

**NRES Committee London - City Road
& Hampstead**

Annual Report

01 April 2013 – 31 March 2014

Part 1 – Committee Membership and Training

Name of REC:	NRES Committee London - City Road & Hampstead
Type of REC:	Authorised REC
Type of Flag:	Establishing Research Tissue Banks
Chair:	Dr David Slovick
Vice-Chair:	Mr Hari Jayaram
Alternate Vice-Chair:	Mr David Burbidge
REC Manager:	Miss Tina Cavaliere
PRSC Co-ordinator:	Miss Tina Cavaliere
Assistant Co-ordinator:	Miss Maeve Groot Bluemink
Committee Address:	Bristol Research Ethics Committee Centre Level 3, Block B Whitefriars Lewins Mead Bristol BS1 2NT
Telephone:	0117 342 1385
Fax:	0117 342 0445
Email:	nrescommittee.london-cityroadandhampstead@nhs.net

Chair's overview of the past year:

I would like to thank all the committee members who give of their time, experience and expertise freely and enthusiastically. Their commitment is to be commended. The full time officers that support the members do so with professional and dedicated zeal and I hope the researchers find that we are approachable, helpful and supportive of the studies. Research is very important in the field of Clinical Knowledge and the most important people involved are the participants that take part. We as a Committee are dedicated to protecting and safeguarding their interests and seek a just and equitable system of fairness to prevail. Thank you to all who make the City Road and Hampstead Research Ethics Committee work well and may it continue to serve the best standards of research expected by its excellent record.

David Burbidge on behalf of the Chair.

NRES Committee London - City Road & Hampstead Membership:

Name	Occupation	Expert or Lay	Dates	
			Appointed	Resigned
Dr Koula Asimakopoulou	Senior Lecturer in Health Psychology	Expert	01/07/2011	
Mr David Burbidge	Retired - Communications/Marketing Development Officer	Lay Plus	01/03/2013	
Mrs Ros Goldfarb	Retired Immigration Judge	Lay Plus	01/08/2009	
Mr Robert Goldstein	Economist	Lay Plus	13/03/2007	14/08/2013
Miss Hattie Ismail	In-house CRA (Clinical Research Associate)	Lay	01/04/2013	
Mr Hari Jayaram	Academic Clinical Lecturer in Ophthalmology	Expert	01/07/2007	
Professor Diana Kornbrot	Professor of Mathematical Psychology	Expert	30/09/2008	
Ms. Sanaz Mehdipour	Senior Dealer Treasury Specialist	Lay Plus	01/12/2011	0/04/2014
Mr Israel Nartey	Associate Specialist/Lead Clinician - Ophthalmology	Expert	01/07/2011	
Dr Seetal Patel	Anaesthetic Registrar	Expert	01/03/2014	
Ms Mary Ryan	Personnel Manager	Expert	19/12/2003	19/12/2013
Dr David Slovick	Consultant Physician	Expert	21/03/2007	
Mr Thomas Weijburg	Lead Complementary Therapist	Lay	04/07/2013	

Co-opted Members

Name	Occupation	Expert or Lay	Meeting date attended
Ms Stephanie Ellis	Former Civil Servant	Lay Plus	08/01/2014, 09/04/2014
Dr Alan Ruben	GP	Expert	09/10/2013, 11/12/2013, 08/01/2014, 12/03/2014
Mrs Sally Gordon-Boyd	Medical Ethicist	Lay Plus	08/05/2014
Ms Fanny Mitchell	Retired	Lay Plus	11/12/2013
Dr Margaret Jones	General Practitioner	Expert	11/12/2013
Professor Liz Meerabeau	University Professor	Expert	09/04/2014, 14/05/2014

NRES Committee London - City Road & Hampstead: Members' Declarations of Interest:

