

NRES Committee London - London Bridge

Annual Report

01 April 2013 – 31 March 2014

Part 1 – Committee Membership and Training

Name of REC:	NRES Committee London - London Bridge
Type of REC:	Type I and Type 3
Type of Flag:	Phase 1
Chair:	Professor David Bartlett
Vice-Chair:	Mr Brady Pohle
Alternate Vice-Chair:	Dr Michael Goggin
REC Manager:	Stephanie Hill
REC Assistant:	Mr. Claude Beckles
Committee Address:	Health Research Agency Skipton House 80 London Road London SE1 6LH
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Chair's overview of the past year:

NRES Committee London - London Bridge continues to be a busy and effective REC. The Committee has maintained a good attendance record (an average of 10.45 members attended each meeting which is an increase of one on to last years, no meetings were cancelled due to inquoracy). The Committee reviewed a total of 59 applications (5.4 studies per meeting and the same as last year 2013). The Committee has received a number of informal comments at the meeting congratulating the committee on its friendliness and also the pre-prepared summary documents for each application. We continue to see most applications on time with few waiting more than 15 minutes for their interview. The scope of the applications continues to be focused on clinical trials of investigational medicinal products or Phase I drug trials (37%). Most decisions were provisional (86%)

The number of applications over 60 days as a whole is down from 16%to 1.7% and the average to make a final decision is 37 days (down from 42 last year). We have a high number of substantial amendments with 83 over the year with 6% over 35 days (down from 46%). Both are a significant improvement on last year and that is down to the effective and efficient staff at our ethics committee office.

The members' declarations of interest are listed and if and when any conflict with an application the member leaves the Committee.

NRES Committee London - London Bridge Membership:

Name	Occupation	Expert or Lay	Dates	
			Appointed	Resigned
Professor David Bartlett	Honorary Consultant	Expert	22/03/2007	
Mrs Tamsin Brownell	Lay Member	Lay	22/07/2011	
Dr Frances Dockery	Consultant Physician	Expert	13/02/2012	
Mr David Gallacher	Consultant Physicist	Expert	22/08/2010	
Dr Michael Goggin	Consultant Physician	Expert	03/08/2009	
Dr Nedim Hadzic	Consultant and Honorary Reader in Paediatric Hepatology	Expert	07/08/2010	
Ms Sarah Kaiser	Diversity Practitioner	Lay Plus	24/04/2013	
Dr Margreet Luchtenborg	Cancer Epidemiologist	Expert	17/08/2010	
Mr Barry Moody	Lay Member	Lay Plus	10/10/2011	
Mr Brady Pohle	Head of Legal Services (Solicitor)	Lay Plus	12/12/2006	
Mr. Bo Povlsen	Consultant Orthopaedic Surgeon	Expert	10/09/2012	26/03/2014
Ms Karen Sanders	Senior Lecturer Nursing, Health Care Ethics & Law	Expert	06/06/2006	
Ms Jane Smith	Lay Member	Lay Plus	01/07/2013	
Miss Josephine Studham	Registered Nurse	Expert	25/02/2010	
Ms Lorna Sutcliffe	Project Manager/Researcher	Expert	14/10/2004	
Mr Paul Tunstell	Pharmacist	Expert	28/03/2006	
Dr Ralph White	Pharmacist	Expert	25/03/2011	

Deputy Members

Name	Occupation	Expert or Lay	Meeting date attended
Mr William Thornhill	Senior Pharmacist	Expert	29 May 2013 28 August 2013 30 October 2013 11 December 2013 26 February 2014

NRES Committee London - London Bridge: Members' Declarations of Interest:

