

**NRES Committee London -
Westminster**

Annual Report

31 March 2011 – 01 April 2012

Part 1 – Committee Membership and Training

| | |
|--------------------------------|---|
| Name of REC: | NRES Committee London - Westminster |
| Type of REC: | Type I and III |
| Type of Flag: | Adults Lacking Capacity |
| Chair: | Dr L Alan Ruben (September 2011 onwards) Dr Robert Carr (up to August 2011) |
| Vice-Chair: | Mr David Hart |
| Alternate Vice-Chair: | Dr Anthony Kaiser |
| Co-ordinator: | Laura Keegan |
| PRSC Co-ordinator: | n/a |
| Assistant Co-ordinator: | Nana Boateng |
| Committee Address: | Health Research Authority Ground Floor, Skipton House 80 London Road London SE1 6LH |
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Chair's overview of the past year:

The preceding year has been most notable for the retirement of our Co-ordinator of very many years, Mrs Stella Hirsch. The committee members were sad to see her go and she had everyone's very best wishes. This heralded considerable upheaval with temporary staff and with the relocation of the office initially to Charing Cross Hospital and soon after to Skipton House. Our thanks are due to all the administrative staff who continued to deliver the service during all these changes.

Unfortunately, quite a few members reached retirement during the year and several others have intimated that they will be leaving soon. Their contributions have all been valuable and much appreciated.

We are look forward to appointing some new members and a period of consolidation in the coming year.

NRES Committee London - Westminster Membership:

| Name | Occupation | Expert or Lay | Dates | |
|-------------------------|--|---------------|------------|------------|
| | | | Appointed | Resigned |
| Mr Alastair Adam | Lay Member | Lay | 24/06/2008 | 29/02/2012 |
| Mrs Emma Bassett | Lay Member | Lay | 11/06/2008 | |
| Dr Robert Carr | Chairman/Consultant Haematologist | Expert | 15/07/2001 | 31/08/2011 |
| Mrs Lesley Graham | Senior Nurse | Expert | 19/07/2007 | |
| Miss Alison Grant | Specialist Pharmacist | Expert | 01/02/2010 | 07/11/2011 |
| Miss Catherine Hamilton | Pharmacist | Expert | 01/01/2010 | |
| Mr David Hart | Vice-Chair/Lay Member | Lay | 01/05/2002 | |
| Mr Andrew Hughes | Lay Member | Lay | 21/01/2011 | |
| Dr Anthony Kaiser | Consultant Neonatologist | Expert | 01/03/2003 | |
| Miss Nina Khazaezadeh | Consultant Midwife | Expert | 01/03/2011 | |
| Mr Douglas Meehan | Lay | Lay | 01/09/2011 | |
| Dr Kevin O'Kane | Consultant Physician | Expert | 01/06/2008 | |
| Dr Mark O'Neill | Consultant Cardiologist & Reader in Clinical Cardiac Electrophysiology | Expert | 01/09/2011 | |
| Dr Marlies Ostermann | Consultant Intensivist | Expert | 01/07/2011 | |
| Dr Christine Patch | Consultant Genetic Counsellor and Manager | Expert | 01/02/2011 | |
| Mr Michael Puntis | ICU/Anaesthetist | Expert | 08/07/2010 | |
| Dr L Alan Ruben | Retired General Practitioner | Expert | 01/09/2011 | |
| Miss Ros Stanbury | Ophthalmologist | Expert | 03/07/2006 | |
| Mr Owain Thomas | Lay Member | Lay | 01/03/2004 | |
| Dr Bridget Wilkins | Consultant Histopathologist | Expert | 01/06/2008 | 13/12/2011 |

Deputy Members

| Name | Occupation | Expert or Lay | Meeting date attended |
|-----------------|------------|---------------|-----------------------|
| Mr Owain Thomas | Lay Member | Lay | None |

Co-opted Members

| Name | Occupation | Expert or Lay | Meeting date attended |
|----------------------|------------|---------------|-----------------------|
| Mr William Thornhill | Pharmacist | Expert | 31/01/2012 |

Member Bank

| Name | Occupation | Expert or Lay | Meeting date attended |
|------|------------|---------------|-----------------------|
| | | | |

