

National Research Ethics
Service


Health Research Authority

NRES Committee London - Dulwich

Annual Report

01 April 2013 – 31 March 2014

Part 1 – Committee Membership and Training

Name of REC:	NRES Committee London - Dulwich
Type of REC:	Type 3
Type of Flag:	Medical Devices
Chair:	Dr Michael Philpot
Vice-Chair:	Mr Colin Standfield
Alternate Vice-Chair:	Dr Thomas Kabir
REC Manager:	Stephanie Hill
Assistant Co-ordinator:	Mr Claude Beckles
Committee Address:	Health Research Authority Skipton House 80 London Road London SE1 6LH
Telephone:	020 7972 2582
Email:	nrescommittee.london-dulwich@nhs.net

Chair's overview of the past year:

During the past year two long-standing members of the REC resigned for work-related reasons. I would like to thank Dr Will Bernal for his 7 years on the Committee providing expert medical advice. Enock Khoromana was promoted to a post outside London but had contributed 3 years' service. We were fortunate to recruit two replacements: Dr Dan Bailey and Joanna Lawson. However, recruitment remains an issue and we no longer have a GP, statistician or child care expert on the REC.

I would like to thank our Coordinator, Stephanie Hill, and Assistant Coordinator, Claude Beckles, who have worked hard to ensure that time-lines are met and other aspects of the REC's work are within accepted standards. Their effort has reduced the proportion of reviews exceeding 60 days from 45% in 2012-13, to 15% this year. There is a similar improvement in the processing of substantial amendments. There has been a further reduction in studies reviewed by the full REC on the previous year. We have noted an improvement in the quality of applications, with only one unfavourable decision. REC members are learning to write their reviews in line with the new template, and while transparency of decision-making is a worthy objective, excessively long minutes seem counterproductive and unnecessarily time-consuming

NRES Committee London - Dulwich Membership:

Name	Occupation	Expert or Lay	Dates	
			Appointed	Resigned
Dr Daniel Bailey	Consultant Physician	Expert	09/01/2014	
Dr Will Bernal	Consultant Liver Intensivist	Expert	31/03/2006	24/05/2013
Mr Kai Loke Chan	Assistant Director of Pharmacy	Expert	20/02/2005	
Ms Madeleine Colvin	Barrister	Lay Plus	17/09/2007	
Mr John Fowler	Policy Manager	Lay	31/05/2005	
Mrs Carole Jordan	Senior Nurse	Expert	01/04/2010	
Dr Thomas Kabir	MHRN Service Users in Research Coordinator	Lay	10/02/2010	
Mr Enock Khoromana	Clinical Research Associate	Lay	01/10/2010	11/07/2013
Ms Joanne Lawson	Lay Member	Lay Plus	11/02/2014	
Dr Michael Philpot	Consultant Psychiatrist	Expert	30/12/2007	
Ms Anna Ramberg	Research Development Manager	Lay Plus	01/10/2010	
Mr Krzysztof Rutkowski	Research Nurse	Expert	01/08/2010	
Mr Colin Standfield	Charity Worker	Lay	01/02/2012	
Ms Catherine Walton	Consultant Midwife	Expert	30/06/2006	

Co-opted Members

Name	Occupation	Expert or Lay	Meeting date attended
Dr Michael Schachter	Clinical Pharmacologist	Expert	08/05/2013
Dr Alan Ruben	Retired GP	Expert	12/06/2013
Stephanie Ellis	Lay Member	Lay	08/05/2013 12/06/2013

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

Name	Declaration of Interest	Date
Dr Daniel Bailey	None	09/01/2014
Mr Kai Loke Chan	None	31/03/2014
Dr Michael Philpot	Member of Alzheimer's Disease International which supports research in dementia	31/03/2014
Ms Anna Ramberg	Professional role as a development manager at City University London.	31/03/2014
Dr Thomas Kabir	Employed at the NIHR CRN Mental Health research network at KCL	31/03/2014
Ms Joanne Lawson	None	11/02/2014
John Fowler	May be connected with research through part-time employment with LGU. Partner (Dr B Cooper) is a Consultant Paediatrician employed by GSTT and may be involved in research.	12/02/2014
Mrs Carole Jordan	None.	15/01/2014
Mr Colin Standfield	May have shares in a managed Pension Fund. Consumer Representative, STOPAH Liver Study, Southampton. Member of NICE Appeals Panel.	15/01/2014

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

Month	Date	Number of Members Present at Meeting
April	10/04/2013	9
May	08/05/2013	9
June	12/06/2013	8
July	10/07/2013	10
October	16/10/2013	8
November	13/11/2013	8
December	04/12/2013	8
January	15/01/2014	8
February	12/02/2014	9
March	12/03/2014	9

