

National Research Ethics  
Service

  
*Health Research Authority*

**NRES Committee London - Central**

**Annual Report**

**01 April 2011 – 31 March 2012**

## Part 1 – Committee Membership and Training

<b>Name of REC:</b>	NRES Committee London – Central
<b>Type of REC:</b>	1 and 3
<b>Type of Flag:</b>	Paediatrics
<b>Chair:</b>	Dr John Keen
<b>Vice-Chair:</b>	Dr Andrew Hilson
<b>Alternate Vice-Char:</b>	none
<b>Co-ordinator:</b>	Ms Julie Kidd
<b>PRSC Co-ordinator:</b>	n/a
<b>Assistant Co-ordinator:</b>	Ms Hayley Fraser
<b>Committee Address:</b>	London REC Centre Health Research Authority Ground Floor Skipton House 80 London Road SE1 6LH
<b>Telephone:</b>	020 797 22555
<b>Fax:</b>	020 797 22592
<b>Email:</b>	nrescommittee.london-central@nhs.net

### Chair's overview of the past year:

2012 saw the departure of our much valued long standing Vice Chair Dr Peter Brodrick.

The committee continues to thrive with well attended meetings at its accessible central London location.

## NRES Committee London - Central Membership:

Name	Occupation	Expert or Lay	Dates	
			Appointed	Resigned
Sir Adrian Baillie	Financial Investment Advisor	Lay Plus	22/12/2006	
Dr Sue Birtwistle	General Practitioner	Expert	01/04/2002	30/03/2012
Dr Daniel Bradford	Pharmacologist	Expert	31/08/2007	
Dr Peter Brodrick	Anaesthetist	Expert	01/09/2002	01/02/2012
Mr Clive Carsley	Retired Lawyer	Lay Plus	08/11/2007	
Mrs Emma Crawford-Collins	Communications Director	Lay Plus	18/08/2009	
Dr Parastou Donyai	Senior Lecturer in Pharmacy Practice	Expert	21/10/2008	27/02/2012
Dr Olivia Festy	Clinical Trials Administrator	Lay	14/04/2006	
Mrs Sophie Forsyth	Lawyer	Lay	01/04/2011	
Mrs Rosie Glazebrook	Consumer Marketing	Lay Plus	18/11/2007	
Dr Frances Goodhart	Consultant Clinical Psychologist	Expert	01/04/2011	
Dr Andrew Hilson	Consultant in Nuclear Medicine	Expert	01/03/2012	
Dr Leslie Huson	Consultant Medical Statistician	Expert	14/09/2007	
Dr John Keen	General Practitioner	Expert	01/04/2002	
Dr Amin Rahemtulla	Consultant Haematologist	Expert	01/01/2004	
Ms Dani Singer	Pyschotherapist	Lay	01/10/2010	
Professor Lewis Spitz	Emeritus Nuffield Professor of Paediatric Surgery	Expert	29/11/2007	
Mr Benjamin Stanfield-Davies	University lecturer	Expert	23/05/2012	
Dr Gareth Tudor-Williams	Consultant in Paediatric Infectious Diseases	Expert	02/02/2011	

### Deputy Members

Name	Occupation	Expert or Lay	Meeting date attended

### Co-opted Members

Name	Occupation	Expert or Lay	Meeting date attended

### Member Bank

<b>Name</b>	<b>Occupation</b>	<b>Expert or Lay</b>	<b>Meeting date attended</b>

## NRES Committee London - Central: Members' Declarations of Interest:

Name	Declaration of Interest	Date
Dr John Keen	None	06/09/2011
Dr Andrew Hilson	None	06/09/2011
Sir Adrian Baillie	None	06/09/2011
Dr Olivia Festy	None	06/09/2011
Dr Daniel Bradford	None	06/09/2011
Professor Lewis Spitz	None	06/09/2011
Mr Clive Carsley	None	06/09/2011
Mrs Rosie Glazebrook	Board member of the Human Tissue Authority. Committee member on Tissue Bank at Imperial College	25/01/2012
Mrs Emma Crawford-Collins	None	06/09/2011
Dr Gareth Tudor-Williams	Actively involved with clinical research with children with HIV	25/01/2012
Dr Frances Goodhart	None	06/09/2011
Mrs Sophie Forsyth	Volunteer advisor for the charity working families which conducts research into finding a better balance between responsibilities at home and work	25/01/2012
Mr Benjamin Stanfield-Davies	None	06/09/2011
Dr Leslie Huson	Director of GNB Ltd Consultancies with various pharma companies and with imperial college	25/01/2012