NRES Committee London - Westminster: Members' Declarations of Interest:

| Name | Declaration of Interest | Date |
|-------------------------|---|-------------|
| Dr L Alan Ruben | None. | 09/10/2012 |
| Dr Anthony Kaiser | None. | 09/10/2012 |
| Miss Catherine Hamilton | None. | 09/10/2012 |
| Dr Kevin O'Kane | None. | 09/10/2012 |
| Mr Michael Puntis | None. | 09/10/2012 |
| Mrs Emma Bassett | None. | 09/10/2012 |
| Mr Andrew Hughes | None. | 09/10/2012 |
| Dr Marlies Ostermann | A member of the NICE clinical guidelines | 26/09/2011 |
| Mr Douglas Meehan | Previously Volunteered with the British Red Cross and Medicine sans frontiers | 27/09/2011 |
| Dr Mark O'Neill | Reader in electrophysiology. Supervise year 3 PHD students, funded by the clinical Research council, British Heart Foundation and St Jude medical. The research leads for clinical cardiac electrophysiology at St Thomas | 30/09/2012 |

Meetings for Full Ethical Review 31 March 2011 - 01 April 2012:

| Month | Date | Number of Members Present at Meeting |
|--------------|-------------|---|
| April | 19/04/2011 | 13 |
| May | 24/05/2011 | 13 |
| June | 28/06/2011 | 11 |
| July | 25/07/2011 | 11 |
| September | 27/09/2011 | 14 |
| October | 25/10/2011 | 10 |
| November | 29/11/2011 | 10 |
| January | 31/01/2012 | 8 |
| February | 28/02/2012 | 10 |
| March | 27/03/2012 | 8 |

10 full committee meetings were held during the reporting period.

Attendance of Members: 31 March 2011 – 01 April 2012:

| Name | Number of Meetings Attended |
|-------------------------|------------------------------------|
| Dr Anthony Kaiser | 9 |
| Mrs Emma Bassett | 8 |
| Dr Christine Patch | 8 |
| Mr Andrew Hughes | 7 |
| Miss Catherine Hamilton | 7 |
| Miss Nina Khazaezadeh | 7 |
| Miss Ros Stanbury | 6 |
| Dr Bridget Wilkins | 6 |
| Dr L Alan Ruben | 6 |
| Mr David Hart | 6 |
| Mrs Lesley Graham | 6 |
| Dr Kevin O'Kane | 5 |
| Dr Marlies Ostermann | 5 |
| Dr Robert Carr | 4 |
| Miss Alison Grant | 4 |
| Dr Mark O'Neill | 4 |
| Mr Douglas Meehan | 4 |
| Mr Michael Puntis | 3 |
| Mr Alastair Adam | 2 |

Number of inquorate meetings held: 0

Training 31 March 2011 – 01 April 2012:

| Name of Member | Date | Event(s) attended |
|-------------------------|-------------------------|--|
| Mr Andrew Hughes | 22/06/2011 - 22/06/2011 | Induction, NRES |
| Miss Ros Stanbury | 26/07/2011 - 26/07/2011 | Medical Devices, NRES |
| Dr Robert Carr | 19/05/2011 - 19/05/2011 | Research with Adolescents – 19/05/2011, NRES |
| Miss Catherine Hamilton | 01/11/2011 - 01/11/2011 | CTIMP, NRES |
| Miss Catherine Hamilton | 18/04/2011 - 18/04/2011 | Information Governance, GSTT |
| Dr L Alan Ruben | 06/12/2011 - 06/12/2011 | NRES chair's national training day, NRES |
| Dr Anthony Kaiser | 07/12/2011 - 07/12/2011 | NRES Stats, NRES |
| Mrs Emma Bassett | 14/07/2011 - 14/07/2011 | Equality & Diversity, NRES |
| Dr L Alan Ruben | 28/02/2012 - 28/02/2012 | Qualitative Research and Ethical Review, NRES |
| Dr L Alan Ruben | 28/02/2012 - 28/02/2012 | NRES Qualitative Research and Ethical Review , HRA |

Part 2: REC workload and activity during the reporting period.

