National Research Ethics Service

Health Research Authority

NRES Committee London - Brent

Annual Report

01 April 2012 – 31 March 2013

Part 1 – Committee Membership and Training

Name of REC:	NRES Committee London - Brent
Type of REC:	Type I and III
Type of Flag:	Research involving children Qualitative research
Chair:	Dr John Keen
Vice-Chair:	Mrs Sunder Chita
Alternate Vice-Char:	Miss Zainab Yate
Co-ordinator:	Mr Danyal Enver
PRSC Co-ordinator:	Mr Danyal Enver
Assistant Co-ordinator:	Ms Amy Spruce
Committee Address:	80 London Road Skipton House London SE1 6LH
Telephone:	0207 972 2536
Fax:	0207 972 2592
Email:	nrescommittee.london-brent@nhs.net

Chair's overview of the past year:

NRES Committee London: Brent experienced a buoyant year in 2012-13, with new members bringing additional expertise and experience, full agendas and lively ethical discussion and debate. Brent REC continues as a committee flagged for CTIMP studies including Phase 1 First-in-Man; the committee was also awarded flagging for Paediatric and Qualitative research, to reflect the committee's particular expertise in these areas.

The committee continued to adopt a facilitative approach to ethical review, by working with researchers where possible to find solutions to ethical barriers that arose as part of their applications.

Towards the end of the year, the committee decided to move its base to provide an easier and more accessible experience for researchers and members at Northwick Park Hospital

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	
Mrs Sunder Chita	Manager	Lay Plus	31/07/2005	
Dr Graham Davison	Pharmaceutical Consultant	Expert	08/06/2010	
Professor Nadey Hakim	Professor Transplantation Surgery	Expert	20/10/2011	30/06/2012
Mr Maurice Hoffman	Work Placement Advisor	Lay Plus	23/07/2008	
Dr John Keen	GP	Expert	01/06/2011	
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	01/04/2013	
Miss Ourania Xeniou	Senior Clinical Research Associate	Lay	30/06/2008	
Miss Zainab Yate	Bioethics Researcher	Lay	21/08/2009	

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
Dr Ina Lisa Lauinger	Any other activities or interests likely or possibly likely to be related to the conduct of research - 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 recieve.	28/05/2012
Professor Nadey Hakim	None	18/10/2012
Mr Alan Smith	None	31/12/2012
Dr Daniel Bradford	Director of his own company (Yoshi Poshi Sushi LTD. which employs him and takes contracts from Pharamaceutical Compnaies or C.R.O.S Currently (as of May 2011) working for Astellas as a medical reviewer Shares owned in Medivation Inc.	31/03/2013
Miss Ourania Xeniou	Employer is EISAI ltd. Committee has up to date details on this as of 24 June 2013	31/03/2013
Dr Manish Saxena	Member of British Hypertension Society. Works as an investigator with different sponsors.	31/03/2013
Mr Adeyemi Olagbegi	None	31/03/2013
Mrs Alison Lee	None	31/03/2013
Dr Graham Davison	Pension paid by Roche.	31/03/2013
Mr Suresh Akula	None	31/03/2013
Dr John Keen	None	31/03/2013
Miss Vashti Ragoonanan	None	31/03/2013
Dr Anke Furck	None	31/03/2013

Meetings for Full Ethical Review 01 April 2012 - 31 March 2013:

Month	Date	Number of Members Present at Meeting
April	30/04/2012	14
May	28/05/2012	14
June	25/06/2012	14
August	20/08/2012	10
September	24/09/2012	12
October	22/10/2012	9
November	26/11/2012	11
December	17/12/2012	7
January	28/01/2013	12
February	25/02/2013	8
March	25/03/2013	10

11 full committee meetings were held during the reporting period.

Proportionate Review Sub Committee Meetings held during 01 April 2012 - 31 March 2013:

Month	Date	Number of Members Present at Meeting
May	24/05/2012	3
July	10/07/2012	3
August	29/08/2012	4
February	15/02/2013	3
February	18/02/2013	3

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

Attendance of Members: 01 April 2012 – 31 March 2013:

Name	Number of Meetings Attended
Dr John Keen	11
Dr Manish Saxena	10
Mrs Alison Lee	10
Mrs Sunder Chita	10
Miss Zainab Yate	9
Mr Maurice Hoffman	9
Dr Graham Davison	9
Miss Ourania Xeniou	8
Mr Suresh Akula	8
Mr Babak Babakinejad	7
Dr Mohd Ezam Mat Ali	7
Dr Zdenek Slavik	6
Mr Adeyemi Olagbegi	6
Dr Ina Lisa Lauinger	5
Miss Vashti Ragoonanan	4
Professor Nadey Hakim	2

