

National Research Ethics  
Service

  
*Health Research Authority*

**NRES Committee London - Brent**

**Annual Report**

**01 April 2011 – 31 March 2012**

## Part 1 – Committee Membership and Training

<b>Name of REC:</b>	NRES Committee London - Brent
<b>Type of REC:</b>	Recognised, Phase I & III
<b>Type of Flag:</b>	Phase I in Volunteers
<b>Chair:</b>	Dr John Keen
<b>Vice-Chair:</b>	Mrs Sunder Chita
<b>Alternate Vice-Char:</b>	Miss Zainab Yate
<b>Co-ordinator:</b>	Mrs Julie Kidd
<b>PRSC Co-ordinator:</b>	None
<b>Assistant Co-ordinator:</b>	Ms Hayley Fraser
<b>Committee Address:</b>	80 London Road Skipton House London SE1 6LH
<b>Telephone:</b>	0207 972 2571
<b>Fax:</b>	020 797 22592
<b>Email:</b>	nrescommittee.london-brent@nhs.net

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

Following the retirement of my predecessor Dr Bernie Calaco I was pleased to take over as Chair of NRES Committee London - Brent in June 2011. I was delighted to find my new committee colleagues are an effective and thorough team, and the committee has continued to have full agendas and busy meetings throughout the year. We have also benefited a number of new committee members, who have given us additional medical, paediatric and dental expertise. The committee goes from strength to strength and will continue to deliver safe, fair and robust ethical opinion in the future.

## NRES Committee London - Brent Membership:

Name	Occupation	Expert or Lay	Dates	
			Appointed	Resigned
Mr Suresh Akula	Retired Civil Servant	Lay Plus	13/02/2009	
Mr Babak Babakinejad	Research Postgraduate	Expert	07/10/2011	
Miss Lara Callaghan	Assistant Coordinator		07/10/2011	23/01/2012
Mrs Sunder Chita	Manager	Lay Plus	31/07/2005	
Dr Graham Davison	Pharmaceutical Consultant	Expert	08/06/2010	
Mr Maurice Hoffman	Work Placement Advisor	Lay Plus	23/07/2008	
Dr John Keen	General Practitioner	Expert	01/04/2002	
Dr Ina Lisa Lauinger	Research Associate	Expert	01/04/2011	
Mrs Alison Lee	Specialist in Special Care Dentistry	Expert	28/11/2011	
Dr Mohd Ezam Mat Ali	Consultant Neonatal Paediatrician	Expert	07/10/2011	
Mr Adeyemi Olagbegi	Clinical Pharmacology Study Data Manager	Lay	18/05/2007	
Miss Vashti Ragoonanan	Specialist Nurse - Haematology	Expert	28/09/2009	
Dr Manish Saxena	Doctor	Expert	30/03/2011	
Dr Zdenek Slavik	Consultant Paediatric Cardiologist/Intensivist	Expert	20/10/2011	
Mr Alan Smith	Barrister's Clerk (Retired)	Lay Plus	28/02/2012	28/02/2012
Miss Ourania Xeniou	Senior Clinical Research Associate	Lay	30/06/2008	
Miss Zainab Yate	Bioethics Researcher	Lay	30/06/2008	
Nadey Hakim	Professor – Transplant Surgery	Expert	20/10/2011	30/06/2012

### 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 - Brent: Members' Declarations of Interest:

Name	Declaration of Interest	Date
Mr Alan Smith	None	19/04/2011
Dr John Keen	None	06/09/2011
Mrs Sunder Chita	None	27/01/2012
Miss Zainab Yate	None	27/01/2012
Mr Adeyemi Olagbegi	None	27/01/2012
Mr Maurice Hoffman	None	27/01/2012
Miss Ourania Xeniou	None	27/01/2012
Miss Vashti Ragoonanan	None	27/01/2012
Dr Graham Davison	Shareholdings in organisations involved in or possibly seeking to be involved in the conduct of research - Glaxosmithkline 650 shares. Oxford Biomedical 5357 shares.	09/02/2011
Dr Ina Lisa Lauinger	Employed by King's College London, honorary contract with St Thomas NHS Trust. Kings Health Partner have a mailing list for recruitment of volunteers for studies which I receive.	28/05/2012
Dr Manish Saxena	None	27/01/2012
Mr Babak Babakinejad	None	27/01/2012
Dr Mohd Ezam Mat Ali	None	27/01/2012
Dr Zdenek Slavik	None	27/01/2012
Mrs Alison Lee	None	27/01/2012
Mr Suresh Akula	None	27/01/2012