10 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 Philpot	10
John Fowler	9
Mr Colin Standfield	9
Mr Kai Loke Chan	9
Mr Krzysztof Rutkowski	8
Dr Thomas Kabir	8
Ms Anna Ramberg	7
Ms Catherine Walton	6
Ms Madeleine Colvin	6
Mrs Carole Jordan	4
Dr Daniel Bailey	3
Dr Will Bernal	1
Mr Enock Khoromana	1
Ms Joanne Lawson	1

Number of inquorate meetings held: None

Training 01 April 2013 – 31 March 2014:

Name of Member	Date	Event(s) attended
Dr Thomas Kabir	06/06/2013 - 06/06/2013	Training Day for New REC Chairs, HRA
Mr Kai Loke Chan	07/05/2013 - 07/05/2013	"Why the exclusion of older people from clinical research must stop", SDL - Private reading, BMJ 26 May 2012
Mr Kai Loke Chan	15/05/2013 - 15/05/2013	Sample size calculations: should the emperor's clothes be off the peg or made to measure, SDL - Private reading, BMJ 15 Sept 2012
Mr Kai Loke Chan	01/04/2013 – 31/05/2013	Basics of qualitative research: Corbin, Juliet M, SDL Private Reading
Mr Krzysztof Rutkowski	02/10/2013 - 02/10/2013	Researcher Training Day, HRA
Mr Krzysztof Rutkowski	08/07/2013 - 08/07/2013	Qualitative Research and Ethical Review, HRA
Mr Krzysztof Rutkowski	13/11/2013 - 13/11/2013	Personal Data in Research - A Workshop, HRA
Ms Catherine Walton	02/10/2013 - 02/10/2013	Researcher Training Day, HRA
John Fowler	20/11/2013 - 20/11/2013	National Member's Training Day, HRA
Mr Colin Standfield	02/09/2013 - 02/09/2013	NREAP Chair's Meeting
Dr Michael Philpot	11/12/2013 - 11/12/2013	National Training Day for NRES Committee Chairs, HTA

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	8	14.81
Phase 1	0	0.00
Gene Therapy	0	0.00
Research Tissue Bank	0	0.00
Research Database	0	0.00
Others	46	85.19
Total Applications Reviewed	54	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	17
Number of paediatric applications reviewed	8
Number of device applications reviewed	10
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	0	0.00
Favourable Opinion with Additional Conditions	8	14.81
Unfavourable Opinion	1	1.85
Provisional Opinion	44	81.48
Invalid	0	0.00
No Opinion Pending Consultation with Referee	0	0.00
Provisional Opinion Pending Consultation with Referee	1	1.85
Not Requiring Review by NHS REC	0	0.00
Total	54	100
Number of studies sent back to full committee meeting for final opinion	1	

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	41	75.93
Further Information Favourable Opinion with Additional Conditions	0	0.00
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	0	0.00
Favourable Opinion with Additional Conditions	8	14.81
Unfavourable Opinion	1	1.85
Provisional Opinion	1	1.85
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	3.70
Not Requiring Review by NHS REC	0	0.00
No decision entered on RED	1	1.85
Number of studies withdrawn after the meeting	0	0.00
Total	54	100

Table 5: Other Management Information for the reporting period:

Average number of applications reviewed per full meeting	5.40
Number of applications for full ethical review over 60 days	8
Number of applications over 60 days as a % of total	14.81%
Number of days taken to final decision - average	44
Number of days taken to final decision - mode	22
Number of SSAs (non-Phase 1) reviewed	3
Number of applications for SSA review over 25 days	0
Number of applications for SSA review over 25 days as % of all non-Phase 1 (SSAs)	0.0%
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	106
Number of substantial amendments over 35 days	2
Number of substantial amendments over 35 days as a % of total substantial amendments	1.9%
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	5
Number of modified amendments over 14 days	1
Number of modified amendments over 14 days as a % of total modified amendments	20.0%