Name	Declaration of Interest	Date
Professor Diana Kornbrot	None	10/05/2013
Dr Koula Asimakopoulou	None	14/05/2013
Mr David Burbidge	None	19/09/2013
Mrs Ros Goldfarb	None	01/10/2013
Miss Hattie Ismail	Works for Novartis	01/10/2013
Mr Thomas Weijburg	St Joseph's Hospice which may host or conduct health and social research locally or in partnership organisations.	01/10/2013
Mr David Burbidge	Member of North East & Central London Local Education Board. Member of Health Education England, Patient's Advisory Committee.	17/01/2014
Professor Diana Kornbrot	None	20/01/2014
Mr Hari Jayaram	None	22/01/2014
Dr David Slovick	Director and shareholder of Nightingale Pharma Ltd	05/02/2014
Dr Seetal Patel	None	08/07/2014

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

Month	Date	Number of Members Present at Meeting
April	10/04/2013	8
May	08/05/2013	8
June	12/06/2013	9
July	10/07/2013	7
August	14/08/2013	9
October	09/10/2013	8
December	11/12/2013	9
January	08/01/2014	8
March	12/03/2014	9

10 full committee meetings were held during the reporting period.

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

Month	Date	Number of Members Present at Meeting
April	10/04/2013	3
May	08/05/2013	3
June	12/06/2013	3
December	11/12/2013	3
February	12/02/2014	3
March	12/03/2014	3

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

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

Name	Number of Meetings Attended
Dr David Slovic	9
Professor Diana Kornbrot	9
Miss Hattie Ismail	8
Mr David Burbidge	8
Mr Hari Jayaram	7
Mr Robert Goldstein	5
Mrs Ros Goldfarb	5
Dr Koula Asimakopoulou	4
Mr Thomas Weijburg	3
Ms. Sanaz Mehdipour	3
Ms Mary Ryan	2
Dr Seetal Patel	1
Mr Israel Narthey	1

Number of inquorate meetings held: 0

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

Name	Number of Meetings Attended
Dr David Slovic	5
Dr Koula Asimakopoulou	2
Mr David Burbidge	2
Professor Diana Kornbrot	2
Mr Hari Jayaram	1
Mr Israel Narthey	1
Mr Thomas Weijburg	1
Mrs Ros Goldfarb	1
Ms Mary Ryan	1
Ms. Sanaz Mehdipour	1

Training 01 April 2013 – 31 March 2014:

Name of Member	Date	Event(s) attended
Mr Robert Goldstein	02/05/2013 - 02/05/2013	Ethical Issues of Research Involving Children, NRES
Miss Hattie Ismail	04/07/2013 - 04/07/2013	Induction, HRA Training
Mr Hari Jayaram	27/05/2013 - 27/05/2013	Equality & Diversity, NRES
Mr David Burbidge	08/08/2013 - 08/08/2013	Equality & Diversity, NRES
Mr David Burbidge	20/11/2013 - 20/11/2013	National Members Training Day, NRES
Dr Koula Asimakopoulou	04/10/2013 - 04/10/2013	Equality & Diversity, HRA online course
Mr Israel Nartey	08/07/2013 - 08/07/2013	Qualitative Research and Ethical Review, HRA
Miss Hattie Ismail	16/01/2014 - 16/01/2014	Equality & Diversity, HRA Training
Mr Thomas Weijburg	02/02/2014 - 02/02/2014	Equality & Diversity, HRA
Dr David Slovick	13/11/2013 - 13/11/2013	REC Training Day, Children's research, Personal Data in Research
Mr Hari Jayaram	13/11/2013 - 13/11/2013	REC Training Day, Children's research, Personal Data in Research
Dr Koula Asimakopoulou	13/11/2013 - 13/11/2013	REC Training Day, Children's research, Personal Data in Research
Professor Diana Kornbrot	13/11/2013 - 13/11/2013	REC Training Day, Children's research, Personal Data in Research
Miss Hattie Ismail	13/11/2013 - 13/11/2013	REC Training Day, Children's research, Personal Data in Research
Mr David Burbidge	13/11/2013 - 13/11/2013	REC Training Day, Children's research, Personal Data in Research

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	0	0.00
Phase 1	0	0.00
Gene Therapy	0	0.00
Research Tissue Bank	0	0.00
Research Database	0	0.00
Others	51	100.00
Total Applications Reviewed	51	100

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	13
Number of student applications reviewed	17
Number of paediatric applications reviewed	7
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:

