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| **Committee:** | Northern A Health and Disability Ethics Committee |
| **Meeting date:** | 12 August 2014 |
| **Meeting venue:** | Novotel Ellerslie, 72-112 Greenlane Rd East, Ellerslie, Auckland |

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| **Time** | **Item of business** |
| 1.00pm | Welcome |
| 1.05 | Confirmation of minutes of meeting of 08 July 2014 |
|  | New applications (see over for details) |
| 1.30-2.00  2.00-2.30  2.30-3.00  3.00-3.30  3.30-4.00  4.00-4.30  4.30-5.00  5.00-5.30 | i 14/NTA/111  ii 14/NTA/112  iii 14/NTA/113  iv 14/NTA/115  v 14/NTA/116  vi 14/NTA/118  vii 14/NTA/119 (Closed)  viii 14/NTA/123 |
| 5.30-5.45 | General business:   * Noting section of agenda |
| 6.00 | Meeting ends |

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| **Member Name** | **Member Category** | **Appointed** | **Term Expires** | **Apologies?** |
| Dr Brian Fergus | Lay (consumer/community perspectives) | 01/07/2012 | 01/07/2015 | Present |
| Ms Susan Buckland | Lay (consumer/community perspectives) | 01/07/2012 | 01/07/2015 | Present |
| Ms Shamim Chagani | Non-lay (health/disability service provision) | 01/07/2012 | 01/07/2015 | Present |
| Mr Kerry Hiini | Lay (consumer/community perspectives) | 01/07/2012 | 01/07/2015 | Present |
| Dr Etuate Saafi | Non-lay (intervention studies) | 01/07/2012 | 01/07/2014 | Present |
| Ms Michele Stanton | Lay (the law) | 01/07/2012 | 01/07/2015 | Present |
| Dr Karen Bartholomew | Non-lay (intervention studies) | 01/07/2013 | 01/07/2016 | Present |
| Dr Christine Crooks | Non-lay (intervention studies) | 01/07/2013 | 01/07/2015 | Present |
| Dr Mathew Zacharias | Non-lay (intervention studies) | 01/07/2013 | 01/07/2015 | Present |

## Welcome

The Chair opened the meeting at 8 July 2014 and welcomed Committee members, noting that apologies had been received from Dr Karen Bartholomew.

Dr Mathew Zacharias confirmed their eligibility, and was 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.

## Confirmation of previous minutes

The minutes of the meeting of 8 July 2014 were confirmed.

## New applications

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| **1** | **Ethics ref:** | **14/NTA/111** |
|  | Title: | Autonomous Paramedic Referral for Primary Percutaneous Coronary Intervention |
|  | Principal Investigator: | Mr Paul Davis |
|  | Sponsor: | AUT University |
|  | Clock Start Date: | 31 July 2014 |

Mr Paul Davis was present by teleconference, and Dr Graham Howie and Dr Bridget Dicker attended in person for discussion of this application.