**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>
May	23/05/2011	12
June	27/06/2011	12
July	25/07/2011	10
August	22/08/2011	7
September	26/09/2011	8
October	24/10/2011	12
November	21/11/2011	12
December	12/12/2011	12
January	30/01/2012	12
February	27/02/2012	13
March	26/03/2012	14

11 full committee meetings were held during the reporting period.

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

<b>Month</b>	<b>Date</b>	<b>Number of Members Present at Meeting</b>
--------------	-------------	---

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>
Mr Maurice Hoffman	11
Dr Graham Davison	10
Dr Manish Saxena	10
Dr Ina Lisa Lauinger	9
Dr John Keen	9
Miss Vashti Ragoonanan	9
Miss Zainab Yate	9
Mrs Sunder Chita	9
Mr Alan Smith	8
Mr Suresh Akula	7
Miss Ourania Xeniou	6
Mr Adeyemi Olagbegi	5
Dr Mohd Ezam Mat Ali	4
Professor Nadey Hakim	4
Mr Babak Babakinejad	4
Mrs Alison Lee	3
Dr Zdenek Slavik	3
Miss Lara Callaghan	3
Dr Neeta Ghosh-Chowdhury	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>
-------------	------------------------------------

**Training 01 April 2011 – 31 March 2012:**

<b>Name of Member</b>	<b>Date</b>	<b>Event(s) attended</b>
Dr Ina Lisa Lauinger	22/06/2011 - 22/06/2011	Induction, NRES
Dr Manish Saxena	22/06/2011 - 22/06/2011	Induction, NRES
Dr Ina Lisa Lauinger	28/09/2011 - 28/09/2011	NRES Phase 1 training (code PO4001), NHS National Research Ethics Service
Dr Ina Lisa Lauinger	01/11/2011 - 01/11/2011	NRES Reviewing Clinical Trials of Investigational Medicinal Products (code - PO1101), NHS National Research Ethics Service
Dr Ina Lisa Lauinger	15/09/2011 - 15/09/2011	NRES Human Tissue Act training (Code PO5001), NHS National Research Ethics Service
Dr Ina Lisa Lauinger	26/07/2011 - 26/07/2011	NRES Medical Devices training (code PO3003), NHS National Research Ethics Service
Dr Ina Lisa Lauinger	01/03/2012 - 01/03/2012	NRES Adults Lacking Capacity (including research in emergency situations) , NRES
Dr Ina Lisa Lauinger	07/12/2011 - 07/12/2011	NRES Statistics Training for NRES REC Members (code OP6002), NRES
Dr Graham Davison	17/07/2011 - 17/07/2011	Equality & Diversity, NRES
Miss Vashti Ragoonanan	11/10/2011 - 11/10/2011	Induction, NRES
Mr Adeyemi Olagbegi	10/01/2012 - 10/01/2012	Induction, NRES
Dr Ina Lisa Lauinger	28/02/2012 - 28/02/2012	NRES Qualitative Research and Ethical Review; OP6001, NRES
Dr Graham Davison	14/03/2012 - 14/03/2012	NRES Members National Training Day - London, NRES
Dr Graham Davison	17/05/2011 - 17/05/2011	Investigational Medicinal Products crossing the divide, BARQA
Dr John Keen	18/10/2011 - 18/10/2011	NREAP Chairs Meeting, NRES
Dr John Keen	31/01/2012 - 31/01/2012	NRES Phase 1 , NRES
Mr Babak Babakinejad	08/02/2012 - 08/02/2012	Induction, NRES
Dr John Keen	16/11/2011 - 16/11/2011	Phase I Advisory Group Meeting, Phase I Advisory Group
Dr John Keen	06/12/2011 - 06/12/2011	Chair's National Training Day, NRES
Mrs Alison Lee	13/02/2012 - 13/02/2012	Induction, NRES
Dr Zdenek Slavik	20/03/2012 - 20/03/2012	Induction, NRES
Mrs Alison Lee		GCP Training
Dr Graham Davison	14/03/2012 - 14/03/2012	National Training Day, NRES
Dr Graham Davison	14/03/2012 - 14/03/2012	Mmembers National Training Day , NRES

