

National Research Ethics  
Service

  
*Health Research Authority*

**NRES Committee London - Brent**

**Annual Report**

**01 April 2013 – 31 March 2014**

## Part 1 – Committee Membership and Training

<b>Name of REC:</b>	NRES Committee London - Brent
<b>Type of REC:</b>	Recognised Type 1 & Type 1 & Type 3
<b>Type of Flag:</b>	Phase 1, Paediatrics and qualitative research
<b>Chair:</b>	Dr John Keen
<b>Vice-Chair:</b>	Mrs Sunder Chita
<b>Alternate Vice-Chair:</b>	Miss Zainab Yate
<b>REC Manager:</b>	Ms Julie Kidd
<b>PRSC Co-ordinator:</b>	Ms Julie Kidd/Ms Hayley Fraser
<b>REC Assistant:</b>	Ms. Hayley Fraser
<b>Committee Address:</b>	80 London Road Skipton House London SE1 6LH
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### Chair's overview of the past year:

Brent REC enjoyed another successful and stimulating year. The committee is now settled in membership, and continues to provide specialised review in paediatric, qualitative and Phase 1 pharmaceutical research. Members of the committee attended a variety of courses throughout the year and shared their learning with the committee. The committee is delighted that its Vice-Chair has been re-appointed for a further five years.

Dr John W Keen

## 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	
Dr Daniel Bradford	Pharmacologist	Expert	01/07/2013	
Mrs Sunder Chita	Manager	Lay Plus	31/07/2005	
Dr Graham Davison	Pharmaceutical Consultant	Lay	08/06/2010	
Dr Anke Furck	Consultant in Paediatric Intensive Care	Expert	10/05/2013	
Mr Maurice Hoffman	Retired	Lay Plus	23/07/2008	
Dr John Keen	GP	Expert	01/06/2011	
Mrs Alison Lee	Specialist in Special Care Dentistry	Expert	28/11/2011	
Dr Mohd Ezam Mat Ali	Consultant Neonatal Paediatrician	Expert	07/10/2011	01/02/2014
Mr Adeyemi Olagbegi	Clinical Pharmacology Study Data Manager	Lay	18/05/2007	
Miss Vashti Ragoonanan	Specialist Nurse - Haematology	Expert	28/09/2009	30/09/2013
Dr Manish Saxena	Clinical Research Fellow	Expert	30/03/2011	
Dr Zdenek Slavik	Consultant Paediatric Cardiologist/Intensivist	Expert	20/10/2011	
Miss Ourania Xeniou	Senior Clinical Research Associate	Lay	30/06/2008	
Miss Zainab Yate	Bioethics Researcher	Lay	10/06/2008	

### Deputy Members

Name	Occupation	Expert or Lay	Meeting date attended

### Co-opted Members

Name	Occupation	Expert or Lay	Meeting date attended

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

Name	Declaration of Interest	Date
Mr Suresh Akula	None	05/12/2013
Dr Anke Furck	None	24/06/2013
Dr Daniel Bradford	Currently (as of May 2011) working for Astellas as a medical reviewer	11/06/2013
Miss Ourania Xeniou	Employer is EISAI Ltd. Committee has up to date details on this as of 24 June 2013	24/06/2013
Dr Manish Saxena	Member of British Hypertension Society	24/06/2013
Mr Maurice Hoffman	None	24/02/2014
Mr Adeyemi Olagbegi	None	24/06/2013
Dr Graham Davison	Pension paid by Roche.	24/06/2013
Dr Zdenek Slavik	Member of Medical Board, Chain of Hope UK Associate Professor of Paediatrics, Charles University Prague Honorary Senior Lecturer, Imperial College London	29/11/2013
Dr John Keen	Member of NREAP (HRA Advisory Panel)	06/02/2014
Ms Alison Lee	None	28/04/2014
Mrs Sunder Chita	Trustee at Tasha Foundation Health Service Research Manager	27/02/2014
Mr Babak Babakinejad	Senior management associate at Quintiles Drug Research unit at Guys Hosp. Smarties Research consultant at Imperial Consultants Research Associate at imperial College London. Visiting research associate at the Institute of Psychiatry	27/02/2014
Zainab Yate	None	01/02/2015

**Meetings for Full Ethical Review 01 April 2013 - 31 March 2014:**

<b>Month</b>	<b>Date</b>	<b>Number of Members Present at Meeting</b>
April	29/04/2013	11
May	20/05/2013	13
June	24/06/2013	11
July	29/07/2013	9
August	19/08/2013	11
September	30/09/2013	8
October	28/10/2013	9
November	25/11/2013	11
January	27/01/2014	10
February	24/02/2014	11
March	31/03/2014	8

11 full committee meetings were held during the reporting period.

