) should outline what could happen if the study generates knowledge that would reduce outcomes, and then how/what extra measures they have in place to ensure equal (or at least population commensurate) Maori **and other populations** participation in order to inform study findings and results, and how those results are interpreted and shared – and how they may be used to reduce inequalities.

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

1. The Committee queried how it is possible to have both increased and decreased potassium page 7. This should be ‘or’.
2. The Committee queried what an ‘informed consent form’ was, and requested that all information in the consent form should be outlined in the participant information form, with very brief bullet pointed information on the consent form.
3. Page 19 – “I understand and agree that if I withdraw from the study, the data collected from me until the time of withdrawal will be kept and used”. The Committee noted that any data that has not been analysed, or tissue, where removal is possible, should also be withdrawn. Any data that has already been analysed can remain in the study as it is no longer possible to withdraw it. Please remove this wording.
4. The Committee noted no need to withdraw from the study in writing (though it can be an option). Verbal withdrawal is an option in New Zealand. If this occurs it should be documented thoroughly by the study doctors.
5. Page 21 – The Committee noted that it is not legal to give consent to research for an adult by another adult. Remove all information following ‘declaration by legally acceptable...”
6. Add contact numbers.

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 address how the study may benefit Māori, and if it will not please explain why (*Ethical Guidelines for Intervention Studies* *para 4.7*).

This following information will be reviewed, and a final decision made on the application, by Dr Melissa Cragg and Dr Cordelia Thomas.

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| **7** | **Ethics ref:** | **15/CEN/172** |
|  | Title: | A phase III study of Lenalidomide and low-dose Dexamethasone with or withoutPembrolizumab (MK3475) in newly diagnosed and treatment naïve Multiple Myeloma(KEYNOTE 185). **(CLOSED)** |
|  | Principal Investigator: | Dr Anupkumar George |
|  | Sponsor: | MSD Australia |
|  | Clock Start Date: | 15 October 2015 |

Dr Anupkumar George and Ms Maureen Blackmore, Ms Menasha Moodie 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 Researcher(s) confirmed that the bio bank was registered.
2. (A.1.5) The Committee queried if it was appropriate to call participants to ‘see if they are alive’. The Researcher(s) stated they could check with the GP. The Researcher(s) clarified consent to contact GP is given by participants. The Committee noted that it would be appropriate to avoid undue harm.
3. The Committee noted that (P.4.1) should include incidence and prevalence of the disorder under study (or treatment indication if a drug trial) in Maori. The Secretariat notes that some disorders are particularly important for Maori health, while others are relatively rare in Maori and may have less of an impact. If the study is an early phase trial, a caveat that no benefit is expected as a direct result of the study. If relevant, please include information on how researchers will ensure that Maori benefit at least equally (and actually how they can disproportionately benefit if they are disproportionately burdened) –for example, what extra measures if any are in place to ensure Maori participation (iwi consultation, Maori researchers, active follow up etc.) as well as interpretation of results and presentation of findings back to those consulted.
4. The Committee noted that (F.1.1 and F.1.2) should outline what could happen if the study generates knowledge that would reduce outcomes, and then how/what extra measures they have in place to ensure equal (or at least population commensurate) Maori **and other populations** participation in order to inform study findings and results, and how those results are interpreted and shared – and how they may be used to reduce inequalities.
5. The Committee noted that there are multiple phases to the study. The Committee asked how long the treatment phase would be, noting it depends on how patients are responding. The Researcher(s) stated in the control arm these patients could be on the drug for up to 3 years.
6. Please clarify what tissue samples are being stored and used for, with respect to the main study and for the optional future unspecified research. For instance, on page 3 of the main study, it states samples will not be used for future testing, page 3 states that they are destroyed, then page 5 states ‘you will be asked to participate in future research’.
7. The Committee asked if there are additional samples taken for future unspecified research, or if it is leftover samples. The Researcher(s) stated is additional samples taken at the same time of main study collection.
8. The Committee noted the optional sub study sample states that samples are taken from ‘leftover samples’ and that this was misleading. The Researcher(s) explained that option B had been removed, and noted the potential for confusion.

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 requested a copy of the study guide that the researchers explained was not able to be submitted with the initial application.