Mr Suresh Akula	25/11/2011 - 25/11/2011	Equality & Diversity
Mr Maurice Hoffman	25/11/2011 - 25/11/2011	Equality & Diversity, NHS North West London
Miss Zainab Yate	01/11/2011 - 01/11/2011	AREC Conferene, 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:**

<b>Applications for full ethical review – Study Type</b>	<b>Number</b>	<b>%</b>
Clinical Trial of Investigational Medicinal Product	18	26.09
Phase 1	6	8.70
Gene Therapy	0	0.00
Research Tissue Bank	0	0.00
Research Database	0	0.00
Others	45	65.22
<b>Total Applications Reviewed</b>	<b>69</b>	<b>100</b>

**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	13
Number of student applications reviewed	15
Number of paediatric applications reviewed	8
Number of device applications reviewed	1
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:**

<b>Decisions taken at meetings following review of applications</b>	<b>Number</b>	<b>%</b>
Favourable Opinion with Standard Conditions	19	27.54
Favourable Opinion with Additional Conditions	21	30.43
Unfavourable Opinion	3	4.35
Provisional Opinion	26	37.68
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>69</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	25	36.23
Further Information Favourable Opinion with Additional Conditions	1	1.45
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	19	27.54
Favourable Opinion with Additional Conditions	21	30.43
Unfavourable Opinion	3	4.35
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>69</b>	<b>100</b>

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

<b>Average number of applications reviewed per full meeting</b>	6.27
<b>Number of applications for full ethical review over 60 days</b>	3
<b>Number of applications over 60 days as a % of total</b>	4.35%
<b>Number of days taken to final decision - average</b>	34
<b>Number of days taken to final decision - mode</b>	28
<b>Number of SSAs (non-Phase 1) reviewed</b>	13
<b>Number of applications for SSA review over 25 days</b>	3
<b>Number of applications for SSA review over 25 days as % of all non-Phase 1 (SSAs)</b>	23.1%
<b>Number of SSAs (Phase 1) reviewed</b>	23
<b>Number of applications for SSA review over 14 days</b>	3
<b>Number of applications for SSA review over 14 days as % of all Phase 1 (SSAs)</b>	13.0%
<b>Number of substantial amendments reviewed</b>	84
<b>Number of substantial amendments over 35 days</b>	3
<b>Number of substantial amendments over 35 days as a % of total substantial amendments</b>	3.6%
<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%

