

NRES Committee London - Bentham

Annual Report

01 April 2011 – 31 March 2012

Part 1 – Committee Membership and Training

Name of REC:	NRES Committee London - Bentham
Type of REC:	Type 3
Type of Flag:	None
Chair:	Professor David Katz
Vice-Chair:	Mrs Michelle McPhail
Alternate Vice-Chair:	n/a
Co-ordinator:	Vacant (contact Atul Patel)
PRSC Co-ordinator:	n/a
Assistant Co-ordinator:	Amy Spruce (temp)
Committee Address:	Health Research Authority NRES Committee London Bentham Ground Floor, Skipton House 80 London Road London SE1 6LH
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Chair's overview of the past year:

Not received by time of publication

NRES Committee London - Bentham Membership:

Name	Occupation	Expert or Lay	Dates	
			Appointed	Resigned
Judge Stuart Appleman	Lawyer/Judge	Lay	07/06/2010	
Dr Joan Box	Medical Practitioner	Expert	07/06/2010	
Mr Adrian Cook	Statistician	Expert	16/08/2010	
Ms Sally Davis	Former Barrister and Civil Servant	Lay	07/06/2010	
Professor David Katz	Professor of Immunopathology	Expert	27/04/2010	
Mr Stephen Leyshon	Patient Safety Lead for Primary Care and Ambulance Services	Expert	07/06/2010	02/06/2011
Dr Vera Mann	Lecturer in Medical Statistics	Expert	07/06/2010	12/05/2011
Dr Jacqueline (Jackie) Maxmin	Retired GP	Expert	07/06/2010	
Mrs Michelle McPhail	Lay member	Lay	27/04/2010	
Mr Robin Offord	Director of Clinical Pharmacy	Expert	07/06/2010	
Dr Nicholas Paton	Senior Clinical Scientist	Expert	07/06/2010	04/08/2011
Mr Jonathan Simons	Investment Manager	Lay	07/06/2010	
Dr Anne Marie Swart	Clinical Epidemiologist	Expert	07/06/2010	
Rev Rachel Taylor	Reverend	Lay	07/06/2010	
Dr Robert Urquhart	Head of Pharmacy & Divisional Clinical Director	Expert	01/06/2010	
Dr Sarah Jane Wong	Associate GP	Expert	07/06/2010	
Ms Vivien Yule	Director, Ruston Poole International	Lay	07/06/2010	

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 - Bentham: Members' Declarations of Interest:

Name	Declaration of Interest	Date
Professor David Katz	Peer reviewer of research for some UK research charities and for Jewish charities. Editor of International Journal of Experimental Pathology	02/03/2012
Mrs Michelle McPhail	Freelance work for Chilvers McCrea Healthcare. Approximately 2 hours per week researching business development opportunities. Lay reviewer for NIHR. Ad hoc lay panel member (PPI) for programme Grants for applied research (PGFAR).Has attended as an observer and potential lay member of R&D committee for East and North Herts NHS Trust. Dissertation supervisor at University of Hertfordshire Business School.	02/03/2012
Mr Jonathan Simons	None.	02/03/2012
Dr Anne Marie Swart	Director of UCL Trials Unit, MRC CTU.	02/03/2012
Dr Joan Box	Volunteer coordinator for a Charity providing social care (Jewish care) which is involved in some research	02/03/2012
Rev Rachel Taylor	None.	02/03/2012
Judge Stuart Appleman	None.	02/03/2012
Ms Vivien Yule	None.	02/03/2012
Mr Robin Offord	Occasional work with the Pharmacy Clinical Trials Team around the implementation of new clinical trials. Occasional critique of clinical trial designs on behalf of various clinical teams within the Trust.	02/03/2012
Dr Sarah Jane Wong	None.	02/03/2012
Dr Robert Urquhart	As the head of pharmacy at UCLH he is involved in the pharmaceutical aspects of managing clinical trials which involves liason with researchers and local R&D managers.	02/03/2012
Ms Sally Davis	Small shreholdings in GSK. Member of Ethox Foundation Charity concerned with improving communication and ethical decision making in healthcare.	02/03/2012
Dr Jacqueline (Jackie) Maxmin	None.	14/03/2012
Mr Adrian Cook	None.	14/03/2012

Meetings for Full Ethical Review 31 March 2011 - 01 April 2012:

Month	Date	Number of Members Present at Meeting
April	07/04/2011	10
May	12/05/2011	10
June	02/06/2011	8
July	07/07/2011	10
August	04/08/2011	12
September	01/09/2011	9
October	06/10/2011	9
November	03/11/2011	10
January	05/01/2012	10
February	09/02/2012	8
March	08/03/2012	10

11 full committee meetings were held during the reporting period.