Table 1: Applications assigned to a full committee meeting held within the reporting period:

| Applications for full ethical review – Study Type | Number | % |
|--|---------------|------------|
| Clinical Trial of Investigational Medicinal Product | 18 | 29.03 |
| Phase 1 | 6 | 9.68 |
| Gene Therapy | 0 | 0.00 |
| Research Tissue Bank | 0 | 0.00 |
| Research Database | 0 | 0.00 |
| Others | 38 | 61.29 |
| Total Applications Reviewed | 62 | 100 |

Table 2: Other REC activity during the reporting period:

| | |
|---|----|
| Number of applications made invalid by co-ordinator | 0 |
| Number of studies withdrawn prior to the meeting | 14 |
| Number of student applications reviewed | 14 |
| Number of paediatric applications reviewed | 10 |
| Number of device applications reviewed | 2 |
| Number of prisoner applications reviewed | 0 |
| Number of applications involving adults unable consent reviewed | 1 |
| Number of applications reviewed funded by the US DHHS | 0 |

Table 3: Decisions given at meetings held within the reporting period:

| Decisions taken at meetings following review of applications | Number | % |
|---|---------------|------------|
| Favourable Opinion with Standard Conditions | 3 | 4.84 |
| Favourable Opinion with Additional Conditions | 6 | 9.68 |
| Unfavourable Opinion | 2 | 3.23 |
| Provisional Opinion | 51 | 82.26 |
| Invalid | 0 | 0.00 |
| No Opinion Pending Consultation with Referee | 0 | 0.00 |
| Provisional Opinion Pending Consultation with Referee | 0 | 0.00 |
| Not Requiring Review by NHS REC | 0 | 0.00 |
| Total | 62 | 100 |
| Number of studies sent back to full committee meeting for final opinion | 0 | |

Table 4: Summary of current status of applications reviewed during the reporting period:

| Status of applications at date of generation of report | Number | % |
|---|---------------|------------|
| Further Information Favourable Opinion with Standard Conditions | 47 | 75.81 |
| Further Information Favourable Opinion with Additional Conditions | 3 | 4.84 |
| Further Information Unfavourable Opinion | 0 | 0.00 |
| Favourable Opinion with Standard Conditions | 3 | 4.84 |
| Favourable Opinion with Additional Conditions | 6 | 9.68 |
| Unfavourable Opinion | 2 | 3.23 |
| Provisional Opinion | 0 | 0.00 |
| Provisional Opinion Pending Consultation with Referee | 0 | 0.00 |
| Invalid | 0 | 0.00 |
| No Opinion Pending Consultation with Referee | 0 | 0.00 |
| Further Information response not complete | 0 | 0.00 |
| Not Requiring Review by NHS REC | 0 | 0.00 |
| No decision entered on RED | 0 | 0.00 |
| Number of studies withdrawn after the meeting | 1 | 1.61 |
| Total | 62 | 100 |

Table 5: Other Management Information for the reporting period:

| | |
|---|--------|
| Average number of applications reviewed per full meeting | 6.20 |
| Number of applications for full ethical review over 60 days | 7 |
| Number of applications over 60 days as a % of total | 11.29% |
| Number of days taken to final decision - average | 40 |
| Number of days taken to final decision - mode | 21 |
| Number of SSAs (non-Phase 1) reviewed | 1 |
| Number of applications for SSA review over 25 days | 0 |
| Number of applications for SSA review over 25 days as % of all non-Phase 1 (SSAs) | 0.0% |
| Number of SSAs (Phase 1) reviewed | 0 |
| Number of applications for SSA review over 14 days | 0 |
| Number of applications for SSA review over 14 days as % of all Phase 1 (SSAs) | 0% |
| Number of substantial amendments reviewed | 92 |
| Number of substantial amendments over 35 days | 16 |
| Number of substantial amendments over 35 days as a % of total substantial amendments | 17.4% |
| Number of Section 30 applications reviewed | 0 |
| Number of Section 30 applications over 60 days | 0 |
| Number of Section 30 applications over 60 days as a % of total Section 30 applications | 0% |
| Number of modified amendments reviewed | 1 |
| Number of modified amendments over 14 days | 1 |
| Number of modified amendments over 14 days as a % of total modified amendments | 100.0% |