Number of inquorate meetings held: 0

Attendance of Members at proportionate review sub-committee meetings: 01 April 2012 – 31 March 2013:

Name	Number of Meetings Attended
Dr John Keen	5
Mrs Sunder Chita	4
Dr Andrew Hilson	2
Dr Graham Davison	1
Andrew Hilson	1
Dr Manish Saxena	1
Miss Zainab Yate	1
Mr Maurice Hoffman	1

Training 01 April 2012 – 31 March 2013:

Name of Member	Date	Event(s) attended
Dr John Keen	13/09/2012 - 13/09/2012	Reviewing Clinical Trials of Investigational Medicinal products, NRES
Dr John Keen	25/04/2012 - 25/04/2012	Statistical Issues and Ethical Debate
Mr Babak Babakinejad	24/10/2012 - 24/10/2012	Committee Members Training Day, NRES
Mr Babak Babakinejad	18/10/2012 - 18/10/2012	Quantitative Research Methods and Statistics for REC's, NRES
Mrs Alison Lee	18/10/2012 - 18/10/2012	Quantitative Research Methods and Statistics
Dr John Keen		Chairs National Training Day V8066, NRES
Mrs Alison Lee	21/11/2012 - 21/11/2012	Adult lacking capacity, NRES
Mr Babak Babakinejad		Medical Devices, NRES
Mrs Sunder Chita	23/11/2012 - 23/11/2012	Annual Excellence Awards, Mrs Sunder Chita
Mr Maurice Hoffman	23/11/2012 - 23/11/2012	R & D Annual Excellence Awards, Mrs Sunder Chita Research & Development
Mr Babak Babakinejad	29/10/2012 - 29/10/2012	Ethics & GCP Forum, Institute of Neurology
Mr Babak Babakinejad	24/10/2012 - 24/10/2012	National Members Training Day, NRES/HRA
Mr Babak Babakinejad	05/11/2012 - 05/11/2012	Medical Devices, Department of Health
Dr Manish Saxena	11/04/2012 - 11/04/2012	ILS Course, Barts Health
Dr Manish Saxena	15/06/2012 – 15/06/2013	Refresher GCP, Barts
Mrs Alison Lee	13/02/2013 - 13/02/2013	Personal Data in Research, 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	19	31.67
Phase 1	7	11.67
Gene Therapy	0	0.00
Research Tissue Bank	0	0.00
Research Database	1	1.67
Others	33	55.00
Total Applications Reviewed	**60**	**100**

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	10
Number of student applications reviewed	14
Number of paediatric applications reviewed	4
Number of device applications reviewed	1
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:

Decisions taken at meetings following review of applications	Number	%
Favourable Opinion with Standard Conditions	15	25.00
Favourable Opinion with Additional Conditions	18	30.00
Unfavourable Opinion	2	3.33
Provisional Opinion	25	41.67
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	**60**	**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	24	40.00
Further Information Favourable Opinion with Additional Conditions	0	0.00
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	15	25.00
Favourable Opinion with Additional Conditions	18	30.00
Unfavourable Opinion	2	3.33
Provisional Opinion	1	1.67
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
Total	**60**	**100**

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

Total Applications Reviewed	**9**

Table 6: Decisions given at proportionate review sub-committee meetings held within the reporting period:

Decisions taken at proportionate review sub-committee meetings	**Number**	**%**
Favourable Opinion with Standard Conditions	1	11.11
Favourable Opinion with Additional Conditions	6	66.67
No Opinion transfer to full committee for review	0	0.00
Provisional Opinion	2	22.22
Unfavourable Opinion	0	0.00
Total	**9**	**100**

Table 7: Other Management Information for the reporting period:

Average number of applications reviewed per full meeting	5.45
Number of applications for full ethical review over 60 days	2
Number of applications over 60 days as a %of total	3.33%
Number of days taken to final decision - average	34
Number of days taken to final decision - mode	22

Number of SSAs (non-Phase 1) reviewed	17
Number of applications for SSA review over 25 days	2
Number of applications for SSA review over 25 days as % of all non-Phase 1 (SSAs)	11.8%

Number of SSAs (Phase 1) reviewed	24
Number of applications for SSA review over 14 days	9
Number of applications for SSA review over 14 days as % of all Phase 1 (SSAs)	37.5%

Number of substantial amendments reviewed	116
Number of substantial amendments over 35 days	8
Number of substantial amendments over 35 days as a % of total substantial amendments	6.9%

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	0
Number of modified amendments over 14 days	0
Number of modified amendments over 14 days as a %of total modified amendments	0%

Number of proportionate review applications for ethical review over 14 days	4
Number of proportionate review applications over 14 days as a %of total	44.4%

