

**NRES Committee London -
Hampstead**

Annual Report

01 April 2011 – 31 March 2012

Part 1 – Committee Membership and Training

Name of REC:	NRES Committee London - Hampstead
Type of REC:	Type I (Patients & Healthy Volunteers) and Type III
Type of Flag:	Paediatrics
Chair:	Dr Michael Pegg
Vice-Chair:	Mr Sia Rafiee
Alternate Vice-Chair:	Dr Andrew Hilson
Co-ordinator:	Mrs Alka Bhayani
PRSC Co-ordinator:	n/a
Assistant Co-ordinator:	Kate Donaldson
Committee Address:	HRA, Ground Floor, Skipton House 80 London Road London SE1 6LH
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Chair's overview of the past year:

Chair during reporting period is no longer in post.

NRES Committee London - Hampstead Membership:

Name	Occupation	Expert or Lay	Dates	
			Appointed	Resigned
Dr Waheeb Atia	Retired Consultant Physician	Expert	01/11/2010	
Mrs Jacqueline Birks	Senior Medical Statistician	Expert	12/10/2008	
Dr Rahul Chodhari	Consultant Paediatrician	Expert	03/04/2008	
Dr Jason Crampton	Reader in Information Security	Lay	21/06/2006	01/11/2011
Mr Michael Fox	Administrator - NRES	Lay	18/05/2011	01/03/2012
Dr Lorna Annabel Charlotte Gibson	General Manager/Head of Research and Innovation – GOSH	Lay	16/04/2009	15/07/2011
Mr Paul Hardiman	Consultant Gynaecologist/Senior Lecturer in Obstetrics and Gynaecology	Expert	01/09/2010	
Dr Andrew Hilson	Consultant in Nuclear Medicine	Expert	02/11/2007	
Miss Monica Jefford	Retired Midwife	Lay	31/08/2011	
Miss Mina Karamshi	Specialist Sister in Radiology	Expert	02/11/2010	
Dr Jane Lees-Millais	GP	Expert	01/07/2011	
Reverend Robert Mitchell	Lead Chaplain	Lay Plus	01/10/2004	
Dr Richard Orrell	Senior Lecturer and Consultant Neurologist	Expert	24/09/2002	
Dr Michael Pegg	Consultant Anaesthetist	Expert	01/11/2002	31/03/2012
Ms Rosa Pizer	Retired Teacher	Lay Plus	14/07/2009	
Mr Sia Rafiee	Pharmacist - Clinical Trials	Expert	20/04/2010	
Mrs Wendy Spicer	Pharmacist	Expert	01/12/2005	
Dr Latha Padma Weston	Consultant Psychiatrist	Expert	14/12/2011	
Miss Sarah Louisa Wisniewski	General Manager for Emergency Services	Lay	18/05/2011	

Deputy Members

Name	Occupation	Expert or Lay	Meeting date attended

Co-opted Members

Name	Occupation	Expert or Lay	Meeting date attended

Member Bank

Name	Occupation	Expert or Lay	Meeting date attended

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

Name	Declaration of Interest	Date
Dr Andrew Hilson	no declared interests.	20/04/2011
Dr Richard Orrell	no declared interests.	14/12/2011
Mrs Wendy Spicer	no declared interests.	14/12/2011
Dr Rahul Chodhari	no declared interests.	14/12/2011
Mrs Jacqueline Birks	no declared interests.	14/12/2011
Mr Paul Hardiman	no declared interests.	14/12/2011
Miss Mina Karamshi	no declared interests.	14/12/2011
Dr Waheeb Atia	no declared interests.	14/12/2011
Miss Sarah Louisa Wisniewski	Informed peer review for local community college hospital "R&D" in medicine board.	14/12/2011
Dr Jane Lees-Millais	Trustee for Swindon Postgraduate Education Trust	20/07/2011
Miss Monica Jefford	PPI member of NCRI CLG chair of SWL CRN consumer research panel. Member of trial management team.	14/12/2011
Reverend Robert Mitchell	no declared interests.	14/12/2011
Dr Latha Padma Weston	no declared interests.	14/12/2011
Dr Michael Pegg	no declared interests.	14/12/2011

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

Month	Date	Number of Members Present at Meeting
April	20/04/2011	8
May	18/05/2011	13
June	22/06/2011	14
July	20/07/2011	9
August	31/08/2011	13
October	19/10/2011	11
November	16/11/2011	12
December	14/12/2011	10
January	18/01/2012	14
February	15/02/2012	11
March	21/03/2012	12

11 full committee meetings were held during the reporting period.