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

<b>Month</b>	<b>Date</b>	<b>Number of Members Present at Meeting</b>
April	27/04/2011	12
May	25/05/2011	13
June	29/06/2011	12
July	27/07/2011	12
August	31/08/2011	11
September	28/09/2011	10
October	26/10/2011	12
November	30/11/2011	12
January	25/01/2012	14
February	29/02/2012	11
March	28/03/2012	12

11 full committee meetings were held during the reporting period.

**Proportionate Review Sub Committee Meetings held during 01 April 2011 - 31 March 2012:**

0 proportionate review sub-committee meetings were held during the reporting period.

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

<b>Name</b>	<b>Number of Meetings Attended</b>
Dr John Keen	11
Dr Daniel Bradford	9
Mrs Rosie Glazebrook	9
Mrs Sophie Forsyth	9
Professor Lewis Spitz	9
Dr Peter Brodrick	8
Dr Sue Birtwistle	8
Mr Clive Carsley	8
Mrs Emma Crawford-Collins	8
Dr Frances Goodhart	8
Dr Amin Rahemtulla	8
Dr Olivia Festy	8
Dr Leslie Huson	7
Dr Gareth Tudor-Williams	6
Sir Adrian Baillie	6
Ms Dani Singer	5
Dr Andrew Hilson	2
Mr Benjamin Stanfield-Davies	1
Dr Parastou Donyai	1

**Number of inquorate meetings held: 0**

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

<b>Name</b>	<b>Number of Meetings Attended</b>
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**Training 01 April 2011 – 31 March 2012:**

<b>Name of Member</b>	<b>Date</b>	<b>Event(s) attended</b>
Dr Gareth Tudor-Williams	11/05/2011 - 11/05/2011	CEC Open Day
Mrs Emma Crawford-Collins	15/09/2011 - 15/09/2011	NRES Human Tissue Act Training (Code PO5001), NRES
Mrs Rosie Glazebrook	01/11/2011 - 01/11/2011	NRES Reviewing Clinical Trials of Investigational Medicinal Products (code PO1101), NRES
Mrs Emma Crawford-Collins	28/02/2012 - 28/02/2012	NRES Qualitative Research and Ethical Review (code OP6001), NRES
Dr Frances Goodhart	18/08/2011 - 18/08/2011	MCA DVD, NRES
Mrs Sophie Forsyth		MCA DVD, NRES
Dr Sue Birtwistle		MCA DVD, NRES
Mrs Emma Crawford-Collins	15/09/2011 - 15/09/2011	Human Tissue Act, NRES
Mrs Emma Crawford-Collins	01/11/2011 - 02/11/2011	CTIMP Training, NRES
Dr Amin Rahemtulla	13/10/2011 - 13/10/2011	Ethical Issues in Clinical Negligence, Imperial College Healthcare
Dr Gareth Tudor-Williams	13/10/2011 - 13/10/2011	Ethical Issues in Clinical Negligence, Imperial college Healthcare
Professor Lewis Spitz		NRES Shared Ethical Debate, NRES
Professor Lewis Spitz	20/11/2011 - 20/11/2011	AREC
Professor Lewis Spitz	19/01/2012 - 19/01/2012	Shared Ethical Debate, NRES
Ms Dani Singer	29/02/2012 - 29/02/2012	Personal Data in Research, NRES
Dr Daniel Bradford		MCA
Ms Dani Singer	29/02/2012 - 29/02/2012	Personal data in research, NRES
Dr Daniel Bradford	13/02/2012 - 13/02/2012	Ethics & GCP Forum , HRA
Dr Andrew Hilson	12/03/2012 - 12/03/2012	Equality, Diversity and Human Rights, Information Governance and Level 1 Safeguarding refreshers, Royal Free
Dr Andrew Hilson	05/01/2012 - 05/12/2012	Chairs national Training Day V8066