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

1. Page 14, third paragraph on the Participant Information Sheet. Please remove this information, as this study is not blinded. ‘What study drug you are on’ etc.
2. Page 14 – The Committee noted no need to withdraw from the study in writing (though it can be an option). Verbal withdrawal is an option in New Zealand. If this occurs it should be documented thoroughly by the study doctors.
3. Page 3 – will this drug be available indefinitely for these participants? The Researcher(s) clarified – study drug will not be available for participants once the study ends.
4. The Researcher(s) explained participants will be in the study for 41 months, after which participants will not be able to access study drug. The Committee stated please amend page 3 statement as it is currently misleading, suggesting that there might be post-study access.
5. Bullet point 2 of page 3 should state held or withheld.
6. Please add telephone numbers.

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*).
* Submit any missing documents from the initial submission.

This following information will be reviewed, and a final decision made on the application, by Dr Patries Herst and Mrs Helen Walker.

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| **8** | **Ethics ref:** | **15/CEN/173** |
|  | Title: | Comparison of symptoms and signs of two forms of the drug budesonide nasal spray in participants with a history of seasonal allergic rhinitis. |
|  | Principal Investigator: | Dr Noelyn Hung |
|  | Sponsor: | AFT Pharmaceuticals Ltd |
|  | Clock Start Date: | 15 October 2015 |

Dr Noelyn Hung and Ms 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 ethical issues (addressed)

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

1. The Committee asked if informing GP of study participation could be optional. The Researcher(s) explained important to know history for safety of participants. Informing GP was therefore mandatory. The Committee acknowledged the response.

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

1. The Committee queried if legal advice is actually able to be reimbursed, as stated currently in the Participant Information Sheet. The Researcher(s) stated it was not, and will remove it.
2. The Committee suggested explaining what the ‘benefit’ is. Could be too generic.
3. Amend reviewing HDEC from STH to CEN.
4. Page 5, ‘does not *usually* interfere with driving’ – The Committee asked what this meant. The Researcher(s) stated they were being cautious. The Committee stated remove it **if** there is no risk or impact on driving ability.
5. The Committee suggested contextualising or quantifying soft drink abuse.
6. Review for grammar, page 3.
7. Pg.2 – separate out inclusion or exclusion criteria.
8. Add statement in Participant Information Sheet about data collection, what is sent overseas, and the FDA requirements that impact their health information.
9. Data statement – The Committee noted that any data that has not been analysed, or tissue, where removal is possible, should also be withdrawn. Any data that has already been analysed can remain in the study as it is no longer possible to withdraw it.

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 Angela Ballantyne and Dr Melissa Cragg.

|  |  |  |
| --- | --- | --- |
| **9** | **Ethics ref:** | **15/CEN/175** |
|  | Title: | Mobile single sided NMR sensor for brain oxygenation monitoring **(CLOSED)** |
|  | Principal Investigator: | Dr Shieak YC Tzeng |
|  | Sponsor: |  |
|  | Clock Start Date: | 15 October 2015 |

Dr Shieak YC Tzeng 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 application is to get blood from healthy participants, if the researchers can’t get enough expired blood from the blood service.

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

1. Remove yes/no from consent form bullet points, unless the statement is truly optional.

Decision

This application was *approved* by consensus.

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| **10** | **Ethics ref:** | **15/CEN/179** |
|  | Title: | BGB-A317 given in increasing dose levels to participants with advanced tumors |
|  | Principal Investigator: | Dr Michael Jameson |
|  | Sponsor: | BeiGene Aus Pty Ltd |
|  | Clock Start Date: | 15 October 2015 |

Dr Michael Jameson and Ms Wendy Thomas 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. (P.4.2) Please clarify what information is given to participants about tissue use and handling, as referred to in the application, noting the Participant Information Sheet and Consent Form does not have any information on options for disposal. The Researcher(s) stated samples could be given back if requested.
2. In future applications the Committee noted that (P.4.1) should include incidence and prevalence of the disorder under study (or treatment indication if a drug trial) in Maori. The Secretariat notes that some disorders are particularly important for Maori health, while others are relatively rare in Maori and may have less of an impact. If the study is an early phase trial, a caveat that no benefit is expected as a direct result of the study. If relevant, please include information on how researchers will ensure that Maori benefit at least equally (and actually how they can disproportionately benefit if they are disproportionately burdened) –for example, what extra measures if any are in place to ensure Maori participation (iwi consultation, Maori researchers, active follow up etc.) as well as interpretation of results and presentation of findings back to those consulted.
3. Similarly, F.1.2 should contain information on other ethnicities.
4. P.4.2 – taking blood might be a cultural issue. The body is considered tapu by Māori and Indigenous people generally. Researchers involved in health or medical research that involves the body, or any part of the body, such as organs, blood, hair, saliva and/or other tissue, must do so in a respectful manner. The collection of human tissue is particularly sensitive when it involves the use of a deceased person’s tissue.