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

Name	Number of Meetings Attended
Dr Andrew Hilson	11
Dr Waheeb Atia	11
Dr Michael Pegg	10
Mrs Jacqueline Birks	10
Miss Mina Karamshi	8
Miss Monica Jefford	7
Miss Sarah Louisa Wisniewski	7
Dr Rahul Chodhari	7
Dr Richard Orrell	7
Mr Paul Hardiman	7
Mr Sia Rafiee	7
Mrs Wendy Spicer	6
Ms Rosa Pizer	6
Dr Jane Lees-Millais	6
Mr Michael Fox	5
Reverend Robert Mitchell	5
Dr Jason Crampton	3
Dr Latha Padma Weston	2
Dr Lorna Annabel Charlotte Gibson	2

Number of inquorate meetings held: 0

**Attendance of Members at proportionate review sub-committee meetings:
01 April 2011 – 31 March 2012:**

Training 01 April 2011 – 31 March 2012:

Name of Member	Date	Event(s) attended
Dr Lorna Annabel Charlotte Gibson	19/05/2011 - 19/05/2011	Ethical issues arising from research involving adolescents , NRES
Dr Andrew Hilson	01/11/2011 - 01/11/2011	NRES Reviewing Clinical Trials of Investigational Medicinal Products (code - PO1101), NRES
Mrs Jacqueline Birks	19/05/2011 - 19/05/2011	Ethical issues arising from research involving adolescents , NRES
Ms Rosa Pizer	01/11/2011 - 01/11/2011	NRES Reviewing Clinical Trials of Investigational Medicinal Products (code - PO1101), NRES
Ms Rosa Pizer	19/05/2011 - 19/05/2011	Ethical issues arising from research involving adolescents, NRES
Mrs Jacqueline Birks	26/07/2011 - 26/07/2011	NRES Medical Devices training (code PO3003), NRES
Dr Jane Lees-Millais	22/06/2011 - 22/06/2011	NRES Members Induction Training (code OP1 001), NRES
Dr Jason Crampton	28/09/2011 - 28/09/2011	NRES Phase 1 training (code PO4001) , NRES
Dr Jason Crampton	26/07/2011 - 26/07/2011	NRES Medical Devices training (code PO3003) , NRES
Dr Rahul Chodhari	20/05/2011 - 20/05/2011	ED Equality and Diversity Online by NRES, NRES
Mr Sia Rafiee	08/11/2011 - 08/11/2011	NRES Training Day for New REC Chairs (code OP3001) , NRES
Dr Richard Orrell	15/09/2011 - 15/09/2011	NRES Human Tissue Act training (Code PO5001) , NRES
Dr Richard Orrell	01/11/2011 - 01/11/2011	NRES Reviewing Clinical Trials of Investigational Medicinal Products (code - PO1101) , NRES
Dr Jane Lees-Millais	28/09/2011 - 28/09/2011	NRES Phase 1 training (code PO4001), NRES
Ms Rosa Pizer	08/05/2011 - 08/05/2011	E & D Online training, NRES
Mrs Wendy Spicer	16/11/2011 - 16/11/2011	NRES Members Induction Training (code 8405) , NRES
Mrs Wendy Spicer	15/09/2011 - 15/09/2011	NRES Human Tissue Act training (Code PO5001) , NRES
Mr Paul Hardiman	16/11/2011 - 16/11/2011	NRES Members Induction Training (code 8403) , NRES
Dr Richard Orrell	16/11/2011 - 16/11/2011	NRES Members Induction Training - ref 8404, NRES
Mr Michael Fox	10/01/2012 - 10/01/2012	NRES Members Induction

		Training (code OP1001) , NRES
Dr Waheeb Atia	16/11/2011 - 16/11/2011	NRES Members Induction Training (code OP1001) , NRES
Miss Sarah Louisa Wisniewski	10/01/2012 - 10/01/2012	NRES Members Induction Training (code OP1001) , NRES
Reverend Robert Mitchell	22/06/2011 - 22/06/2011	NRES Induction Training for members, NRES
Mrs Jacqueline Birks	15/08/2011 - 15/08/2011	Equality & Diversity, NRES
Miss Mina Karamshi	22/06/2011 - 22/06/2011	Induction, NRES
Mr Michael Fox	07/12/2011 - 07/12/2011	NRES Statistics Training for NRES REC Members; OP6002, NRES
Miss Monica Jefford	08/02/2012 - 08/02/2012	Induction, NRES
Dr Jane Lees-Millais	19/01/2012 - 19/01/2012	NRES Shared Ethical Debate, NRES
Ms Rosa Pizer	13/02/2012 - 13/02/2012	ICR GCP Forum, NRES