Decisions taken at meetings following review of applications	Number	%
Favourable Opinion with Standard Conditions	1	1.96
Favourable Opinion with Additional Conditions	11	21.57
Unfavourable Opinion	3	5.88
Provisional Opinion	36	70.59
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	51	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	32	62.75
Further Information Favourable Opinion with Additional Conditions	1	1.96
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	1	1.96
Favourable Opinion with Additional Conditions	11	21.57
Unfavourable Opinion	3	5.88
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	2	3.92
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	1.96
Total	51	100

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

Total Applications Reviewed	10
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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	2	20.00
Favourable Opinion with Additional Conditions	2	20.00
No Opinion transfer to full committee for review	0	0.00
Provisional Opinion	6	60.00
Unfavourable Opinion	0	0.00
Total	10	100

Table 7: Other Management Information for the reporting period:

Average number of applications reviewed per full meeting	5.6
Number of applications for full ethical review over 60 days	2
Number of applications over 60 days as a % of total	3.92%
Number of days taken to final decision - average	40
Number of days taken to final decision - mode	30
Number of SSAs (non-Phase 1) reviewed	1
Number of applications for SSA review over 25 days	1
Number of applications for SSA review over 25 days as % of all non-Phase 1 (SSAs)	100.0%
Number of SSAs (Phase 1) reviewed	0
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%
Number of substantial amendments reviewed	29
Number of substantial amendments over 35 days	1
Number of substantial amendments over 35 days as a % of total substantial amendments	3.4%
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	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	6
Number of proportionate review applications over 14 days as a % of total	60.0%

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
13/LO/0476	Child and adolescent AN : cardio-metabolic risk a pilot study	40
13/LO/0477	Investigation of molecular mechanisms in obesity and weight loss.	53
13/LO/0598	Exercise physiology in Cardiovascular Disease	46
13/LO/0600	Attitudes of haemophilia carriers towards prenatal diagnosis	42
13/LO/0624	Ototoxicity monitoring in aminoglycoside/cisplatin exposed patients-v1	48
13/LO/0636	Magnetic Sentinel Node and Occult Lesion Localisation (MagSNOLL)	51
13/LO/0732	Audio-recordings effect on post prostatectomy regret	37
13/LO/0734	Outcomes of a Community Pain Service: A Mixed Method Analysis	32
13/LO/0819	Prospective memory and cognitive bias in alcohol dependence	43
13/LO/0832	FES Cycling in SCI	42
13/LO/0836	Evaluating an intraoperative Toric intraocular lens alignment system	30
13/LO/0837	Young Peoples Personal Experiences of Lung Transplantation	47
13/LO/0981	The SCIN (Skin Care intervention in Nurses) Trial	50
13/LO/0999	Regulating inflammation in autoimmune rheumatic disease	55
13/LO/1012	Barts Study on Oral Tests for Use, Collection of HPV and Evaluation	34
13/LO/1023	Development of a QoL assessment for patients undergoing TAVI	56
13/LO/1132	Phenotype and function of IgE+ B cells in human bone marrow	44
13/LO/1144	Bioavailability of functional food ingredients in food matrices	59
13/LO/1164	The scenes and spaces of hospital life	67
13/LO/1166	Cost & benefits of introducing a point-of-care chlamydia test (V.1)	38
13/LO/1204	Resilience and recovery in young people	36
13/LO/1413	Clinically isolated syndrome 14 yr follow up study	39
13/LO/1434	Hyperthermia for Intermediate risk bladder cancer(HIVEC-II)	30
13/LO/1442	Morbidity after paediatric cardiac surgery	24
13/LO/1472	Thrombosis and its Resolution: Mechanisms and Imaging	42
13/LO/1794	Pilot study to assess the effects of exercise during dialysis	43
13/LO/1853	Pilot study of the eye colour & serum bilirubin level in newborns (v1)	66
13/LO/1895	Randomized bilateral study of trans-epithelial corneal cross-linking	57
13/LO/1923	Non-contact screening methods for the detection of narrow AC angles	20
13/LO/1925	Perceval S real life registry	17