**Proportionate Review Sub Committee Meetings held during 01 April 2013 - 31 March 2014:**

<b>Month</b>	<b>Date</b>	<b>Number of Members Present at Meeting</b>
May	17/05/2013	4
June	17/06/2013	4
September	16/09/2013	3
September	23/09/2013	3
October	14/10/2013	3
October	21/10/2013	3
November	11/11/2013	3
December	13/12/2013	0
January	17/01/2014	3

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

**Attendance of Members: 01 April 2013 – 31 March 2014:**

<b>Name</b>	<b>Number of Meetings Attended</b>
Dr John Keen	11
Dr Manish Saxena	11
Mr Maurice Hoffman	10
Dr Graham Davison	9
Mr Babak Babakinejad	8
Mrs Sunder Chita	8
Dr Zdenek Slavik	8
Miss Ourania Xeniou	8
Mr Adeyemi Olagbegi	7
Mr Suresh Akula	7
Mrs Alison Lee	7
Dr Mohd Ezam Mat Ali	5
Dr Anke Furck	5
Dr Daniel Bradford	3
Miss Vashti Ragoonanan	3
Miss Zainab Yate	2

**Number of inquorate meetings held: None**

**Attendance of Members at proportionate review sub-committee meetings:  
01 April 2013 – 31 March 2014:**

<b>Name</b>	<b>Number of Meetings Attended</b>
Dr John Keen	8
Mrs Sunder Chita	7
Mr Maurice Hoffman	4
Dr Manish Saxena	3
Miss Zainab Yate	3
Mr Suresh Akula	1

**Training 01 April 2013 – 31 March 2014:**

<b>Name of Member</b>	<b>Date</b>	<b>Event(s) attended</b>
Mr Maurice Hoffman	23/07/2013 - 23/07/2013	Summer Collaborative Learning and Delivery Event., NIHR CLAHRC for Northwest London
Dr John Keen	25/04/2013 - 25/04/2013	HRA Interest in Good Research Conduct workshop, Health Research Authority
Dr Graham Davison	01/09/2013 - 01/09/2013	Oxford Diocesan Ethics course
Dr Anke Furck	18/09/2013 - 18/09/2013	Induction, HRA
Dr Anke Furck	24/09/2013 - 24/09/2013	Qualitative methods & statistics workshop, HRA
Dr Zdenek Slavik	02/10/2013 - 02/10/2013	Research Training Day, HRA
Dr Graham Davison	20/11/2013 - 20/11/2013	National Members Training Day, HRA
Dr John Keen	11/12/2013 - 11/12/2013	National Training Day for NRES Committee Chairs, NHS / HRA
Mrs Sunder Chita	23/07/2013 - 23/07/2013	Summer collaborative Learning and Delivery, Local R&D
Dr John Keen	02/09/2013 - 02/09/2013	NREAP, HRA
Dr John Keen	15/01/2014 - 15/01/2014	NREAP Training , HRA
Dr Manish Saxena	19/03/2014 - 19/03/2014	HTA at Hampstead REC Meeting, Hampstead Committee
Dr Manish Saxena	19/12/2013 - 19/12/2013	Equality & Diversity, HRA
Miss Ourania Xeniou	03/12/2013 - 03/12/2013	Equality & Diversity
Mr Suresh Akula	04/03/2014 - 04/03/2014	NIHR CLAHRC , CLAHRC
Dr Daniel Bradford	01/12/2013 - 01/12/2013	Training on patents & work (Astellas), Astellas
Dr Daniel Bradford		Updated training in GCP GMP GLP and GPVP
Mr Adeyemi Olagbegi	10/01/2014 - 10/01/2014	Refresher course for GCP in the NHS
Mr Adeyemi Olagbegi	25/09/2013 - 25/09/2013	Data Protection/How to handle clinical trials, Novartis

**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	12	19.67
Phase 1	14	22.95
Gene Therapy	0	0.00
Research Tissue Bank	0	0.00
Research Database	1	1.64
Others	34	55.74
<b>Total Applications Reviewed</b>	<b>61</b>	<b>100</b>

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

Number of applications made invalid by co-ordinator	3
Number of studies withdrawn prior to the meeting	10
Number of student applications reviewed	10
Number of paediatric applications reviewed	5
Number of device applications reviewed	3
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	12	19.67
Favourable Opinion with Additional Conditions	16	26.23
Unfavourable Opinion	1	1.64
Provisional Opinion	32	52.46
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>61</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	30	49.18
Further Information Favourable Opinion with Additional Conditions	1	1.64
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	12	19.67
Favourable Opinion with Additional Conditions	16	26.23
Unfavourable Opinion	1	1.64
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	1.64
<b>Total</b>	<b>61</b>	<b>100</b>