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	25.71
Phase 1	1	1.43
Gene Therapy	0	0.00
Research Tissue Bank	0	0.00
Research Database	0	0.00
Others	51	72.86
Total Applications Reviewed	70	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	9
Number of student applications reviewed	18
Number of paediatric applications reviewed	22
Number of device applications reviewed	2
Number of prisoner applications reviewed	0
Number of applications involving adults unable consent reviewed	0
Number of applications reviewed funded by the US DHHS	1

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	5	7.14
Favourable Opinion with Additional Conditions	10	14.29
Unfavourable Opinion	5	7.14
Provisional Opinion	50	71.43
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	70	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:

Further Information Favourable Opinion with Standard Conditions	48	68.57
Further Information Favourable Opinion with Additional Conditions	1	1.43
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	5	7.14
Favourable Opinion with Additional Conditions	10	14.29
Unfavourable Opinion	5	7.14
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	1.43
Total	70	100

Table 5: Applications assigned to a proportionate review sub-committee within the reporting period:

Average number of applications reviewed per full meeting	6.36
Number of applications for full ethical review over 60 days	3
Number of applications over 60 days as a % of total	4.29%
Number of days taken to final decision - average	40
Number of days taken to final decision - mode	49
Number of SSAs (non-Phase 1) reviewed	3
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	1
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)	0.0%
Number of substantial amendments reviewed	147
Number of substantial amendments over 35 days	2
Number of substantial amendments over 35 days as a % of total substantial amendments	1.4%
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	0
Number of modified amendments over 14 days as a % of total modified amendments	0.0%

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/0224	BAX 326 Continuation study	37
11/LO/0425	SYCAMORE	47
11/LO/0527	Dried Blood Spot screening for Hepatitis B (version2, April 2011)	50
11/LO/0600	Sensory mechanisms in silent myocardial infarction and ischaemia	39
11/LO/0608	Phase 2 study of MDV3100 for metastatic prostate cancer	45
11/LO/0687	The effects of insulin detemir in type 1 diabetes	48
11/LO/0845	In vitro screening using PBMCs from Hepatitis B Virus Infected Donors	49
11/LO/0848	To determining the degree of social anxiety in hyperhidrosis patients	50
11/LO/0865	Investigating the attitudes of children when assessed for puberty	53
11/LO/0901	Changing Illness Perceptions in Chronic Urticaria: Pilot Study and RCT	39
11/LO/1019	(duplicate) Future 4	30
11/LO/1075	Distraction for children undergoing dressing changes	46
11/LO/1076	Women's health study of Mycoplasma genitalium: a feasibility study	45
11/LO/1077	Small Wonders Change Programme Evaluation	42
11/LO/1084	TEG and thromboprophylactic LMWH in post-natal women	69
11/LO/1238	BAX 326 Surgery	49
11/LO/1293	A phase 1 study of AEB071 in patients with CD79 mutant lymphoma	43
11/LO/1295	INPUT version 1	51
11/LO/1331	A pilot qualitative study of severe and enduring eating disorders	32
11/LO/1355	The Pulsecor Study	44
11/LO/1356	Coagulation Factor levels in women with recurrent miscarriage	44
11/LO/1367	EBUS-TBNA vs. EBUS-TBNB	43
11/LO/1634	MRI assessment of small bowel motility	51
11/LO/1655	Protein C in NEC V1	39
11/LO/1658	Bimatoprost 0.03% Preservative-free Ophthalmic Solution in Paediatric	38
11/LO/1696	Progression of atherosclerosis in diabetic subjects	59
11/LO/1705	Birdshot Uveitis Survey	48
11/LO/1793	The cellular and molecular mechanisms of COPD exacerbations	35
11/LO/1804	MDex vs BMDex in systemic light-chain (AL) amyloidosis	74
11/LO/1805	A phase 1 study of AEB071 in patients with metastatic uveal melanoma	50