Table 8: 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**
12/LO/0585	Comparing peretinoin in Japanese & Caucasian volunteers; ver 1	33
12/LO/0631	Effects of blood transfusion on serum markers and tumour MRI	46
12/LO/0663	Safety and Efficacy Study of Boceprevir/PegI/Ribavirin -Short Duration	50
12/LO/0781	SIGNIFY Version 1.6	35
12/LO/0981	The phenomenology of intrusive thoughts in the postnatal period	66
12/LO/1286	A COMPARISON BETWEEN TWO BUPRENORPHINE TABLETS AND THE EFFECT OF FOOD	29
12/LO/1291	Detecting Retinal Changes in ARSACS & Other Ataxias Using OCT	40
12/LO/1337	How do women make the decision to seek help for AMI? Final version_1.0	45
12/LO/1360	Qualitative study of dietary decision making in families	53
12/LO/1434	RENEW study	43
12/LO/1499	Delivering Tobramycin using the TobrAir device (QBR112053)	41
12/LO/1647	Minocycline Microspheres for Peri-Implantitis	19
12/LO/1661	Evaluation of the effects of treatment on cancer tissue V1.1	41
12/LO/1862	Feasibility study of Cognitive Behaviour Therapy in secure services	30
12/LO/1876	GO28141 PhIII Vemurafenib Vs Vemurafenib + GDC-0973 in Melanoma	46
12/LO/1879	(duplicate) (duplicate) Prediction of Preterm Birth in Symptomatic Wom	50
12/LO/1950	C25003 Ph3 A+AVD vs ABVD Frontline in Patients with Hodgkin Lymphoma	58
12/LO/1984	Inpatient stay improvement study (ISIS)	39
12/LO/1998	Mind-body interaction in patients with mood disorder	44
13/LO/0077	The HALT Hepatitis Study	58
13/LO/0078	Metabolomics for monitoring dietary exposure	63
13/LO/0088	Daytime Impact Sleep Study - DAISS	44
13/LO/0124	Internet Use in Pregnancy - Version 1	55
13/LO/0206	Daclatasvir/pegIFN Lambda/RBV or Telaprevir/pegIFN Alfa/RBV in HCV G1b	36
13/LO/0215	Screening for Viral Hepatitis in Migrants in East London V2	46
13/LO/0385	GABA and Glutamate in ADHD - A [1H]MRS Study	52

Further Information Favourable Opinion with Additional Conditions		
REC Reference	**Application Short Title**	**Number of Days on Clock**

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/0782	Is the mobilisation of patients on inotropes and vasopressors safe? v1	34
12/LO/0985	Prolonged Release Fampridine Effect on Walking Ability, Balance in MS	16
12/LO/0996	Cervico-vaginal immune responses to 3 deltoid or thigh IM TicoVac	16
12/LO/1203	Physical activity levels and lithotripsy for urinary tract stones	8
12/LO/1265	A study of blood levels & side effects of avibactam and aztreonam; v1	27
12/LO/1267	Safety and blood levels of RV568; version1	27
12/LO/1490	Safety & Efficacy of 2 Alternative Forms of Oral Buprenorphine (v10)	25
12/LO/1616	Safety and toleration of OZ439 OD administered for 3 days	13
12/LO/1618	Safety, PK and PD of lomitapide in Japanese and Caucasasians	20
12/LO/1625	London Sendai pre-study	22
12/LO/1654	CTC characterization in neuroendocrine and gastrointestinal tumours v1	22
12/LO/1657	The Medicines Advice Service Evaluation	22
12/LO/1875	Assessing booster responses to routine immunisation in infants	23
12/LO/1885	Unexplained Physical Symptoms in Primary Care	23
13/LO/0199	UK Ileal pouch registry	20
13/LO/0391	CFTR in PCD v1	28

Favourable Opinion with Additional Conditions		
REC Reference	**Application Short Title**	**Number of Days on Clock**
12/LO/0628	Effect of reducing FODMAP intake on functional symptoms in IBD.	32
12/LO/0639	A-PREDICT	22