Table 6: Breakdown of current status of all applications reviewed within the reporting period:

| Further Information Favourable Opinion with Standard Conditions | | |
|--|--|--------------------------------|
| REC Reference | Application Short Title | Number of Days on Clock |
| 11/LO/0316 | Phase 1 study to assess ADME after oral 14C labelled NKTR-118 | 37 |
| 11/LO/0320 | To assess a safe suprathapeutic dose of TC-5214 and effect on QT/QTc | 37 |
| 11/LO/0346 | Erythropoietin to facilitate stroke recovery | 43 |
| 11/LO/0418 | Grand MuTHER | 35 |
| 11/LO/0446 | Dietary Nitrate and Monocyte-platelet aggregates in Atherosclerosis | 33 |
| 11/LO/0473 | Patient Preference: Comparison of AZARGA/COSOPT for OAG/OH patients | 42 |
| 11/LO/0629 | An evaluation of parent/ professional perception of videofluoroscopy | 46 |
| 11/LO/0633 | OEP measurements in emphysema patients before and after LVR. | 54 |
| 11/LO/0637 | Gradual vs abrupt Weaning from Nasal CPAP in Preterm Infants with HMD | 54 |
| 11/LO/0649 | Diurnal and food effects on the PK/PD profile of ONO-5334 | 35 |
| 11/LO/0658 | Hypoglycaemia in people with type 1 diabetes and adrenal insufficiency | 49 |
| 11/LO/0693 | The Effect of Asymmetry on Smile Aesthetic | 37 |
| 11/LO/0833 | Clinical Assessment of a Closed Loop Insulin Delivery System | 29 |
| 11/LO/0849 | Mechanisms of Regulation of Vascular Function | 21 |
| 11/LO/0854 | Phase 2, Abiraterone Acetate in Metastatic Breast Cancer 212082BCA2001 | 36 |
| 11/LO/0879 | Drug-related problems in paediatric patients with kidney disease | 25 |
| 11/LO/0896 | Reliability of the SGMST (v1) | 30 |
| 11/LO/0921 | A study of asthma medication/inhaler combinations | 23 |
| 11/LO/0976 | Capillary and venous blood analysis for gamma-hydroxybutyrate (GHB) | 21 |
| 11/LO/1004 | PD study comparing Fluticasone dose/response through FENO inhibition | 29 |
| 11/LO/1071 | Validation of Methodology for PET-CT Radiotherapy Treatment Planning | 30 |
| 11/LO/1083 | PD study comparing Salmeterol dose/response through bronchodilation | 30 |
| 11/LO/1114 | Managing hot flushes and night sweats following prostate cancer | 37 |
| 11/LO/1117 | Comparing outcomes of managing blood pressure in preterm infants | 57 |
| 11/LO/1296 | Vitamin D in left Ventricular hypertrophy Diabetes (VIVID) Trial. | 37 |
| 11/LO/1470 | Investigation of the vascular effects of arterial microbubbles | 50 |
| 11/LO/1477 | A study of Y242 in healthy adult men | 38 |
| 11/LO/1481 | A randomised controlled trial of rehabilitation in OHS | 41 |
| 11/LO/1489 | Functional imaging for early response assessment in rectal cancer | 78 |
| 11/LO/1492 | TNBC:Novel functional imaging to determine early chemotherapy response | 32 |