Name	Declaration of Interest	Date
Ms Jane Smith	Occasional freelance work for the BMJ. The BMJ publishes clinical research.Owns unit trusts/managed funds that include investments in pharmaceutical companies.	02/07/2013
Ms Karen Sanders	Senior Lecturer, South Bank University. Vice-Chair, Healthcare Professionals for Assisted Dying. Member, London South Bank University, Health and Social Care, Faculty Research Ethics Committee	26/11/2013
Professor David Bartlett	GSK. Dental/Oral care lectures/consultancies, British Society for oral & Dental research treasurer	31/03/2014
Mr David Gallacher	None	31/03/2014
Mr Barry Moody	Family Shareholding in GSK PLC. Part time Volunteer - Prostate Cancer UK	31/03/2014
Ms Lorna Sutcliffe	Occasional reviewer for journal of SSI's & Journal of AIDS & HIV. Healthy Technology assessment - Occasional reviewer.	31/03/2014
Dr Frances Dockery	NICE CGG memeber- 2012 (Fragility fractures, Risk assessment).	31/03/2014
Miss Josephine Studham	Member of Imperial College research ethics Committee (Non-NRES Committee).	31/03/2014
Mr Paul Tunstell	None	31/03/2014
Ms Sarah Kaiser	None	31/03/2014
Mrs Tamsin Brownell	Research worker in section for recovery at the institute of Psychiatry, Kings College London	31/03/2014
Dr Michael Goggin	Has shares in unit trusts that may involve relevant companies. Trustee in a charitable body that funds research	29/01/2014
Dr Ralph White	Director, PPMLD Ltd, which offers a staff training and development consultancy to the pharmaceutical industry. Personally not directly involved in the design and conduct of research. Owner, PPMLD Ltd. Shares in PPMLD Ltd. Shares in GlaxoSmithKline Plc. Registered with the General Pharmaceutical Council. Member of the Royal Pharmaceutical Society which occasionally ask opinion about pharmaceutical practice research. Fellow of the Royal Society of Arts, Manufacture and Commerce, who occasionally engage in social research, unlikely to be personally involved .Retired Member of the British Pharmacological Society but do not undertake pharmacological research.	08/01/2014
Dr Nedim Hadzic	Regular reviewer for international and national journals; Associate Editor, Journal Paediatric Gastroenterology and Nutrition	31/03/2014
Mr Brady Pohle	Director and Chair of Trustees, Northern Lights Symphony Orchestra (Registered Charity).President-Elect (and Fellow), Patient	31/03/2014

	Section, Royal Society of Medicine. Chair, NHS Lawyers' Group. Employee (Head of Legal Services), Royal Free London NHS Foundation Trust.	
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Meetings for Full Ethical Review 01 April 2013 - 31 March 2014:

Month	Date	Number of Members Present at Meeting
April	24/04/2013	13
May	29/05/2013	10
June	26/06/2013	9
August	28/08/2013	9
September	25/09/2013	12
October	30/10/2013	11
November	20/11/2013	12
December	11/12/2013	9
January	29/01/2014	10
February	26/02/2014	11
March	26/03/2014	9

11 full committee meetings were held during the reporting period.

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

Name	Number of Meetings Attended
Dr Michael Goggin	10
Dr Ralph White	9
Professor David Bartlett	9
Ms Sarah Kaiser	8
Mrs Tamsin Brownell	8
Ms Jane Smith	8
Dr Frances Dockery	8
Miss Josephine Studham	8
Mr Barry Moody	8
Mr David Gallacher	8
Ms Lorna Sutcliffe	7
Dr Nedim Hadzic	6
Mr Paul Tunstell	5
Mr Brady Pohle	5
Ms Karen Sanders	5
Mr. Bo Povlsen	3

Number of inquorate meetings held: None

Training 01 April 2013 – 31 March 2014:

Name of Member	Date	Event(s) attended
Dr Ralph White	01/12/2013 – 01/12/2013	Equality & Diversity
Mr. Bo Povlsen	04/07/2013 - 04/07/2013	Induction, HRA
Dr Michael Goggin	08/07/2013 - 08/07/2013	Qualitative Research and Ethical Review, HRA
Ms Jane Smith	09/09/2013 - 09/09/2013	Induction, HRA
Dr Frances Dockery	20/11/2013 - 20/11/2013	National Members Training Day, HRA
Ms Jane Smith	13/11/2013 - 13/11/2013	Personal Data in Research, HRA
Mr David Gallacher	11/03/2014 - 11/03/2014	Medical Devices Training Day, HRA
Ms Jane Smith	23/12/2013 - 23/12/2013	Equality & Diversity, HRA - Online
Mr Barry Moody	05/02/2014 - 05/02/2014	Researcher Training Day, HRA
Dr Nedim Hadzic	01/11/2013 - 01/11/2013	SDL - Editorial written for "Liver Transplantation"
Dr Nedim Hadzic	02/12/2013 - 02/12/2013	SDL - Reading medical student pieces on Ethics in medicine
Dr Ralph White	01/09/2013 – 01/09/2013	SDL - Mentor for a new member of the London Bridge REC – Ms Jane Smith
Professor David Bartlett	13/02/2014 - 13/02/2014	Equality & Diversity, GSTT/KCL
Ms Karen Sanders	15/04/2013 - 15/04/2013	SDL - Teaching – Research Ethics
Ms Karen Sanders	27/09/2013 - 27/09/2013	SDL - Actively involved in Data collection at Guys and St Thomas's Hospital Trust (as part of a team)
Ms Karen Sanders	17/10/2013 - 17/10/2013	SDL - Actively involved in Data Analysis of the Data collected at Guys and St Thomas's Hospital Trust
Ms Karen Sanders	27/10/2013 - 27/10/2013	SDL - Teaching – Mental Capacity Act and Consent
Miss Josephine Studham	31/05/2013 - 31/05/2013	GCP Refresher - , SDL
Miss Josephine Studham	01/04/2013 - 01/04/2013	Laboratory Training for basic sample handling, SDL
Mr Paul Tunstell	01/05/2013 - 01/05/2013	Ethics of Psychiatric Research, reviewed HRA presentation, SDL
Mr Paul Tunstell	01/12/2013 - 01/12/2013	Review HRA workshop on HTA, SDL
Mr Paul Tunstell	01/10/2013 - 01/10/2013	Review of Qualitative research, SDL
Mr Paul Tunstell	03/03/2014 - 03/03/2014	Review of Informed consent and the Law, SDL
Ms Lorna Sutcliffe	01/07/2013 - 01/07/2013	Workplace experience and practice: active involvement in research, teaching research ethics , SDL

Ms Lorna Sutcliffe	01/05/2013 - 30/09/2013	Reading and Using guidance from the MRC data toolkit to write specification for Online Clinical Care, SDL
Ms Lorna Sutcliffe	01/06/2013 - 01/06/2013	Teaching and guiding a colleague on how to use and complete an IRAS application and how to submit, SDL
Ms Sarah Kaiser	06/11/2013 - 07/11/2013	Facilitator of management training course in E & D, SDL
Ms Sarah Kaiser	10/02/2014 - 10/02/2014	Brent Council's e-learning module on equality and diversity as part of induction into new role, SDL
Ms Sarah Kaiser	24/03/2014 - 24/03/2014	Brent Council's mandatory data protection e-learning module, SDL
Mr Brady Pohle	15/10/2013 - 15/10/2013	Ellison-Little Lecture Royal Society of Medicine, SDL – Genetic Disorders research
Mr Brady Pohle	14/06/2013 - 14/06/2013	Patient Safety and the Law: Changes and Challenges, SDL
Mr Brady Pohle	06/01/2014 - 06/01/2014	E & D training at Royal Free, SDL
Mrs Tamsin Brownell	14/08/2013 - 14/08/2013	Good Clinical Practice Training for position as Research Worker in the Section for Recovery., SDL
Mrs Tamsin Brownell	01/07/2013 - 01/07/2013	Research worker post – conducted trial of a new therapy for people with psychosis, SDL

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	13	22.03
Phase 1	9	15.25
Gene Therapy	0	0.00
Research Tissue Bank	0	0.00
Research Database	0	0.00
Others	37	62.71
Total Applications Reviewed	59	100