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

<b>Total Applications Reviewed</b>	<b>14</b>
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**Table 6: Decisions given at proportionate review sub-committee meetings held within the reporting period:**

<b>Decisions taken at proportionate review sub-committee meetings</b>	<b>Number</b>	<b>%</b>
Favourable Opinion with Standard Conditions	5	35.71
Favourable Opinion with Additional Conditions	4	28.57
No Opinion transfer to full committee for review	0	0.00
Provisional Opinion	5	35.71
Unfavourable Opinion	0	0.00
<b>Total</b>	<b>14</b>	<b>100</b>

**Table 7: Other Management Information for the reporting period:**

<b>Average number of applications reviewed per full meeting</b>	5.55
<b>Number of applications for full ethical review over 60 days</b>	0
<b>Number of applications over 60 days as a % of total</b>	0.00%
<b>Number of days taken to final decision - average</b>	31
<b>Number of days taken to final decision - mode</b>	25
<b>Number of SSAs (non-Phase 1) reviewed</b>	11
<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>	18.2%
<b>Number of SSAs (Phase 1) reviewed</b>	5
<b>Number of applications for SSA review over 14 days</b>	1
<b>Number of applications for SSA review over 14 days as % of all Phase 1 (SSAs)</b>	20.0%
<b>Number of substantial amendments reviewed</b>	135
<b>Number of substantial amendments over 35 days</b>	1
<b>Number of substantial amendments over 35 days as a % of total substantial amendments</b>	0.7%
<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>	0
<b>Number of modified amendments over 14 days</b>	0
<b>Number of modified amendments over 14 days as a % of total modified amendments</b>	0%
<b>Number of proportionate review applications for ethical review over 14 days</b>	1
<b>Number of proportionate review applications over 14 days as a % of total</b>	7.1%

**Table 8: 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>
13/LO/0536	Lactate Imaging Version 1	41
13/LO/0538	TREAT Evaluation	49
13/LO/0550	IUI vs IVF for first line treatment of unexplained infertility - A RCT	42
13/LO/0698	Safety, PK and PD of oral BGB324 in healthy male volunteers after SAD	24
13/LO/0729	Size of the HIV-1 reservoir and ongoing replication in defined cohorts	40
13/LO/0739	Bladder Cancer Biomarkers	45
13/LO/0766	Phase 4 Study of Bone Mineral Density in HIV-1 Infected Subjects	44
13/LO/0787	Burns Wound Dressing Volatile Compounds- Pilot Study (DRESSVOCS)	14
13/LO/0855	Idelalisib in Combination with Rituximab for Previously Treated iNHL	32
13/LO/1006	Effect of GnRH analogues on BMI in children with precocious puberty	7
13/LO/1022	308: Phase 3 study of XL184 vs Everolimus in subjects with RCC	32
13/LO/1038	Understanding the impact of DBT on adults with a learning disability	52
13/LO/1071	DS-1093a – first doses in humans; version 1	33
13/LO/1084	Phenotype/genotype correlation of inherited corneal dystrophies v1	28
13/LO/1187	Attention and Interpretation biases in Paranoid Psychosis	34
13/LO/1378	Dose-escalation Trial to assess selumetinib Safety, Tolerability & PK	21
13/LO/1392	Narcolepsy EEG-fMRI Version 2.0	35
13/LO/1483	Young People Living with Liver Disease	11
13/LO/1503	Transcranial Doppler Ultrasound in Children with Sickle Cell Disease	25
13/LO/1575	Study of safety and effects of HTL0009936 in healthy subjects	47
13/LO/1580	FiH, single-rising dose study with ASP7962, incl. food-effect in HVs.	25
13/LO/1618	TELEPATH (Expanded Treatment for Carcinoid Syndrome Symptoms)	28
13/LO/1638	Processes which lead to apathetic behaviour in Huntington's disease	17
13/LO/1682	Study of Maintenance Rucaparib in Relapsed High-grade Ovarian Cancer	39
13/LO/1792	A PET scan study of [18F]-FBA-A20FMDV2; ver 1	19
13/LO/1898	Achilles Registry; Version B	24
14/LO/0088	Onapristone prostate phase 1-2	27
14/LO/0105	A Process Evaluation of ICU Telemedicine	44
14/LO/0117	Ablation Versus Anti-arrhythmic Therapy in reducing hospital episodes	43
14/LO/0274	SARAH pilot study	29

14/LO/0476	Transcoronary Myocardial Cooling	35
14/LO/0488	Anal screening in the UK	35
14/LO/0490	EROV-108-COMP	37
14/LO/0504	Arterial Resection for Locally Advanced Pancreatic Cancer	34