| | | |
|------------|--|-----|
| 11/LO/1561 | Metacognitive beliefs in PTSD & brain injury. (Version One) | 44 |
| 11/LO/1564 | The Effect of GLP-1 on Exercise Physiology in Patients with IHD. | 61 |
| 11/LO/1573 | ProBono 2-Vitamin D Substudy | 25 |
| 11/LO/1626 | The effect of low dose vitamin D2 on cardiovascular risk | 40 |
| 11/LO/1627 | Validation of AVAPS-AE in COPD | 36 |
| 11/LO/1664 | AOLVBP | 61 |
| 11/LO/1848 | Artemis UK | 61 |
| 11/LO/1893 | Tricalcium silicate cement as a new material for pulp capping version1 | 48 |
| 11/LO/1896 | Circulating micro RNA and mRNA levels in obesity | 60 |
| 11/LO/1955 | Juvenile SLE Investigation V1 | 28 |
| 12/LO/0118 | Study of CC-223 in patients with advanced solid tumours,NHL or MM | 58 |
| 12/LO/0134 | Safety, tolerability, PK and PD of GSK1995057 in healthy subjects | 45 |
| 12/LO/0153 | Nerve & Muscle Excitability studies - Mitochondrial Disease & IBM | 70 |
| 12/LO/0233 | Mild erythropoietic protoporphyria: genetics and enzyme study | 29 |
| 12/LO/0301 | The IMAGINE 4 Study | 119 |
| 12/LO/0447 | How do we remember our past? A memory research study. Version 1 | 31 |
| 12/LO/0481 | To compare Eposartan and Eprosartan Mesylate in hypertension-M13-85 | 55 |

Further Information Favourable Opinion with Additional Conditions

| REC Reference | Application Short Title | Number of Days on Clock |
|---------------|--|-------------------------|
| 12/LO/0069 | A study of neuropeptide receptors in human intestinal tissue | 68 |
| 12/LO/0361 | 8HA02PED-VIII Fc Fusion Protein Paediatric Subjects with Haemophilia A | 60 |
| 12/LO/0370 | 9HB02PED-Paediatric Subjects with Haemophilia B | 56 |

Further Information Unfavourable Opinion

| REC Reference | Application Short Title | Number of Days on Clock |
|---------------|-------------------------|-------------------------|
|---------------|-------------------------|-------------------------|

Favourable Opinion with Standard Conditions

| REC Reference | Application Short Title | Number of Days on Clock |
|---------------|---|-------------------------|
| 12/LO/0227 | Flora Twin Study | 28 |
| 12/LO/0242 | Caries-associated biofilm and tooth / restoration interface | 32 |
| 12/LO/0306 | Mechanisms of allergen immunotherapy | 31 |

| Favourable Opinion with Additional Conditions | | |
|--|---|--------------------------------|
| REC Reference | Application Short Title | Number of Days on Clock |
| 11/LO/1115 | MRI of human heart fibre direction - feasibility study | 29 |
| 11/LO/1667 | Validation of Respiration Rate Algorithms | 21 |
| 11/LO/1832 | Violence & abortion: Stakeholder needs analysis & feasibility study | 21 |
| 11/LO/1838 | Investigate the pharmacokinetics of a novel fluticasone inhaler | 15 |
| 12/LO/0165 | Prevalence of domestic violence in elective abortion setting 1 | 21 |
| 12/LO/0457 | Defining the benchmark for optimal human ageing | 40 |

| Unfavourable Opinion | | |
|-----------------------------|---|--------------------------------|
| REC Reference | Application Short Title | Number of Days on Clock |
| 11/LO/1118 | To determine acceptability and uptake of bereavement services | 29 |
| 12/LO/0472 | Aflibercept EAP (AFLIBC06097) | 30 |

| Provisional Opinion | | |
|----------------------------|--------------------------------|--------------------------------|
| REC Reference | Application Short Title | Number of Days on Clock |
| | | |

| Provisional Opinion Pending Consultation with Referee | | |
|--|--------------------------------|--------------------------------|
| REC Reference | Application Short Title | Number of Days on Clock |
| | | |

| Further information response not complete | | |
|--|--------------------------------|--------------------------------|
| REC Reference | Application Short Title | Number of Days on Clock |
| | | |

| Withdrawn after the meeting | | |
|------------------------------------|--|--------------------------------|
| REC Reference | Application Short Title | Number of Days on Clock |
| 12/LO/0232 | Myoblast Proliferation and Differentiation in acute exacerbations COPD | N/A |

| Invalid Application | | |
|----------------------------|--------------------------------|--------------------------------|
| REC Reference | Application Short Title | Number of Days on Clock |
| | | |

| No Opinion Pending Consultation with Referee | | |
|---|--------------------------------|--------------------------------|
| REC Reference | Application Short Title | Number of Days on Clock |
| | | |

| Not Requiring Review by NHS REC | | |
|--|--------------------------------|--------------------------------|
| REC Reference | Application Short Title | Number of Days on Clock |