13/LO/1962	Dabrafenib Metastatic Melanoma Chart Review (DESCRIBE)	50
14/LO/0025	tDCS in anorexia nervosa and bulimia nervosa	40
14/LO/0026	The long-term safety and effect of renal denervation	33
14/LO/0360	Multi-Lead surface ECG Analysis of Inherited Cardiac Disease	38
14/LO/0388	B Lymphocyte Subset Analysis in Patients with Chronic Fatigue Syndrome	55
14/LO/0400	LV Endocardial Cardiac Resynchronisation Therapy	30
14/LO/0491	UKOSS: Pregnancy in women with gastric bypass	14

Further Information Favourable Opinion with Additional Conditions

REC Reference	Application Short Title	Number of Days on Clock
13/LO/0974	Changes in Gastrointestinal Homeostasis in Critically Ill Children	16
13/LO/1882	Borderline personality disorder: experiences of diagnosis - version 1.0	35

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/0597	Survey of patients with Inflammatory Bowel Disease views of nutrition	14
13/LO/0735	Focus groups with 'hear and treat' ambulance service users	25
13/LO/0960	Electronic alerting tool to help prevent Acute kidney injury	49

Favourable Opinion with Additional Conditions

REC Reference	Application Short Title	Number of Days on Clock
13/LO/0462	Finding the hip joint centre using functional methods	28
13/LO/0475	Qualitative research to test feasibility of behavioural surveillance	44
13/LO/0635	Impact of calcium channel blockers on cognitive function	33
13/LO/0639	Accuracy and diagnostic impact of radiographer chest x-ray reporting	33
13/LO/0803	FICE-DC (VERSION 5)	21
13/LO/0824	The Benefits of Extended Screening Testing for congenital CMV - BEST 2	28
13/LO/0936	Spain-UK-Czech E-cigarette Study (SUKCES)	40
13/LO/1142	VEWS index relationship to ischaemic ulcer outcome. V2	29
13/LO/1560	In vivo cone imaging in glaucoma and AMD	24
13/LO/1858	Dislocation after hip replacement: an interview study	27

14/LO/0039	REACH: Retention and Engagement Across Care services for HIV v1	34
14/LO/0480	The prescription of antibiotics by nurse prescribers	14
14/LO/0484	The HALT Hepatitis Peer Advocate qualitative study	13

Unfavourable Opinion

REC Reference	Application Short Title	Number of Days on Clock
13/LO/1471	Ripple mapping identifies arrhythmogenic conduction channels	30
13/LO/1892	Validation of the UEL Test Set in Community Stroke Services	27
14/LO/0237	Mechanisms of Primary Lymphoedema	24

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
14/LO/0320	Subclinical semantic deficits in autoimmune conditions. Version 1	N/A
14/LO/0377	Using rewards to improve children's behaviour in the dental setting	N/A

Withdrawn after the meeting

REC Reference	Application Short Title	Number of Days on Clock
14/LO/0028	Imaging Amyloidosis with PET/MRI	29

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 9: Items exceeding timelines:

Full applications for ethical review over 60 day timeline		
REC Reference	Application Short Title	Number of Days on Clock
13/LO/1164	The scenes and spaces of hospital life	67
13/LO/1853	Pilot study of the eye colour & serum bilirubin level in newborns (v1)	66

Proportionate review applications for ethical review over 14 days timeline		
REC Reference	Application Short Title	Number of Days on Clock
13/LO/0732	Audio-recordings effect on post prostatectomy regret	37
13/LO/0735	Focus groups with 'hear and treat' ambulance service users	25
13/LO/0734	Outcomes of a Community Pain Service: A Mixed Method Analysis	32
13/LO/0974	Changes in Gastrointestinal Homeostasis in Critically Ill Children	16
13/LO/1923	Non-contact screening methods for the detection of narrow AC angles	20
13/LO/1925	Perceval S real life registry	17

SSAs (non Phase 1) over 25 days timeline		
REC Reference	Application Short Title	Number of Days on Clock
13/LO/1069	Spain-UK-Czech E-cigarette Study (SUKCES)	28

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
13/LO/1442/AM02	Morbidity after paediatric cardiac surgery	Amendment 2- 12th March 2014	43

Modified Amendments over 14 day timeline

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