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

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

<b>Applications for full ethical review – Study Type</b>	<b>Number</b>	<b>%</b>
Clinical Trial of Investigational Medicinal Product	24	32.43
Phase 1	0	0.00
Gene Therapy	0	0.00
Research Tissue Bank	0	0.00
Research Database	0	0.00
Others	50	67.57
<b>Total Applications Reviewed</b>	<b>74</b>	<b>100</b>

**Table 2: Other REC activity during the reporting period:**

Number of applications made invalid by co-ordinator	1
Number of studies withdrawn prior to the meeting	8
Number of student applications reviewed	20
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	0

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

<b>Decisions taken at meetings following review of applications</b>	<b>Number</b>	<b>%</b>
Favourable Opinion with Standard Conditions	21	28.38
Favourable Opinion with Additional Conditions	17	22.97
Unfavourable Opinion	2	2.70
Provisional Opinion	34	45.95
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
<b>Total</b>	<b>74</b>	<b>100</b>
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:**

<b>Status of applications at date of generation of report</b>	<b>Number</b>	<b>%</b>
Further Information Favourable Opinion with Standard Conditions	33	44.59
Further Information Favourable Opinion with Additional Conditions	1	1.35
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	21	28.38
Favourable Opinion with Additional Conditions	17	22.97
Unfavourable Opinion	2	2.70
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	0	0.00
<b>Total</b>	<b>74</b>	<b>100</b>

**Table 5: Other Management Information for the reporting period:**

<b>Average number of applications reviewed per full meeting</b>	6.73
<b>Number of applications for full ethical review over 60 days</b>	2
<b>Number of applications over 60 days as a % of total</b>	2.70%
<b>Number of days taken to final decision - average</b>	34
<b>Number of days taken to final decision - mode</b>	24

<b>Number of SSAs (non-Phase 1) reviewed</b>	4
<b>Number of applications for SSA review over 25 days</b>	2
<b>Number of applications for SSA review over 25 days as % of all non-Phase 1 (SSAs)</b>	50.0%

<b>Number of SSAs (Phase 1) reviewed</b>	1
<b>Number of applications for SSA review over 14 days</b>	0
<b>Number of applications for SSA review over 14 days as % of all Phase 1 (SSAs)</b>	0.0%

<b>Number of substantial amendments reviewed</b>	101
<b>Number of substantial amendments over 35 days</b>	2
<b>Number of substantial amendments over 35 days as a % of total substantial amendments</b>	2.0%

<b>Number of Section 30 applications reviewed</b>	0
<b>Number of Section 30 applications over 60 days</b>	0
<b>Number of Section 30 applications over 60 days as a % of total Section 30 applications</b>	0%

<b>Number of modified amendments reviewed</b>	5
<b>Number of modified amendments over 14 days</b>	1
<b>Number of modified amendments over 14 days as a % of total modified amendments</b>	20.0%