#### Further Information Favourable Opinion with Additional Conditions

REC Reference	Application Short Title	Number of Days on Clock
13/LO/1390	Cerebrovascular endpoints with cholesterol lowering	59
13/LO/1637	Monaural hearing aid fitting and neuroplasticity	10

#### 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
13/LO/0551	PEPtalk 2	29
13/LO/0670	Pilot study of cotinine levels in foot and ankle surgical patients	26
13/LO/1046	Hospital resource use & patient quality of life for C.Diff infection	51
13/LO/1078	Developing depression screening for South Asian ESRD patients	43
13/LO/1133	Safety, PK and PD of multiple oral BGB324 in healthy male volunteers	15
13/LO/1491	Volatile Organic Compounds as Biomarkers of Malignant Melanoma	14
13/LO/1666	The HALT-LTBI Study	18
13/LO/1722	Sleep and VicksRub	24
13/LO/1800	Tachycardia electrograms for testing S-ICD discrimination algorithm	4
13/LO/1802	Will online videos providing allergy information be accessed?	13
13/LO/1804	A new method of measuring tissue perfusion and oxygenation in the foot	12
13/LO/1963	A two-way cross-over study to compare the PK of LUC-06 and Carbaglu®.	25
14/LO/0167	Recognition Perimetry Using High Pass Filtered Letter Targets	13
14/LO/0205	First study of DS-1971a in humans; version 1	11
14/LO/0276	RCT Induced Sputum Sample Processing Methodology Study	24
14/LO/0326	Extra Lung	17
14/LO/0466	Blood levels of vedolizumab in Japanese & non-Japanese volunteers; v1	15

#### Favourable Opinion with Additional Conditions

REC Reference	Application Short Title	Number of Days on Clock
13/LO/0681	Multiboost - MCC plus pertussis booster in adolescents	24
13/LO/0778	Training study to characterize biomic profiles of Fendrix/Energix B.	25
13/LO/0786	Measurement of Stress Responses to the NLS Airway Test	10
13/LO/0882	SWS And daytime Functioning in chronic Fatigue syndrome (SAFFE)	25
13/LO/0916	fMRI study to investigate the effects of Breathe Right Nasal Strips v1	35
13/LO/0917	Profile of UK patients prescribed Dymista® for Allergic Rhinitis	28
13/LO/0918	A PET study to assess brain uptake of RO5545965, version 1	25
13/LO/1003	VOICE: Views of Individuals Concerning Research	8
13/LO/1008	NHS Psoriasis Management with single and multiple biologic therapies	8
13/LO/1183	A study of risperidone, olanzapine and haloperidol using fMRI; ver 1	37
13/LO/1206	Low Intensity GAD Intervention: A Feasibility and Acceptability Study	28
13/LO/1389	LCM Oral and IV safety, tolerability and PK in Japanese participants.	41
13/LO/1409	Acupuncture in the treatment of Phantom Limb Syndrome. Version: 01	49
13/LO/1498	Developing a smartphone App for HIV care	10
13/LO/1536	Exenatide-PD	23
13/LO/1675	An imaging study of the effect of creatine on muscle & brain;v1	18
13/LO/1690	GSK2793660 - first doses in humans; version 1	18
14/LO/0102	SNF472 SAD & MAD in healthies, SAD in haemodialysis patients	22
14/LO/0111	Cognitive dysfunction and emotion processing in bipolar disorder	39
14/LO/0330	Imagery rescripting with people with psychosis and social anxiety	19

#### Unfavourable Opinion

REC Reference	Application Short Title	Number of Days on Clock
13/LO/1603	Achilles Registry study; Version A	33

#### 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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<b>Withdrawn after the meeting</b>		
<b>REC Reference</b>	<b>Application Short Title</b>	<b>Number of Days on Clock</b>
13/LO/1393	Stability and utility of HGF.	32

<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 9: 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>	
<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>	
13/LO/1638	Processes which lead to apathetic behaviour in Huntington's disease	17	
<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>	
13/LO/1217	Phase I study to evaluate Laninamivir Octanoate	30	
13/LO/1458	fMRI scan study to find out how nalmefene works (ver 1)	27	
<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>	
13/LO/0590	Safety, blood levels and effects of AUT00063: first doses in humans;v1	18	
<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/1523/AM02	A Ketogenic Diet in Sickle Cell Disease	(Our Ref Amd 02) Version 4 - 13th March 2013	36
<b>Modified Amendments over 14 day timeline</b>			
<b>Amendment Reference</b>	<b>Application Short Title</b>	<b>Amendment Title</b>	<b>Number of Days on Clock</b>
<b>Section 30 application over 60 day timeline</b>			
<b>Amendment Reference</b>	<b>Application Short Title</b>	<b>Amendment Title</b>	<b>Number of Days on Clock</b>