Potential conflicts of interest

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

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

Summary of ethical issues

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

* The Committee confirmed this application would require a change to hospital protocols and standing orders.
* The Researchers explained that PCI (percutaneous coronary intervention)is the most effective treatment for STEMI (ST elevation myocardial infarction) heart attack patients. This is a time dependent treatment, where early intervention confers the greatest clinical benefits and results.
* Current practice is for an ambulance to take heart attack patients to ED, then for ED assessment & referral as appropriate to a Catheterisation lab. The study protocol aims to take the ED out of the equation, instead trialling an autonomous paramedic model taking patients from the field by ambulance directly to the Catheterisation Lab without prior hospital physician oversight and authorisation
* Please explain why this application has been submitted to HDEC. The researchers explained that patient care referral will be changed as a result of this study.
* The Committee queried if the paramedic is conducting an ECG. The researcher confirmed yes, within 5-6 minutes of first contact. This is standard care for these patients.In this pilot the paramedic will make the decision of whether PCI treatment is appropriate. The paramedic will not consult with a physician at the hospital but instead refer the patient to the Cath lab directly.
* Under this pilot the paramedic will act autonomously under standing orders that have been previously developed and approved in conjunction with St John Ambulance Services by registered health practioners. Only paramedics with appropriate advanced knowledge and skill will be authorised to make these decisions.
* The researcher explained that by being taken directly to the Cath lab the patient will benefit from reduced hospital admission times and earlier access to oversight by an interventional cardiologist. The researchers hypothesize this approach will led to improved patient outcomes compared to the current model
* The Committee queried how going to the Cath lab unnecessarily would be mitigated.
* The researcher explained that paramedic staff are trained in reading ECGs. This treatment pathway is operating well in overseas jurisdictions.
* The Committee queried if it was possible to pass the ECG wirelessly to the hospital. The researcher stated that this was possible and is standard practice although in parts of NZ wireless coverage has proved to be problematic at times and there have been technological failings.
* The Committee asked whether the cardiologists in Auckland had agreed to this new referral pathway? Researchers explained that in concept, yes. The next step is to formalise locality approval and agreement from the DHB.
* The Committee noted that AUT should involve cardiologists in the research team
* The Committee confirmed that all ambulances carry standard equipment including cardiac resuscitation equipment.
* The researchers noted that this study will only involve intermediate or advanced level paramedics.
* Committee queried whether these paramedics are registered health practitioners? The researchers explained that paramedics are not currently registered health practitioners under the HPCA Act but that the paramedic training is comprehensive. (3 year degree)
* Committee confirmed that standing orders will continue to apply albeit in a modified form after the changes are made to the referral processes.
* The Committee queried whether this would transfer ED bottleneck pressures to cardiology, and potentially increase wait times for some patients depending on availability of cath lab facilities. The researchers explained that the cardiologists are very keen and on-board for the proposed changes, recognising that their treatment is time critical. Locality assessments will need to be formalised to ensure services can be delivered as contemplated.
* The Committee queried whether there was any data safety monitoring committee in place and asked how the researchers plan to identify negative trends. The researchers have criteria that would result in termination of the study. The data will be reviewed by the St John Clinical Audit & Research Group, which has the ability to stop the study. The Committee noted that this was an internal data monitoring committee and suggested sourcing external experts to join the existing committee.
* The Committee queried if there are any fiscal concerns. The researchers stated there were not.
* The Committee required a cardiologist on the study team, as well as the locality practice changes.
* Cardiologists must be satisfied with the training of the paramedics.

Decision

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

* Studies should be undertaken only by investigators and research teams with the necessary skills and resources to do so. These skills and resources include those needed to deal with any contingencies that may affect participants. Please include a cardiologist on the research team and external expertise to supplement the data safety monitoring committee(*Ethical Guidelines for Intervention Studies 5.36*).
* An investigator should proceed with a study only when the locality (eg, staff, facilities and equipment) is known to be adequate. This includes the capability to provide emergency medical care of an acceptable standard, if required. Please ensure the localities are on board with the proposed changes to the referral process and provide formal evidence of this consultation, with protocols in place (*Ethical Guidelines for Intervention Studies 5.38*).

This following information will be reviewed, and a final decision made on the application, by Dr Mathew Zacharias and Ms Michele Stanton.

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| **2** | **Ethics ref:** | **14/NTA/112** |
|  | Title: | Autonomous Paramedic Delivered Pre-Hospital Thrombolysis |
|  | Principal Investigator: | Mr Paul Davis |
|  | Sponsor: | AUT University |
|  | Clock Start Date: | 31 July 2014 |

Mr Paul Davis was present by teleconference, and Dr Graham Howie and Dr Bridget Dicker attended in person for discussion of this application.

Potential conflicts of interest

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

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

Summary of ethical issues

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

* The researchers explained the study and drug used in thrombolysis.
* Treatment is already established, but requires authorisation from physician.
* Currently ECGs are read by the ambulance crew and by an ED physician
* Technological failures in the field are currently problematic for paramedics using physician authorised telemetry based systems in certain areas of NZ.
* The paramedics already do this procedure themselves, after the approval is sought.
* The standing order would be altered to include inclusion and exclusion criteria, and then it would allow the paramedics to conduct this treatment themselves under standing orders.
* Patient location determines the treatment. Thrombolysis is the only option available in some parts of NZ where patients have no access to a catheterisation lab.
* The protocol will be very similar to the physician protocol, but it will be followed by the paramedics.
* The Committee suggests an independent data safety monitoring committee.
* Training will occur before rolling out this system, with testing to ensure paramedics are appropriately trained.

Decision

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

* An investigator should proceed with a study only when the locality (eg, staff, facilities and equipment) is known to be adequate. This includes the capability to provide emergency medical care of an acceptable standard, if required. Please ensure the localities are on board with the proposed changes to the referral process and provide formal evidence of this consultation, with protocols in place (*Ethical Guidelines for Intervention Studies 5.38*).
* A data safety monitoring committee should be established including external representation and a cardiologist should be recruited to the research team.