**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/0548	TKI258 v sorafenib in metastatic renal cell carcinoma PA02 090211	39
11/LO/0646	Taste in Crohn's	35
11/LO/0679	MK-4618 in Patients with Overactive Bladder	44
11/LO/0914	V81444: first doses in humans; version 1	41
11/LO/0978	Ranibizumab (Lucentis) for treatment of Uveitic Macular Oedema (LIMO)	41
11/LO/1072	Young women's fertility knowledge	47
11/LO/1090	MAXIM	50
11/LO/1095	SM101 in Lupus Erythematosus (SMILE)	45
11/LO/1103	GLP-1 Response in Type 2 Diabetes Mellitus	55
11/LO/1121	Changes in saliva composition in dry mouth patients	60
11/LO/1127	Preparation groups prior to entering day patient services	58
11/LO/1133	'Conditioning' in forensic settings: Version 1	60
11/LO/1261	INOVATYON SECOND LINE CHEMOTHERAPY OVARIAN CANCER	34
11/LO/1283	Midwifery one to one support in labour	28
11/LO/1292	Neuromuscular calf stimulation compared to pneumatic compression	41
11/LO/1473	Determinants of repeat abortion among young women: version one.	56
11/LO/1535	Long Term Outcomes of Bladder Exstrophy and its Treatment	50
11/LO/1663	A new approach to luteal phase support in IVF	69
11/LO/1684	Seeking help and receiving appropriate treatment for OCD	37
11/LO/1688	Menstruation and Contraception (Version 1)	45
11/LO/1726	Varenicline and Cognitive Bias Modification on Smoking Cue Response	55
11/LO/1869	A7471009 EFFICACY & SAFETY STUDY OF PF-00299804 VS ERLOTINIB IN NSCLC	34
11/LO/1892	Identification of Biomarkers for Burn Pain	48
11/LO/2005	Tocilizumab (TCZ) for the treatment of systemic sclerosis	28
12/LO/0440	AMG 785/Placebo in Postmenopausal Women with Osteoporosis- 20070337	37

<b>Further Information Favourable Opinion with Additional Conditions</b>		
<b>REC Reference</b>	<b>Application Short Title</b>	<b>Number of Days on Clock</b>
11/LO/1909	Renal Denervation in Congestive Cardiac Failure	31

<b>Further Information Unfavourable Opinion</b>		
<b>REC Reference</b>	<b>Application Short Title</b>	<b>Number of Days on Clock</b>

<b>Favourable Opinion with Standard Conditions</b>		
<b>REC Reference</b>	<b>Application Short Title</b>	<b>Number of Days on Clock</b>
11/LO/0855	Investigation of steroid metabolism in congenital adrenal hyperplasia	28
11/LO/0856	Investigation of steroid metabolism in 5a-reductase 2 deficiency	28
11/LO/0857	Steroid metabolism in children presenting with genital hair at <2y old	28
11/LO/0858	Investigation of steroid metabolism in salt wasting conditions	28
11/LO/1308	Study in patients who experienced an allergic reaction to Taspoglutide	21
11/LO/1522	Tissue engineering airways	24
11/LO/1533	Genetic markers affecting radiosensitivity in breast cancer	24
11/LO/1534	inducible pluripotent stem cells	26
11/LO/1691	Investigation of the sleep EEG of IGE patients with nocturnal seizures	37
11/LO/1700	EuroNeut-41: Safety & immunogenicity of immunisations with HIV vaccine	37
11/LO/1855	11-023 Blood samples for medicines research; version 1	22
11/LO/2020	ECG early repolarisation in chronic kidney disease	19
12/LO/0109	Effect of lorazepam on side effects & blood levels of DS-5565; ver 1	21
12/LO/0281	Resilience, Positive Symptoms & Stress in Early Psychosis	24
12/LO/0282	Novel Cancer Biomarkers in Blood and Urine	28
12/LO/0298	Digitally coloured maxillofacial prosthetics	49
12/LO/0311	LY3016859 – first doses in humans; version 1	23
12/LO/0400	Safety & blood levels of GSK2339345 in a new inhaler; version 1	23
12/LO/0429	Safety and blood levels of RV568; version1	23

<b>Favourable Opinion with Additional Conditions</b>		
<b>REC Reference</b>	<b>Application Short Title</b>	<b>Number of Days on Clock</b>
11/LO/0624	Post traumatic amnesia following traumatic brain injury	72
11/LO/0625	Does Forgiveness Influence Trajectories of PTSD During Treatment?v1	74
11/LO/0634	Blood levels and effects of 2 medicines for COPD; ver 1	25
11/LO/0919	Inter-Rater Reliability Test of Patient Response Style Scale (PRSS)	35
11/LO/1298	Surgical Metabolic Modelling of Renal Transplantation	22
11/LO/1302	Relationship between learning English and psychological well-being	26