11/LO/1815	Tacking of hernia sac vs no tacking to improve outcome	38
11/LO/1824	Nephrotoxicity in patients with psoriasis receiving ciclosporin	44
11/LO/1858	Effects of Stress Relieve through Meditation in Special Education (1)	27
11/LO/1864	An exploration of the use of ACT for borderline personality disorder	35
11/LO/1867	imaging of the pelvic floor after obstetric trauma	28
11/LO/1998	Pneucast13	42
11/LO/2028	The effects of serial casting on paediatric idiopathic toe walkers	52
11/LO/2036	Phase I/II Safety, PK & Efficacy Study of Oral Rucaparib	27
12/LO/0035	Monitoring the health of children taking allergy medications	49
12/LO/0075	Does a change in main meal time shift biological rhythms? version 1	32
12/LO/0198	EPHRATA Study	26
12/LO/0208	MDT planning & preparation for paediatric venepuncture MRES1	48
12/LO/0216	Validation of a strabismus detection technology	59
12/LO/0231	ARD12181: SAR302503 in MF patients previously treated with Ruxolitinib	32
12/LO/0261	HARMONY trial	61
12/LO/0373	Pathogenesis and therapeutic targets in the antiphospholipid syndrome	58
12/LO/0393	CAM-THY	38
12/LO/0399	Is fluid administration using Quench the same as free oral intake?	51

Further Information Favourable Opinion with Additional Conditions

REC Reference	Application Short Title	Number of Days on Clock
11/LO/2015	Gene Expression in Diffuse and Focal Hyperinsulinism using Microarray	24

Further Information Unfavourable Opinion

REC Reference	Application Short Title	Number of Days on Clock
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Favourable Opinion with Standard Conditions

REC Reference	Application Short Title	Number of Days on Clock
11/LO/0353	Profiling the index lesion in the prostate	15
11/LO/1054	Mitochondrial DNA Transmission in Children Born After ART	27
11/LO/1147	Predictors 4 New tests for cervical screening Version 1	33
12/LO/0025	NN7088-3859 Trial Evaluating Safety and Efficacy of N8-GP in Haem A	22
12/LO/0026	NN7088-3860 Efficacy and Safety of N8-GP during Surgery in Haem A	22

Favourable Opinion with Additional Conditions		
REC Reference	Application Short Title	Number of Days on Clock
11/LO/0401	Evaluation study of Band 6 midwives perception of leadership	22
11/LO/0405	3 in 1 study (pooling specimens for CT and NG in MSM)	28
11/LO/0677	Filter of high physiological uptake signal in F-18 FDG PET studies.	30
11/LO/0898	Psychological factors in episodic non-adherence to Chelation Therapy	29
11/LO/1157	First-In-Man study to assess doses of NI-0501	32
11/LO/1630	The MRC/ABPI COPD Cohort v 1.7	28
11/LO/1709	Rare headache and facial pain syndromes: a prospective clinical study	29
12/LO/0078	The effects of Early Palliative Care in Mesothelioma	22
12/LO/0219	A pedometer intervention to increase walking in adults: PACE-UP trial	29
12/LO/0416	B1831077 moderately severe or severe haemophilia	29

Unfavourable Opinion		
REC Reference	Application Short Title	Number of Days on Clock
11/LO/0291	Study on fertility and pregnancy experience	49
11/LO/0607	Ultrasound Study for Carpal Tunnel: Version 1	49
11/LO/0864	PTSD, parenting and adult attachment in parents of a paediatric sample	36
11/LO/2057	COPD diary signifiers feasibility study	54
12/LO/0386	COPD diary signifiers feasibility study (REC 12/LO/0386)	45

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
11/LO/0564	Neuroblastoma presenting with spinal cord compression	30

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/1084	TEG and thromboprophylactic LMWH in post-natal women	69
11/LO/1804	MDex vs BMDex in systemic light-chain (AL) amyloidosis	74
12/LO/0261	HARMONY	61

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
10/H0720/71/AM02	Active Dialysis	1, 27/6/2011	37
08/H0720/4/AM09	Carer interventions as suppleiment to standard care in EDs- Version a	Addition of two new researchers and changes to protocol	62

Modified Amendments over 14 day timeline			
Amendment Reference	Application Short Title	Amendment Title	Number of Days on Clock

Section 30 application over 60 day timeline			
Amendment Reference	Application Short Title	Amendment Title	Number of Days on Clock