**\*NB – Proportionate Review Service was in pilot phase until September 2011 and was an aim not a target**

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

<b>Further Information Favourable Opinion with Standard Conditions</b>		
<b>REC Reference</b>	<b>Application Short Title</b>	<b>Number of Days on Clock</b>
11/LO/0394	Head Start for Heart Babies	23
11/LO/0402	Patent foramen ovale in GOLD II COPD	43
11/LO/0449	Axitinib plus BSC v Placebo plus BSC in Advanced HCC Patients	55
11/LO/0452	Comparing long-acting insulins during exercise in Type 1 Diabetes	56
11/LO/0530	Q4883g: Omalizumab compared with placebo in patients with CIU	27
11/LO/0537	Natalizumab in Secondary Progressive Multiple Sclerosis	57
11/LO/0630	Complex intervention for PTSD-SP	55
11/LO/0660	Collection of Urine for protein purification Version 1	35
11/LO/0841	GDC-0068 with docetaxel or mFOLFOX for advanced solid tumours	43
11/LO/0913	Measuring Biomarkers in People with Inherited Cardiomyopathies	48
11/LO/0925	Investigating the child's experience of premenarcheal anorexia nervosa	64
11/LO/0936	AN INVESTIGATION OF IMMEDIATELY LOADED IMPLANTS PLACED IN THE MAXILLAE	25
11/LO/1094	Intellikine 1117-001	41
11/LO/1124	Florbetapir 18F (18F-AV-45) amyloid PET imaging in focal dementia	43
11/LO/1146	Body composition/ metabolic profile in child end stage liver disease	43
11/LO/1150	Quantifying nerve injury during correction of knee flexion deformity	50
11/LO/1156	Pulmonary rehabilitation and sleep quality in patients with COPD	38
11/LO/1271	Effect of Anamorelin HCl on Non-Small Cell Lung Cancer - Cachexia	34
11/LO/1272	Anamorelin HCl effect on Non-Small Cell Lung Cancer-Cachexia Extension	41
11/LO/1314	The HICCUP Study (V1 25/7/11)	46
11/LO/1315	Epigenetic fetal programming and neonatal profile in growth disorders	43
11/LO/1399	A Phase I study of MK-8242 in patients with Advanced Solid Tumours	46
11/LO/1487	UKALL 2011	45
11/LO/1506	PO7614 PK of Boceprevir in CHC Paediatric Patients	48
11/LO/1589	DNA Polymorphisms in mental illness in a Bangladeshi population	52
11/LO/1685	Ozurdex in PVR	35
11/LO/1728	Ivabradine Study in Children with Chronic Heart Failure and DCM	39
11/LO/1778	Experiences of young people who have a LD and/or autism and a cleft	30

11/LO/1911	Childhood adversity, stress sensitivity, and psychosis	34
11/LO/1949	Temporal summation with age and glaucoma: an exploratory study.	45
12/LO/0050	Study of Tadalafil in Children with Pulmonary Arterial Hypertension(a)	43
12/LO/0267	Plasma, Serum & DNA bank from patients with antiphospholipid antibodies	64
12/LO/0456	PCD4989g Phase 1 study in patients with solid tumours	31

#### Further Information Favourable Opinion with Additional Conditions

REC Reference	Application Short Title	Number of Days on Clock
11/LO/1141	Bacteria and glucose control	58

#### 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/0445	The challenge of providing co-ordinated care in a diverse NHS	45
11/LO/0651	Exploring psychological well-being in a help-seeking population	37
11/LO/0838	Hypocalcaemic Seizures Due To Vitamin D Deficiency In Children	22
11/LO/0917	Patient and carer views on clinical trials using immunotherapy	33
11/LO/0928	Forensically investigating internal child sex trafficking (ICST) v1	26
11/LO/1110	Mortality in Children Born after ART	28
11/LO/1152	Stress and Cardiovascular Risk in Adolescent Morbid Obesity	25
11/LO/1299	Thinking styles and eating disorders - Version 1.0	22
11/LO/1344	The effect on sexual function of sacral nerve stimulation	21
11/LO/1345	Sacral nerve stimulation constipation parameters study	21
11/LO/1443	CHAFFINCH Trial - Pilot study	22
11/LO/1508	Functional Image Analysis of the Knee. Version 1	24
11/LO/1560	1970 British Cohort Study - Age 42 Follow-Up	28
11/LO/1693	CT coronary artery calcification in patients with non-acute chest pain.	28
11/LO/1711	Avastin Colorectal Non-Interventional Study.	32
11/LO/1720	Prospective cohort study of patients with pulmonary embolism Version 1	28
12/LO/0108	Sex differences in oral bacteria	24
12/LO/0122	Peer-Support weight action programme (SWAP)	24