Summary of ethical issues (outstanding)

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

1. Clarify if there will be future unspecified research.

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

1. Page 2, fourth paragraph down. Explains components, dose escalation phase. Tense is confusing, switches into past tense. The Committee understands why this occurs, but notes that it is very confusing. Please amend to current or future tense.
2. Page 3, treatment phase, access to drug after treatment ‘you will be allowed to continue on treatment after approval from sponsor + continued availability of the drug’. The Committee requested more information about criteria, or what the sponsor will take into account, to grant this. Furthermore, the Committee noted on page 17 it states post study access to drug is not available at all, which is correct? The Researcher(s) explained that the sponsor has told them that access to study drug after the study would not be made available.
3. The Committee asked why the drug would not be made available. The Researcher(s) stated the sponsor might decide not to continue development of the drug, though even if they do continue to develop the drug, all studies are proposed to stop after 2 years.
4. The Committee noted if drug is not accessible page 3 needs to be clarified for participants, as page 3 suggests participants could continue on study drug.
5. Page 9 – ‘may’ be reimbursed for reasonable expenses. The Committee requested it states you will be.
6. Add ethics committee contact details, see HDEC template participant information sheet for guidance.
7. The Committee queried the requirement for requiring written consent. The Committee noted no need to withdraw from the study in writing (though it can be an option). Verbal withdrawal is an option in New Zealand. If this occurs it should be documented thoroughly by the study doctors.
8. Third bullet point, consent form. The Committee noted that any data that has not been analysed, or tissue, where removal is possible, should also be withdrawn. Any data that has already been analysed can remain in the study as it is no longer possible to withdraw it.
9. Page 5, first dot point - ‘sample taken for analysis stored indefinitely, or when sample all used up’ on page 17 states samples destroyed, which is it?
10. The Committee noted if samples are stored indefinitely it needs a separate Participant Information Sheet for future unspecified research. If this is the case, please submit a separate, optional information sheet and consent form. The Committee noted that there would only be once chance to review this document, so please ensure all of the following are met:

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

Decision

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

* Please provide a separate Participant Information Sheet and Consent Form for the use of tissue for future unspecified research (*Guidelines for the Use of Human Tissue for Future Unspecified Research Purposes, para 2*).
* Please 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 Angela Ballantine and Dr Patries Herst.

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| **11** | **Ethics ref:** | **15/CEN/181** |
|  | Title: | The Nest Study |
|  | Principal Investigator: | Prof Julian Crane |
|  | Sponsor: |  |
|  | Clock Start Date: | 15 October 2015 |

Prof Julian Crane and Ms Caroline Shorter were present in person for discussion of this application.

Potential conflicts of interest

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

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

Summary of Study

1. This study is HRC funded.
2. The study will investigate the effect of insulation of homes that also incorporates an intervention study that compares 3 different bedding types. The bedding idea comes from a large series of observational studies that suggest that feather bedding results in less wheezing in later life. This study will validate or disprove this claim.
3. Primary outcome will be on reported wheezing.

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 what parts of the study are optional. The Researcher(s) responded that it was the blood pricks. The Committee explained that this must be clear in the Participant Information Sheet.
2. The Researcher(s) asked if they could explain what is mandatory, but leave out parts that are not, without explaining them in full. The Committee noted this would be acceptable.
3. The Committee queried if a participant’s home can’t be insulated are they excluded. The Researcher(s) stated no, but they will note that on the records, so it won’t impact scientific validity. The Researcher(s) explained that the houses would have some insulation in most cases. Only access issues such as not being able to get under a house would result in less insulation.
4. The Committee suggested using the HDEC informed consent template (<http://ethics.health.govt.nz/>) in terms of a more extensive introduction. The Committee noted the need to keep the document short, though aspects such as the voluntary nature of participation and what happens to health information was important to facilitate informed consent.
5. The Researcher(s) confirmed the study is for non-Maori, Pacifica and Maori.
6. In future the Committee noted that (P.4.1) should include incidence and prevalence of the disorder under study (or treatment indication if a drug trial) in Maori. The Secretariat notes that some disorders are particularly important for Maori health, while others are relatively rare in Maori and may have less of an impact. If the study is an early phase trial, a caveat that no benefit is expected as a direct result of the study. If relevant, please include information on how researchers will ensure that Maori benefit at least equally (and actually how they can disproportionately benefit if they are disproportionately burdened) –for example, what extra measures if any are in place to ensure Maori participation (iwi consultation, Maori researchers, active follow up etc.) as well as interpretation of results and presentation of findings back to those consulted.
7. Similarly, please consider whakama as a cultural concern, as participants may have shame about their houses not being safe or healthy for their children.
8. The Committee noted that (F.1.1 and F.1.2) should outline what could happen if the study generates knowledge that would reduce outcomes, and then how/what extra measures they have in place to ensure equal (or at least population commensurate) Maori **and other populations** participation in order to inform study findings and results, and how those results are interpreted and shared – and how they may be used to reduce inequalities.
9. The Committee queried why only mothers are asked to consent. The Researcher(s) noted that the first consent time point is at hospital, where mothers will be there. Generally we ask for one parent to consent, and that it will primarily be mothers.
10. The Researcher(s) explained that his views on the three bedding options were in equipoise.