This following information will be reviewed, and a final decision made on the application, by Dr Mathew Zacharias and Ms Michele Stanton.

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| **3** | **Ethics ref:** | **14/NTA/113** |
|  | Title: | Omega-3 and vitamin D supplementation in children with ASD |
|  | Principal Investigator: | Dr Pamela von Hurst |
|  | Sponsor: | Massey University |
|  | Clock Start Date: | 31 July 2014 |

Dr Pamela Von Hurst and Dr Catherine Conlon attended in person for discussion of this application.

Potential conflicts of interest

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

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

Summary of ethical issues

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

* The population of children with Autism Spectrum Disorder often have nutrient deficiencies. Investigation to assess these deficiencies and their impact is not currently publicly funded unless the child is failing to thrive.
* The study has two primary aims. The study will collect substantial baseline data on 200 children, and the study is also a randomised controlled trial to test the impact of improving vitamin D and omega 3 levels.
* The researcher explained the novel research on the genetic relationship with vitamin D supplementation.
* There have not been any genetic studies on children with autism in New Zealand.
* The genetic study aims to answer the question ‘why do some people respond to treatment, and others don’t.
* Plan to recruit through child development team at DHB.
* The researcher stated children have already been medically diagnosed with ASD.
* The Committee queried what ‘light sedation’ will be offered for children who show signs of distress during the blood tests. The researchers explained the blood test may present minor discomfort but this is outweighed by the value of the data resulting from the test. Discomfort will be minimised by using an EMLA patch to numb the area prior to doing the blood test. If necessary paediatricians can provide sedation to assist.
* Maori are underrepresented in the WDHB. This study will collect more information on this demographic.
* The Committee asked whether the researchers would be collecting tissue and analysing it, or using it for future unspecified research? The researchers explained that the genetic analysis and some other testing may only occur if funding is secured. Any future research would only be in relation to the current study.
* The Committee confirmed that tissue cannot be returned.
* The Committee requested clarification be included in the PIS/CF with regards to the future testing of tissue.
* The Committee asked the researcher to justify choice of age group. The researcher wanted to start as young as possible due to neuroplasticity. The outcome measure is set for 3 to 8 years old, so participants will only be recruited if they don’t turn 8 during the study.
* The Committee asked the researcher to explain the possibility of deficiency in vitamin D and or omega 3 in children who don’t have ASD. A study indicated 1,300 preschool children who don’t have ASD. 50% were below the minimum level of adequate levels of vitamin D. We expect children with ASD will be 100% under the minimum.
* The researchers believe there may be a metabolic factor involved. The researchers are exploring the possibility that low vitamin D results in increased autism.
* The committee queried if 200 children would be feasible? The researchers explained that they were informed 200 children would not present any trouble for recruitment.
* Who will provide the supplements? Douglas Nutrition will provide nearly $30 000 of material at no cost for the study.
* The researchers confirmed the study participants must be fluent in English.
* The parents will receive full study results.
* Please provide information the optimum levels of Vitamin D. The researchers stated this was not known.
* The Committee asked if there is there any risk of going over the optimum levels? The researcher responded that they knew about upper levels with respect to safety, even without knowing the optimum levels.
* Please explain the health risks for high levels of calcium. Include this information in lay language, in the patient information sheet.
* Committee confirmed there was no specific research for 3-7 year olds, relating to ASD or vitamin D.
* The Committee queried whether it was possible to do the observations first, and then run an intervention afterwards. The researcher explained the focus of the study is nutritional adequacy, bringing participants up to optimal levels – rather than pharmacy level doses.
* Please submit a PIS/CF for parents, as they will take part. The current PIS only relates to parents consenting for their children to participate.
* The Committee confirmed the liver test is due to the livers function in vitamin D processing.
* Committee suggested contacting HDEC with respect to future funding dependent testing and any testing on the tissue that will occur as the study develops.
* The Committee requested the following changes to the Participant Information Sheet and Consent Form:
* Requires information on ACC.
* Please include contact information for the co-ordinating investigator.
* Please include information on ‘what will happen to my tissue’.
* Include information on samples being sent overseas, and where this testing will occur.
* The committee requested technical language is explained, or modified.
* The Committee suggested storing the samples for 5 years, after which the samples are destroyed.
* Please view information on future unspecified research to inform changes that have been requested to PIS/CF.

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 or genetic 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 Secretariat.