12/LO/0752	Comparing different treatment schedules of ceftaroline; version 1	22
12/LO/0772	Feasibility of Neopterin as a diagnostic marker for IBS. Version no:3	23
12/LO/0841	Investigate antipruritic effects of SB-705498	23
12/LO/0901	Development of a Statistical Model of Dental Root Geometry	14
12/LO/0906	Prognostic Indicators of Response to US guided Steroid Injection	11
12/LO/1193	Biological and Functional Characterisation of Bone Marrow Diseases	14
12/LO/1273	Sequencing Based Analysis of SLE	31
12/LO/1342	SAD and MAD safety assessment of Rec 27/1819 in healthy volunteers.	26
12/LO/1357	The pathophysiology of electromechanical dysfunction in the heart, v1	29
12/LO/1460	Clinician Fatigue in Catheter Ablation Procedures V 1.0	48
12/LO/1472	EBGen	33
12/LO/1820	Safety, blood levels and effects of GSK2269557 in smokers (v1)	22
12/LO/1966	TELESTAR (Telotristat Etiprate for SSA Refractory Carcinoid Syndrome)	32
13/LO/0071	ETPOS European Transfusion Practice and Outcome Survey: Version 1	50
13/LO/0081	Benefits Research	50
13/LO/0207	Echocardiography in Kids Intensive Care Decision Support - ECHOKIDS	46
13/LO/0240	Child Talk - What Works (Phase 2)	14
13/LO/0241	Experiences of Chronic Lung Disease	24
13/LO/0354	Macrophage plasticity in COPD	28
13/LO/0380	RV1729 - first doses in humans; ver 1	28
13/LO/0386	Nilotinib treatment-free remission study in CML patients-ENESTFreedom	24
13/LO/0436	Families reporting safety concerns in a children's hospital	56

Unfavourable Opinion		
REC Reference	**Application Short Title**	**Number of Days on Clock**
12/LO/0851	Minocycline Microspheres for Peri-Implantitis	18
12/LO/1239	Minocycline Microspheres for Peri-Implantitis	28

Provisional Opinion		
REC Reference	**Application Short Title**	**Number of Days on Clock**
12/LO/0632	Ex-vivo cultivated limbal epithelial cell transplantation	N/A

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

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 9: Items exceeding timelines:

Full applications for ethical review over 60 day timeline		
REC Reference	**Application Short Title**	**Number of Days on Clock**
12/LO/0981	The phenomenology of intrusive thoughts in the postnatal period	66
13/LO/0078	Metabolomics for monitoring dietary exposure	63

Proportionate review applications for ethical review over 14 days timeline		
REC Reference	**Application Short Title**	**Number of Days on Clock**
12/LO/1337	How do women make the decision to seek help for AMI? Final version_1.0	45
12/LO/1357	The pathophysiology of electromechanical dysfunction in the heart, v1	29
12/LO/1360	Qualitative study of dietary decision making in families	53
13/LO/0241	Experiences of Chronic Lung Disease	24

SSAs (non Phase 1) over 25 days timeline		
REC Reference	**Application Short Title**	**Number of Days on Clock**
12/LO/0619	MR1704 – first doses in humans; version 2	26
12/LO/1485	A study to evaluate the use of CHF6001 DPI in adult asthmatics	27

SSAs (Phase 1) over 14 days timeline		
REC Reference	**Application Short Title**	**Number of Days on Clock**
12/LO/1388	Single Ascending Doses of ALN-TTR02 in Healthy Volunteers	25
12/LO/1999	Lu AF35953 - first doses in humans, ver 1	34
12/LO/1996	Study to Investigate a New Drug in Healthy Subjects (SAD,FE,MAD,DDI)	15
13/LO/0138	FKB327 – first doses in humans & comparison with Humira	19
13/LO/0139	Blood levels and effects of SAR236553 given by injection, v1	23
13/LO/0290	Study to Investigate a New Drug in Healthy Subjects (SAD,MAD)	28

13/LO/0289	Study to Investigate a New Drug in Healthy Subjects (SAD,MAD)	27
13/LO/0251	ALN-TTRSC-001 SAD/MAD	25
13/LO/0437	PK study of Esketamine nasal spray in Healthy Japanese subjects	24

Substantial Amendments over 35 day timeline			
Amendment Reference	**Application Short Title**	**Amendment Title**	**Number of Days on Clock**
11/LO/1503/AM08	ARD12042- SAR302503 in patients with PV or ET	SAR302503 - Urgent Safety Measure dated 2 February	88
10/H0717/61/AM14	Novartis Vaccine N. menigitidis Carriage Trial	Reminder Text message regarding prior MenC Vaccina	159
11/LO/1503/AM09	ARD12042- SAR302503 in patients with PV or ET	Urgent Safety Information - Dose Escalation - 16/0	112
11/H0717/1/AM01	MEG changes in tinnitus	1, 03/08/2012	81
11/LO/1090/AM03	MAXIM	Substantial Amendment 3.0 Protocol version 6.0 15.	85
10/H0717/68/AM15	V212 in Recipients of Autologous Hematopoietic Cell Transplants (001)	SA17 V212-001-03 dated 26 Sept 2012	36
11/LO/1503/AM13	ARD12042- SAR302503 in patients with PV or ET	Protocol Amendment 4: version 1	38
11/LO/2025/AM02	The Impact of Omalizumab Treatment in UK Clinical Practice	Amendment 2 28 11 12	53

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**