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	6
Number of student applications reviewed	11
Number of paediatric applications reviewed	6
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	1.69
Favourable Opinion with Additional Conditions	2	3.39
Unfavourable Opinion	5	8.47
Provisional Opinion	51	86.44
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	59	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	43	72.88
Further Information Favourable Opinion with Additional Conditions	0	0.00
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	1	1.69
Favourable Opinion with Additional Conditions	2	3.39
Unfavourable Opinion	5	8.47
Provisional Opinion	7	11.86
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	1	1.69
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	59	100

Table 5: Other Management Information for the reporting period:

Average number of applications reviewed per full meeting	5.36
Number of applications for full ethical review over 60 days	1
Number of applications over 60 days as a % of total	1.69%
Number of days taken to final decision - average	36
Number of days taken to final decision - mode	22
Number of SSAs (non-Phase 1) reviewed	9
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)	11.1%
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	83
Number of substantial amendments over 35 days	5
Number of substantial amendments over 35 days as a % of total substantial amendments	6.0%
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	2
Number of modified amendments over 14 days	1
Number of modified amendments over 14 days as a % of total modified amendments	50.0%

Table 6: 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/0527	APL-1 SAD/ MAD study in healthy subjects	23
13/LO/0542	Fingolimod in optic neuritis (ADON)	46
13/LO/0633	Independence for People with Chronic Schizophrenia and Their Families	59
13/LO/0645	Autistic-like traits in young adults diagnosed with psychosis	26
13/LO/0683	Predicting Delirium After Neck of Femur Fracture	38
13/LO/0691	Patient-consented samples for STI diagnostic & biomarker evaluation	26
13/LO/0736	GP15-302: Randomised Study To Compare GP2015 and Enbrel in Psoriasis	40
13/LO/0737	A study to assess the safety and tolerability of AZP-531	32
13/LO/0790	An immunohistological, biochemical and microbiological study of PMR	28
13/LO/1011	FLT-PET in HCC	37
13/LO/1120	Cardiovascular Disease in Chronic Inflammatory Disease's	46
13/LO/1179	Pre-operative Profiling of DCIS of the Breast Using PET Imaging	41
13/LO/1192	Pharmacokinetic profile and patch adhesion of HP-3070-9.0	22
13/LO/1202	ePrescribing Systems a national evaluation: Patient Experience Study	52
13/LO/1239	Cardiovascular Morbidity and Mortality in Subjects with CVD	48
13/LO/1290	M13-102: Follow-up study for DAA therapies in previous HCV studies	41
13/LO/1341	Women's experiences of follow-up for ovarian cancer (Version 1.0)	26
13/LO/1382	Understanding patient pathways to care in oral cancer	22
13/LO/1386	Endoscopic Radiofrequency Ablation for Inlet patch	65
13/LO/1522	LTS13632 Long-term phase 2 study of rhASM in ASMD patients	45
13/LO/1523	DFI12712 ASCEND Acid Sphingomyelinase Comparison of Efficacy aNd Dose	45
13/LO/1526	Bioavailability of Belimumab given by Syringe or Autoinjector	31
13/LO/1535	Rapid Medical Donation Programme for Breast Cancer	25
13/LO/1545	Imaging liver inflammation	21
13/LO/1578	A longitudinal study of cognition in people over 50	34
13/LO/1620	Phase 1 study of ALN-AT3SC in Healthy Males and Haemophilia Patients	35
13/LO/1688	Safety PK and PD of multiple doses of Sulforadex in healthy males	36
13/LO/1714	NOX-H94 in ESA-hyporesponsive anaemia in dialysis patients V2.0	37