Table 7: Items exceeding timelines:

| Full applications for ethical review over 60 day timeline | | |
|--|---|--------------------------------|
| REC Reference | Application Short Title | Number of Days on Clock |
| 11/LO/1489 | Functional imaging for early response assessment in rectal cancer | 78 |
| 11/LO/1564 | The Effect of GLP-1 on Exercise Physiology in Patients with IHD. | 61 |
| 11/LO/1664 | AOLVBP | 61 |
| 11/LO/1848 | Artemis UK | 61 |
| 12/LO/0069 | A study of neuropeptide receptors in human intestinal tissue | 68 |
| 12/LO/0153 | Nerve & Muscle Excitability studies - Mitochondrial Disease & IBM | 70 |
| 12/LO/0301 | The IMAGINE 4 Study | 119 |

| SSAs (non Phase 1) over 25 days timeline | | |
|---|--------------------------------|--------------------------------|
| REC Reference | Application Short Title | Number of Days on Clock |

| SSAs (Phase 1) over 14 days timeline | | |
|---|--------------------------------|--------------------------------|
| REC Reference | Application Short Title | Number of Days on Clock |

| Substantial Amendments over 35 day timeline | | | |
|--|---|------------------------|--------------------------------|
| Amendment Reference | Application Short Title | Amendment Title | Number of Days on Clock |
| EC01/020/AM06 | South London Stroke Register | SAO7, 24/03/2011 | 39 |
| 09/H0802/80/AM13 | rehabilitation following critical illness | 5, 16 May 2011 | 44 |
| 09/H0802/126/AM01 | PRISM CRT Randomised Controlled Trial Version 1.0 | 1 | 49 |
| 08/H0802/131/AM03 | Using saliva as a indicator for activity of dental erosion | SAO3 | 41 |
| 10/H0802/24/AM01 | Integrated dietary intervention to lower cardiovascular risk | SAO1 | 36 |
| 06/Q0702/22/AM02 | JWCI Multicenter Selective Lymphadenectomy trial II (MSLT II) | SAO2, 15/09/2011 | 37 |
| 11/H0802/10/AM07 | An Investigation of Humidification in | SAO4 | 74 |

| | | | |
|------------------|--|--|----|
| | Non-invasive Ventilation | | |
| 11/LO/0404/AM01 | RIPC in CKD Version 1 | 1 | 85 |
| 11/LO/0045/AM01 | Peanut Allergy Sensitisation Study (PAS Study) | SAO1 21 Nov 2011 | 40 |
| 11/LO/0854/AM04 | Phase 2, Abiraterone Acetate in Metastatic Breast Cancer 212082BCA2001 | SAO2 - Your ref INT-3 | 70 |
| 10/H0802/52/AM03 | Relationship between nitrate/nitrate handling and clucose tolerance | SAO3 | 49 |
| 11/LO/1296/AM02 | Vitamin D in left Ventricle hypertrophy Diabetes (VIVID) Trial. | Substantial Amendment 1 - Letter from GP | 43 |
| 05/Q0702/89/AM03 | Conscious and non-conscious stress | Substantial Amendment 3 | 54 |
| 11/LO/0473/AM03 | Patient Preference: Comparison of AZARGA/COSOPT for OAG/OH patients | Substantial Amendment 2 - Aforementioned study | 63 |
| 11/LO/1114/AM01 | Managing hot flushes and night sweats following prostate cancer | Substantial Amendment 1 - Protocol Amendment | 36 |
| 10/H0802/50/AM03 | Assessment of female sexual difficulties after pelvic radiotherapy V1. | Amendment 2 | 61 |

Modified Amendments over 14 day timeline

| Amendment Reference | Application Short Title | Amendment Title | Number of Days on Clock |
|---------------------|-------------------------|---------------------|-------------------------|
| EC04/015/AM21/1 | Twins UK | Mitochondrial Study | 21 |

Section 30 application over 60 day timeline

| Amendment Reference | Application Short Title | Amendment Title | Number of Days on Clock |
|---------------------|-------------------------|-----------------|-------------------------|
|---------------------|-------------------------|-----------------|-------------------------|