12/LO/0286	AYAPK- Adolescents and Young Adults PK	22
12/LO/0444	An investigation of supported decision making in pregnancy in PLD.	24
12/LO/0480	Acceptance and Commitment Therapy for Psychosis	21

#### Favourable Opinion with Additional Conditions

REC Reference	Application Short Title	Number of Days on Clock
11/LO/0407	NURSE-LED COMPREHENSIVE GERIATRIC ASSESSMENT IN PATIENTS WITH CANCER	49
11/LO/0408	Validity and reliability of caregiver stress measure in kidney disease	55
11/LO/0667	Haemodynamics after coarctation repair during isometric exercise	17
11/LO/0923	BO25041 Paed HGG	22
11/LO/1444	Laparoscopic inguinal hernia repair in children using tissue adhesives	23
11/LO/1712	Comparative study of 2 optical technologies in colonoscopy	31
11/LO/1852	Oxidative stress and innate immune dysfunction in COPD	41
11/LO/1860	Phase I study of AT13148, a novel AGC kinase inhibitor	24
11/LO/1870	New method for diagnosing small intestinal bacterial overgrowth	24
11/LO/1901	Foster Parents' experiences of caring for traumatised children	31
12/LO/0005	Mitogent Study V1	24
12/LO/0124	Management and Outcome of Post Dural Puncture Headache	24
12/LO/0138	An extension to an open label study of canakinumab in paediatrics	25
12/LO/0273	Pilot study: Prevalence of joint hyper-mobility in anorexia nervosa	35
12/LO/0313	Phase I/IIa FTIH study of GSK2636771 in PTEN- solid tumour patients	22
12/LO/0455	neoGent. Version 1	25
12/LO/0512	HGS1006-C1115 Phase 3 Belimumab Administered SC to patients with SLE	17

#### Unfavourable Opinion

REC Reference	Application Short Title	Number of Days on Clock
11/LO/1701	Clinical Trial to Evaluate Femtosecond Laser Assisted Lens Surgery	34
12/LO/0072	Phase I/IIa FTIH study of GSK2636771 in PTEN- solid tumour patients	25

#### Provisional Opinion

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

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

REC Reference	Application Short Title	Number of Days on Clock
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**Withdrawn after the meeting**

REC Reference	Application Short Title	Number of Days on Clock
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**Invalid Application**

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

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

REC Reference	Application Short Title	Number of Days on Clock
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**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/0925	Investigating the child's experience of premenarcheal anorexia nervosa	64
12/LO/0267	Plasma, Serum & DNA bank from patients with antiphospholipid antibodies	64

**Proportionate review applications for ethical review over 14 days timeline**

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

REC Reference	Application Short Title	Number of Days on Clock
11/LO/1005	Impact of Stem Cell and Bone Marrow Harvesting on Unrelated Donors	27
11/LO/2062	IMM-101 treatment, combined with CyberKnife, in Colorectal Cancer	28

**SSAs (Phase 1) over 14 days timeline**

REC Reference	Application Short Title	Number of Days on Clock
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**Substantial Amendments over 35 day timeline**

Amendment Reference	Application Short Title	Amendment Title	Number of Days on Clock
11/LO/0530/AM10	Q4883g: Omalizumab compared with placebo in patients with CIU	Amendment 6, 28 February 2012, Closure of 2 study	70
09/H0718/51/AM25	TORPEDO-CF	16. 28 Feb 2012	40

**Modified Amendments over 14 day timeline**

Amendment Reference	Application Short Title	Amendment Title	Number of Days on Clock
08/H0718/65/AM11/1	3200K1-4000: MNTX in Adults with Advanced Illness and OIC	Modified Amendment 3 dated 5th April 2011	15

**Section 30 application over 60 day timeline**



<b>Amendment Reference</b>	<b>Application Short Title</b>	<b>Amendment Title</b>	<b>Number of Days on Clock</b>
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