13/LO/1782	Effects of an IWMP on Oral Health Status	34
13/LO/1791	Social cognition in psychosis: a feasibility study	29
13/LO/1864	Are closer Real Ear Measurements to prescribed targets worth it?	49
13/LO/1875	The pathophysiology of mental stress induced myocardial ischaemia	43
13/LO/1886	IPI-145 in subjects with refractory iNHL	34
13/LO/1906	RA-EXTEND	26
13/LO/1954	Study to Assess the ADME of a Single Oral Dose of 14C labelled AZD1722	55
14/LO/0053	Positive Mental Training Tool (PosMT) for stroke	41
14/LO/0081	EMR700461-023: Phase IIb Study of Atacicept in SLE	40
14/LO/0094	Non-invasive determination of left ventricular pressure	50
14/LO/0110	Xbox Kinect For Upper Limb Function in Cerebral Palsy Version One	46
14/LO/0125	Black and Asian patients' experience of talking therapy - version 1	56
14/LO/0280	Monitoring Scoliosis with 3D Ultrasound	43
14/LO/0311	VIBRaNT	46
14/LO/0434	PK and D2 Occupancy of HP-3070 in patients with Schizophrenia	33

Further Information Favourable Opinion with Additional Conditions

REC Reference	Application Short Title	Number of Days on Clock
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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
14/LO/0267	FIBCON: Fibrinogen concentrate in paediatric cardiopulmonary bypass	27

Favourable Opinion with Additional Conditions

REC Reference	Application Short Title	Number of Days on Clock
13/LO/0922	Measurement of pulse wave velocity	22
13/LO/1188	Safety tolerability PK and PD of SC and IV SOBI002	14

Unfavourable Opinion

REC Reference	Application Short Title	Number of Days on Clock
13/LO/0949	Cardiovascular disease in chronic inflammatory conditions	22
13/LO/1193	Rapid Medical Donation Programme for Breast Cancer	28
13/LO/1366	Non-motor symptoms outcome after deep brain stimulation	21
13/LO/1773	Osteopathy in infantile colic	45
13/LO/1874	An Investigation of Hip Joint Functioning	29

Provisional Opinion

REC Reference	Application Short Title	Number of Days on Clock
14/LO/0221	Qualitative Study of Massive Obstetric Haemorrhage	N/A
14/LO/0225	Comparison of efficacy of three orthodontic appliances	N/A
14/LO/0287	Real time imaging of regulatory T cells in healthy volunteers	N/A
14/LO/0437	EMR700461-024: Phase IIb Long-Term Extension Study of Atacicept in SLE	N/A
14/LO/0448	Kinematics and Kinetics of cam hip impingement	N/A
14/LO/0464	Characterising airway epithelium and smooth muscle in severe asthma	N/A
14/LO/0474	Retention of CD16+ monocytes in the ischaemic limb	N/A

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/0440	IOL + LRI vs Toric IOL for corneal astigmatism during cataract surgery	N/A

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

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/1386	Endoscopic Radiofrequency Ablation for Inlet patch	65	
Proportionate review applications for ethical review over 14 days timeline			
REC Reference	Application Short Title	Number of Days on Clock	
SSAs (non Phase 1) over 25 days timeline			
REC Reference	Application Short Title	Number of Days on Clock	
13/LO/0509	Multiple Ascending Dose study of AZD7624	31	
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
08/H0804/94/AM01	Regulation of Immunoglobulin Class Switching version 1	Increase sample size	79
11/LO/1572/AM04	Graded Exercise Therapy guided SElf-help Treatment for CFS/ME	4: 01.05.2013	38
09/H0804/110/AM08	Randomized trial of rituximab in renal transplantation	Am08: ReMIND protocol V2.2, 21st January 2013	69
13/LO/0736/AM02	GP15-302: Randomised Study To Compare GP2015 and Enbrel in Psoriasis	Substantial Amendment #2 - ICF Version 2.1, dated	36

10/H0804/66/AM02	Pathological changes in airway smooth muscle in asthma	Am02: Miscellaneous changes	44
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Modified Amendments over 14 day timeline

Amendment Reference	Application Short Title	Amendment Title	Number of Days on Clock
12/LO/1289/AM04/1	PROUD v 1.0	Am04: Revised documents for modified amendment	26

Section 30 application over 60 day timeline

Amendment Reference	Application Short Title	Amendment Title	Number of Days on Clock
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