11/LO/1502	EFC12153: Phase 3 SAR302503 Study	21
11/LO/1503	ARD12042- SAR302503 in patients with PV or ET	21
11/LO/1523	A Ketogenic Diet in Sickle Cell Disease	25
11/LO/1686	MR1704 – first doses in humans; version 1	37
11/LO/1853	Siltuximab in Patients with High-risk Smoldering Multiple Myeloma	22
11/LO/1967	Absorption and elimination of radiolabelled AME001; ver 1	22
11/LO/1968	GW824575 - first doses in humans, version1	22
11/LO/2025	The Impact of Omalizumab Treatment in UK Clinical Practice	21
12/LO/0119	Parent-child interactions & treatment of anxious adolescents (v1)	22
12/LO/0123	Obeticholic acid in bile acid diarrhoea (v1.0)	22
12/LO/0139	New technologies to nutrition research	28
12/LO/0283	Understanding the effects of BCG on bladder function	27
12/LO/0308	A study to evaluate the effects of Sabarep™ cream (zinc lactate 1% w/w)	23
12/LO/0487	Small-scale pilot study of a psychological skills training manual	26
12/LO/0488	A qualitative study into the care giving experience.	23

#### Unfavourable Opinion

REC Reference	Application Short Title	Number of Days on Clock
11/LO/1073	Sexual Health Outreach Services for Young People in West Kent	28
11/LO/1291	Workplace Fun and Team Resilience and its Correlates	22
12/LO/0116	Single Administration of KBSA301 in Patients with Severe Pneumonia.	28

#### 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
---------------	-------------------------	-------------------------

<b>Invalid Application</b>		
----------------------------	--	--

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

<b>No Opinion Pending Consultation with Referee</b>		
---	--	--

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

<b>Not Requiring Review by NHS REC</b>		
--	--	--

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

**Table 7: Items exceeding timelines:**

<b>Full applications for ethical review over 60 day timeline</b>			
<b>REC Reference</b>	<b>Application Short Title</b>	<b>Number of Days on Clock</b>	
11/LO/0624	Post traumatic amnesia following traumatic brain injury	72	
11/LO/0625	Does Forgiveness Influence Trajectories of PTSD During Treatment?v1	74	
11/LO/1663	A new approach to luteal phase support in IVF	69	

  

<b>Proportionate review applications for ethical review over 14 days timeline</b>		
<b>REC Reference</b>	<b>Application Short Title</b>	<b>Number of Days on Clock</b>

  

<b>SSAs (non Phase 1) over 25 days timeline</b>		
<b>REC Reference</b>	<b>Application Short Title</b>	<b>Number of Days on Clock</b>
11/LO/1107	MK-4618 in Patients with Overactive Bladder	27
11/LO/2074	PD study comparing Fluticasone dose/response through FENO inhibition	47
11/LO/2075	PD study comparing Salmeterol dose/response through bronchodilation	47

  

<b>SSAs (Phase 1) over 14 days timeline</b>		
<b>REC Reference</b>	<b>Application Short Title</b>	<b>Number of Days on Clock</b>
11/LO/0774	Comparing tablets & injections of Keppra in Japanese volunteers; ver 1	19
11/LO/1568	Side effects, blood levels & effects of TAK-385	17
11/LO/1787	Effects, side effects & blood levels of hyoscine & physostigmine; v1	20

  

<b>Substantial Amendments over 35 day timeline</b>			
<b>Amendment Reference</b>	<b>Application Short Title</b>	<b>Amendment Title</b>	<b>Number of Days on Clock</b>
11/LO/1261/AM02	INOVATYON SECOND LINE CHEMOTHERAPY OVARIAN CANCER	Temporary Halt, V 1 1 December 2011	42
10/H0717/14/AM10	Prognostic Evaluation of Diagnostic IGRA Consortium - UK PREDICT Study	Amendment to patient information sheet	93



11/LO/1855/AM02	11-023 Blood samples for medicines research; version 1	2, 28th February 2012	38
-----------------	--	-----------------------	----

**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
---------------------	-------------------------	-----------------	-------------------------