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

1. Add Maori contact numbers.

Decision

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

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| **12** | **Ethics ref:** | **15/CEN/182** |
|  | Title: | The RESTORE feasibility study |
|  | Principal Investigator: | Dr Dougal McClean |
|  | Sponsor: |  |
|  | Clock Start Date: | 15 October 2015 |

Dr Dougal McClean 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 study investigates a treatment for patients who have been turned down for surgery.
2. The study compares a stent that dissolves after a year or a permanent metal stent. The idea is that after dissolving the patients might be eligible for surgery.

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 if after the stent dissolves whether the artery would close up again. The Researcher(s) stated that experience with balloon stents suggest that after 3-6 months the vessel heals.
2. The Committee queried whether the registry participants are the control cohort? The Researcher(s) stated sort of, they are patients who do not have stents, and are on medical treatments.
3. R.1.1 and R.1.6 – can participants have dissolvable stents outside of the study, noting participants may prefer it because it is new or promising. The Researcher(s) stated the RCT must occur in this population to know it works, is safe, effective etc. The Researcher(s) explained it is unlikely that they can get one outside of this trial.
4. The Committee asked about the benefits of the mental stents. The Researcher(s) explained they know a lot more about metal stents, and metal stents gotten better over time as the technology develops.
5. The Committee noted importance of explaining each option equally. The Researcher(s) agreed.
6. The Committee asked about the data safety monitoring arrangements. The Researcher(s) explained the arrangements and noted they were independent.
7. The Researcher(s) clarified that identifiable health information is not disclosed to researchers without patient consent. Instead, doctors screen briefly and approach potential participants, who then indicate they would be interested. After consent, patient information is screened further.

A note for future applications:

1. The Committee noted that (P.4.1) should include incidence and prevalence of the disorder under study (or treatment indication if a drug trial) in Maori. The Secretariat notes that some disorders are particularly important for Maori health, while others are relatively rare in Maori and may have less of an impact. If the study is an early phase trial, a caveat that no benefit is expected as a direct result of the study. If relevant, please include information on how researchers will ensure that Maori benefit at least equally (and actually how they can disproportionately benefit if they are disproportionately burdened) –for example, what extra measures if any are in place to ensure Maori participation (iwi consultation, Maori researchers, active follow up etc.) as well as interpretation of results and presentation of findings back to those consulted.
2. The Committee noted that (F.1.1 and F.1.2) should outline what could happen if the study generates knowledge that would reduce outcomes, and then how/what extra measures they have in place to ensure equal (or at least population commensurate) Maori **and other populations** participation in order to inform study findings and results, and how those results are interpreted and shared – and how they may be used to reduce inequalities.
3. (P.4.2)The Committee noted blood is tissue. The body is considered tapu by Māori and Indigenous people generally. Researchers involved in health or medical research that involves the body, or any part of the body, such as organs, blood, hair, saliva and/or other tissue, must do so in a respectful manner. The collection of human tissue is particularly sensitive when it involves the use of a deceased person’s tissue.

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

1. Add lay language title.
2. The Committee suggested that the researchers look at the HDEC template Participant Information Sheet, for guidance.
3. The Committee suggested adding small diagram of a heart with a stent in the artery.
4. Add page numbers.

Decision

This application was *approved* by consensus.

## 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:** | 24 November 2015, 08:00 AM |
| **Meeting venue:** | Freyberg Building, Ground Floor, Room G.04, 20 Aitken Street, Wellington , 6011 |

The following members tendered apologies for this meeting.

* Mrs Helen Walker.

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 4.30pm