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| **4** | **Ethics ref:** | **14/NTA/115** |
|  | Title: | TEMP-AF |
|  | Principal Investigator: | Dr Ian Crozier |
|  | Sponsor: | Securus Medical Group |
|  | Clock Start Date: | 31 July 2014 |

Dr Ian Crozier was not present for discussion of this application.

Potential conflicts of interest

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

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

Summary of ethical issues

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

* Study will monitor temperature.
* Please clarify the status of this device in the global sense, has it been registered for use in other countries?.
* Please provide further safety information on the device.
* The study involves gastroscopy following the ablationscopy which is not standard practice. Please provide more information about the risks associated with gastroscopy.
* Please include an adverse event monitoring system.
* The Committee requested the following changes to the Participant Information Sheet and Consent Form:
* Pg.6 of 10 – committee notes once this intervention has been conducted you can’t be ‘withdrawn’.
* Please make it clear what procedures are standard treatments, and what is additional due to study participation, to facilitate informed consent.
* Please use consistent language when referring to endogastroduodenoscopy.

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 Ms Shamim Chagani and Dr Brian Fergus.

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| **5** | **Ethics ref:** | **14/NTA/116** |
|  | Title: | A clinical study involving previously untreated patients (infants and children)with haemophilia A, looking at the safety of rFVIIIFc and how well it works to prevent and stop bleeds in this population |
|  | Principal Investigator: | Dr Mark Smith |
|  | Sponsor: | Quintiles Pty Limited |
|  | Clock Start Date: | 31 July 2014 |

Dr Mark Smith was not present for discussion of this application.

Potential conflicts of interest

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

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

Summary of ethical issues

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

* The Committee queried what training was required for parents/young people to administer/self administer injections.
* The drug is developed specifically for this rare condition.
* This study is a phase III study. We note that post study access is confirmed to study drug if found to provide benefit.
* The Committee noted that the study has been submitted to SCOTT and that there will be an independent data safety monitoring committee.
* The Committee requested the following changes to the Participant Information Sheet and Consent Form:
* Queried ‘model’ on the PIS parent guardian main PIS title – remove if error.
* Please clarify if any future unspecified research results could provide results to participants.

Decision

This application was *approved* by consensus.

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| **6** | **Ethics ref:** | **14/NTA/118** |
|  | Title: | BMN 701, GILT-tagged recombinant human GAA |
|  | Principal Investigator: | Dr David Hutchinson |
|  | Sponsor: | BioMarin Pharmaceutical |
|  | Clock Start Date: | 31 July 2014 |

Dr Emma Glamuzina was present by teleconference for discussion of this application.

Potential conflicts of interest

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

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

Summary of ethical issues

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

* The study is a continuation of a clinical trial based in Adelaide and Brisbane. This application is for New Zealand sites (4 participants).
* Study is phase II. There have been no reported major safety issues. There have been some cases of hyperglycaemia.
* There is a theoretical risk of developing antibodies that will limit established treatment for their disease. None of the patients show evidence of this, and continued monitoring will occur. There is also a process in place to desensitise participants to the drug.
* Dr Glamuzina explained the disease.
* The study noted there are five optional sub studies.
* The participants are all over the age of 16.
* 258 weeks of treatment.
* SCOTT review is being sought.
* The Committee requested the following changes to the Participant Information Sheet and Consent Form:
* Please update Maori contact details.
* Please amend the title for the muscle biopsy optional study.
* Remove interpreter box if it not required.
* The committee noted the wording on prior consent to the earlier study could be improved. Currently is confusing.
* Please clarify if future unspecified research results will be communicated with participants. Be explicit, one way or the other.
* Please explain what ‘extra procedures’ will need to be performed. Dr Glamuzina stated that this related to PK testing. Please clarify for participants.
* Include information on disposal of human tissue.
* Please include lab and country in relation to tissue testing.
* Explain risks of study related procedures more clearly.
* Pg.13 – ACC reference. ACC changed its name in 2010 to the Accident Compensation Act 2001 – please amend.

Decision

This application was *approved* by consensus, with non-standard conditions submitted for completeness.