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/0353	Engager™ Direct Aortic Study	36
13/LO/0390	How does our mind and brain interpret unusual experiences?	49
13/LO/0394	Syncope: Pacing or Recording in the Later Years (SPRITELY)	51
13/LO/0471	The C-Seal Trial	36
13/LO/0573	Validity and Reliability of the IPOS	63
13/LO/0579	Superficial partial thickness wound treatment with NOx	33
13/LO/0589	Exploration of longitudinal injectable opiate treatment (ELIOT)	56
13/LO/0615	SGI-110 in patients with platinum-resistant recurrent ovarian cancer	44
13/LO/0623	Genomic signatures in melanoma and other cutaneous tumours.	70
13/LO/0797	Basal cell carcinoma margin mapping using optical coherence tomography	31
13/LO/0830	Lambda/Daclatasvir/Ribavirin for treatment of HCV/HIV co-infection	32
13/LO/0842	Understanding the care needs of people with severe liver disease v2.0	55
13/LO/0857	Pulmonary fibrosis in Interstitial Lung Diseases v2.0	69
13/LO/0858	Understanding the unmet needs of patients with benign brain tumours.	58
13/LO/0859	SVOP in children	49
13/LO/0879	IATS	31
13/LO/0914	Measurement of Salivary Cortisol & Cortisone by LC-MS/MS	26
13/LO/0947	Prevalence of mental health problems and unmet needs in police custody	25
13/LO/0970	Assessment of inhalation profiles in patients affected by lung disease	29
13/LO/0972	The PEACE Study	33
13/LO/1424	Valiant Mona LSA Thoracic Stent Graft Early Feasibility Study	57
13/LO/1435	The Leaflex Catheter System FIM Study	50
13/LO/1462	COOL-AMI EU Case series clinical study EDC-2191,Revision: 1.1	62
13/LO/1468	Patients perception of anticoagulation therapy	68
13/LO/1475	CRT in narrow QRS heart failure with MRI dyssynchrony assessment	26
13/LO/1542	Haemodynamic Changes After Percutaneous Aortic Valve Intervention	65
13/LO/1651	Evaluation of the NSPCC UK Minding the Baby Programme	60
13/LO/1658	Locating gynaecological tumours using Haptic Indentation device	43
13/LO/1664	Inflammation and monocyte-platelet aggregates	48

13/LO/1686	Fovista and Lucentis compared to Lucentis® alone in patients with AMD	58
13/LO/1821	HypoAwARE: Hypo Awareness restoration& Assoc Regional cerebral Effects	50
13/LO/1838	deferasirox plus erythropoietin vs erythropoietin alone in MDS	32
13/LO/1844	NERVES	72
14/LO/0052	MASTER SL clinical study	53
14/LO/0140	Validation of the Social Inclusion Scale	115
14/LO/0157	A Phase 2 Study of SGI-110 in HCC patients (SGI110-03)	33
14/LO/0182	RCT of Normothermic Perfusion Vs Cold Storage in Liver Transplant v1	44
14/LO/0192	A pilot study of imagery rescripting for survivor guilt after trauma	55
14/LO/0214	Percutaneous tibial nerve stimulation (PTNS) for chronic constipation	45
14/LO/0307	An exploration into the experiences of MSM when engaging in PN -1.0	38
14/LO/0353	PERIGON Pivotal Trial	47

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
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Favourable Opinion with Additional Conditions

REC Reference	Application Short Title	Number of Days on Clock
13/LO/0442	INTEGRATE Final V2.0	22
13/LO/0459	A study to develop a diagnostic assay for Group A Streptococcus	22
13/LO/0625	Evaluating HELP: A multi-site study comparing HELP to usual care.	41
13/LO/0907	NAPPA (version 1.0)	19
13/LO/1372	Using Fibrillation Factor to Predict the Source of VT in Man	22
13/LO/1584	Patient Reported Outcome Measure for Addiction Recovery (PROM-AR)V1	26
14/LO/0083	CV risk in HIV patients switching from a boosted PI to DTG	23
14/LO/0342	Spontaneously Occurring Images in Substance Misuse	24

Unfavourable Opinion		
REC Reference	Application Short Title	Number of Days on Clock
14/LO/0074	Spontaneously Occurring Images in Substance Misuse	22
Provisional Opinion		
REC Reference	Application Short Title	Number of Days on Clock
14/LO/0020	Neurofeedback for Stroke Rehabilitation	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
13/LO/1789	Long Term Outcomes of Obstetric Anal Sphincter Injury	N/A
14/LO/0223	A Qualitative Study of the Lived Experience of Offence Related Trauma	N/A
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
13/LO/0623	Genomic signatures in melanoma and other cutaneous tumours.	70
13/LO/0573	Validity and Reliability of the IPOS	63
13/LO/0857	Pulmonary fibrosis in Interstitial Lung Diseases v2.0	69
13/LO/1462	COOL-AMI EU Case series clinical study EDC-2191,Revision: 1.1	62
13/LO/1468	Patients perception of anticoagulation therapy	68
13/LO/1542	Haemodynamic Changes After Percutaneous Aortic Valve Intervention	65
13/LO/1844	NERVES	72
14/LO/0140	Validation of the Social Inclusion Scale	115

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

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
06/Q0703/40/AM04	PEG-IFN ± Lamivudine for chronic HBV infection in children	Am04: Change in sponsorship	37
11/LO/0775/AM03	Lactose Intolerance in Children with Cow's Milk Allergy	Am03: Carmine Red dye omitted from protocol	36

Modified Amendments over 14 day timeline			
Amendment Reference	Application Short Title	Amendment Title	Number of Days on

			Clock
11/LO/1253/AM04/1	A survey study on surgical complications and patient wellbeing	Amendment 4 Revised, 25/03/2013	15

Section 30 application over 60 day timeline

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