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| **7** | **Ethics ref:** | **14/NTA/119** (CLOSED AGENDA ITEM) |

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| **8** | **Ethics ref:** | **14/NTA/123** |
|  | Title: | The PATCH Study |
|  | Principal Investigator: | Dr Colin McArthur |
|  | Sponsor: |  |
|  | Clock Start Date: | 31 July 2014 |

Dr Colin McArthur, Mr Bruce Northey and Lynette Newby 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 ethical issues

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

* The researchers explained the study.
* The Committee confirmed the response of the paramedics is likely to be within the timeframe for treatment.
* The researcher explained that both placebo and treatment arm were standard treatment in NZ. Tranexamic acid is used widely in hospital and primary care settings.
* The prior study, CRASH II, was on 20 000 participants. This study indicated a benefit, showing statistical evidence that the drug was effective in reducing death from bleeding.
* Helicopter services in Auckland and Dunedin currently administer tranexamic acid to patients being transported to hospital.
* The reasoning for this study is to see the impact of the use of this drug in a higher income country which will isolate the impact of the drug, as the CRASH II study had a number of confounding factors, including variable standard of pre hospital care provided.New Zealand and Australia have consistent high quality standards of pre-hospital care.
* This study drug is used widely in hospital treatment for trauma and bleeding that does not resolve.
* There is some variation across New Zealand and Australia in how tranexamic acid is used.
* The Committee was satisfied that the study was comparing two standard treatments and could be said to offer the prospect of therapeutic benefit to patients.
* The Committee was satisfied that reasonable steps would be taken to seek family assent.
* All trauma centres and two ambulance centres (6 sites), with an attempt of 120 recruited.
* The Committee queried how participants were chosen? The paramedics are trained to apply the inclusion/ exclusion criteria, to assess eligibility for the study and appropriateness of treatment.
* Please explain if the patient has an option to withdraw, both from follow up or data collection. The researchers stated that it will not be clinically appropriate or practicable to seek the patient’s consent within the 8 hour period while acute trauma is being dealt with. After this period there will be time where their family, and later, the patient, will be consulted and consent sought.
* After the initial intervention there are a few additional blood tests, but these tests form part of standard care– the only difference will be the time intervals at which they are performed.
* There will be an ultrasound examination of the legs to assess blood clots, which is a primary risk outcome.
* Family and patient consent will be sought to the follow up measures.
* The researchers explained their experience in the emergency research setting, citing 95% have agreed (retrospectively) to participate in trials.
* What would occur if the family arrived in ED halfway through the transfusion / IV and they asked for it to stop? The researchers explained that it would not be in the best interests of the patient to stop what is a standard (and clinically indicated) treatment
* The setting of this trial is high risk, in general, there has been a 30%mortality rate due to underlying injuries in the Australian arm of this study.
* Due to the time critical and urgent nature of the initial treatment to stabilise the patient in practice retrospective consent is most likely to be sought after the initial intervention but before the subsequent follow up
* Please add patient information and consent form for the follow up procedures.
* The standard clinical information and treatments are normal treatment, this data would be readily available. The primary outcome data sought (death and morbidity) is routinely available to the treating team. The researchers want to be able to use this routine outcome data even if the patient withdraws consent to the other follow up tests. The Committee was satisfied with this.
* The committee clarified the drug administration process that the paramedics follow. This will all fall under standing orders, noting the existing protocols are robust and extensive.
* How will you know that the 1-3 hour window will be respected? The researcher explained that if it was not able to be determined with certainty the participant will be excluded.
* Committee noted the name of the ACC Act had name had changed, and needs to be amended on brochure to the Accident Compensation Act 2001.
* The committee queried whether tranexamic acid could still be administered to patients on the placebo arm if this was clinically indicated.The study involves comparison between two standard treatments.
* The evidence for the study drug providing a benefit resulting from less bleeding is established from CRASH II study.
* The Committee was satisfied with the ‘on the ground’ measures to reduce risk and identify the eligible participants.
* Is there a minimum standard of education or qualification for the paramedics administering the treatment? The researchers explained it is not ‘just any ambulance officer’ but they are adequately trained.
* The Committee queried if researcher was informing family of involvement in research, if they died, even if relating to non-research elements. Researcher stated yes, after 4-6 weeks the family would be informed.

Decision

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

* Please submit an information sheet and consent form (*Ethical Guidelines for Intervention Studies* *para 6.22*).

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

## General business

1. The Committee noted the content of the “noting section” of the agenda.
2. The Chair reminded the Committee of the date and time of its next scheduled meeting, namely:

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| **Meeting date:** | 09 September 2014, 01:00 PM |
| **Meeting venue:** | Novotel Ellerslie, 72-112 Greenlane Rd East, Ellerslie, Auckland |

The following members tendered apologies for this meeting.

1. Ms Susan Buckland
2. **Problem with Last Minutes**

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

The meeting closed at 5.30pm