Proportionate Review Sub Committee Meetings held during 31 March 2011 - 01 April 2012:

Month	Date	Number of Members Present at Meeting
February	09/02/2012	8

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

Attendance of Members: 31 March 2011 – 01 April 2012:

Name	Number of Meetings Attended
Professor David Katz	11
Dr Joan Box	10
Mrs Michelle McPhail	10
Dr Jacqueline (Jackie) Maxmin	10
Ms Sally Davis	8
Ms Vivien Yule	8
Mr Jonathan Simons	8
Rev Rachel Taylor	7
Dr Anne Marie Swart	7
Mr Adrian Cook	7
Dr Sarah Jane Wong	6
Mr Robin Offord	6
Judge Stuart Appleman	4
Dr Robert Urquhart	2
Dr Nicholas Paton	1
Mr Stephen Leyshon	1

Number of inquorate meetings held:

**Attendance of Members at proportionate review sub-committee meetings:
01 April 2011 – 31 March 2012:**

Name	Number of Meetings Attended
Dr Joan Box	1
Dr Anne Marie Swart	1
Dr Jacqueline (Jackie) Maxmin	1
Dr Sarah Jane Wong	1
Mr Jonathan Simons	1
Mrs Michelle McPhail	1
Ms Vivien Yule	1
Professor David Katz	1

Training 31 March 2011 – 01 April 2012:

Name of Member	Date	Event(s) attended
Mrs Michelle McPhail	04/05/2011 - 04/05/2011	Introduction to GCP Training, East and North Herts Trust
Professor David Katz	26/09/2011 - 26/09/2011	NRES Update Session, NRES
Dr Joan Box	29/02/2012 - 29/02/2012	NRES Personal Data in Research- Code PO1005, NRES
Ms Sally Davis	28/02/2012 - 28/02/2012	NRES Qualitative Research and Ethical Review, Code OP6001, NRES
Professor David Katz	06/12/2011 - 06/11/2011	National Chair's Training Day Meeting, NRES
Rev Rachel Taylor	28/02/2012 - 28/02/2012	Qualitative Research and ethical review , NRES
Rev Rachel Taylor	13/01/2012 - 13/01/2012	Adults lacking capacity to consent Online Training, NRES
Professor David Katz	19/01/2012 - 19/01/2012	NRES Shred Ethical Debate, NRES
Mrs Michelle McPhail	19/01/2012 - 19/01/2012	NRES Shared Ethical Debate, NRES
Ms Sally Davis	29/02/2012 - 29/02/2012	Personal Data in Research, NRES
Mr Adrian Cook	14/03/2012 - 14/03/2012	Members National Training Day, NRES
Rev Rachel Taylor	14/01/2012 - 14/01/2012	Human Tissue Act Training, MRC
Ms Vivien Yule	01/03/2012 - 01/03/2012	Adults lacking capacity (including research in emergency situations) workshop for RECs, NRES
Dr Jacqueline (Jackie) Maxmin	14/03/2012 - 14/03/2012	NRES Members National Training Day, NRES
Dr Robert Urquhart	22/01/2012 - 22/01/2012	Mental Capacity Act Training (online module), NRES
Mrs Michelle McPhail	28/02/2012 - 28/02/2012	NRES Qualitative Research and Ethical Review , NRES
Mr Jonathan Simons	01/03/2012 - 01/03/2012	Adults lacking capacity (including research in emergency situations) workshop for RECs, NRES
Mrs Michelle McPhail	29/02/2012 - 29/02/2012	NRES Personal Data in Research- Code PO1005, NRES
Professor David Katz	02/02/2012 - 02/02/2012	Human Tissue Act Training, NRES

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	10	17.86
Phase 1	0	0.00
Gene Therapy	0	0.00
Research Tissue Bank	0	0.00
Research Database	0	0.00
Others	46	82.14
Total Applications Reviewed	56	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	6
Number of student applications reviewed	21
Number of paediatric applications reviewed	7
Number of device applications reviewed	1
Number of prisoner applications reviewed	0
Number of applications involving adults unable consent reviewed	1
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	18	32.14
Unfavourable Opinion	4	7.14
Provisional Opinion	34	60.71
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	56	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	21	37.50
Further Information Favourable Opinion with Additional Conditions	6	10.71
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	0	0.00
Favourable Opinion with Additional Conditions	18	32.14
Unfavourable Opinion	4	7.14
Provisional Opinion	3	5.36
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	3	5.36
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	1.79
Total	56	100

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

Total Applications Reviewed	3
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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	0	0.00
Favourable Opinion with Additional Conditions	0	0.00
No Opinion transfer to full committee for review	2	66.67
Provisional Opinion	1	33.33
Unfavourable Opinion	0	0.00
Total	3	100

Table 7: Other Management Information for the reporting period:

Average number of applications reviewed per full meeting	5.09
Number of applications for full ethical review over 60 days	12
Number of applications over 60 days as a % of total	21.43%
Number of days taken to final decision - average	52
Number of days taken to final decision - mode	48
Number of SSAs (non-Phase 1) reviewed	19
Number of applications for SSA review over 25 days	3
Number of applications for SSA review over 25 days as % of all non-Phase 1 (SSAs)	15.8%
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	144
Number of substantial amendments over 35 days	28
Number of substantial amendments over 35 days as a % of total substantial amendments	19.4%
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	1
Number of modified amendments over 14 days	1
Number of modified amendments over 14 days as a % of total modified amendments	100.0%
Number of proportionate review applications for ethical review over 14 days*	1
Number of proportionate review applications over 14 days as a % of total	100.00%

***NB – Proportionate Review Service was in pilot phase until September 2011 and was an aim not a target**

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
11/LO/0262	The Clinical Effect of Monodisperse Fluticasone Propionate in Asthma	52
11/LO/0330	Investigation of rheumatic disease in teenagers and adults : v1.0	46
11/LO/0575	To assess the feasibility of using the Goal Attainment Scale (v1)	38
11/LO/0578	Pathophysiology of pyuria in MS and OAB	55
11/LO/0584	Evaluating National Developments in Service User involvement Englandv1	62
11/LO/0701	Automation bias in clinical decision support systems	72
11/LO/0713	HIV TB Study	51
11/LO/0726	HIV Reverse Cholesterol Transport Study	69
11/LO/0731	Hand Hygiene Monitoring System	67
11/LO/0938	Parents of Children with Gender Identity issues	78
11/LO/0952	Cognitive and emotional processing in eating disorders: brain imaging	68
11/LO/1016	Endothelial Progenitor Cells in Diabetic eye disease	67
11/LO/1163	NGF and TRPV1 after intra-detrusor BoNT/A injections in DO	68
11/LO/1310	Preoperative treatment of a low haemoglobin in cardiac surgery	57
11/LO/1346	The Dental Student Operator-Assistant Pair	59
11/LO/1384	A working memory intervention for children following childhood stroke	51
11/LO/1608	BLVR for heterogeneous emphysema with intact interlobar fissures	68
11/LO/1717	Family members narrating the impact of dementia on their family	48
11/LO/1750	BO25734/TDM4997g:T-DM1 vs Treatment of Physician's choice in HER2+ MBC	36
12/LO/0066	AXMUS-C	61
12/LO/0244	Can we measure moisture in venous leg ulcers and does it matter?	50
12/LO/0245	The "PAN" Project	44
12/LO/0246	Views of type 2 diabetic patients on clinical trial participation	38

Further Information Favourable Opinion with Additional Conditions		
REC Reference	Application Short Title	Number of Days on Clock
11/LO/0835	VELVET	66
11/LO/1600	aMASE: advancing Migrant Access to health Services in Europe	78
11/LO/1610	Effects on blood cells with B-cell targeted therapies	46
12/LO/0279	Developing a decision making aid for orthodontic treatment	57

12/LO/0327	Survivors of Rape and Serious Sexual Assault: The Effect on Memory	37
12/LO/0332	Brain Connectivity in Paediatric Movement Disorders	48
12/LO/0346	The CoMPASs:IO Study:workshops for carers & people with dementia v1	47

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
11/LO/0278	WV21913 Study in Hepatitis C Patients who failed previous therapy	51
11/LO/0333	Qualitative Study of the Quality of Life of Refugees	59
11/LO/0336	Evaluating outcomes of ADM breast reconstruction.(POBRAD)11/LO/0336 V1	58
11/LO/0337	A case study of the nurse practitioner consultation in primary care	59
11/LO/0561	Novel methods for pre-surgical assessment of epilepsy	34
11/LO/0585	IGF system proteins as nutritional markers (11/LO/0585)	36
11/LO/0732	Preterm birth and dopamine function - Version 1	48
11/LO/0939	Biomechanical aspects of enamel and dentine	53
11/LO/1096	MSU CSU Comparison	41
11/LO/1170	Exploring the pathogenesis of thyroid eye disease	55
11/LO/1171	Developing an in-vitro model for cutaneous scarring	55
11/LO/1172	Roles of IGF1 in the pathogenesis and treatment of thyroid eye disease	54
11/LO/1173	Novel anti-scarring agents for trachoma related fibrosis	54
11/LO/1325	OT clinical decision making on discharge from acute care. V3.1	50
11/LO/1380	Evaluation of two methods of cryoablation for treating paroxysmal AF	48
11/LO/1721	Parental adjustment and coping after a child is supported on ECMO	47
12/LO/0011	Transcutaneous SNS	48
12/LO/0014	Investigation into breakdown of blood sugar in Parkinson's disease	52

Unfavourable Opinion		
REC Reference	Application Short Title	Number of Days on Clock
11/LO/1187	Family members narrating the impact of dementia on their family	56
11/LO/1756	AXMUS-C	34
12/LO/0010	Sling versus sphincter for post prostatectomy incontinence	52
12/LO/0013	Transperineal USS, fetal head position and ventouse cup placement (1)	48

Provisional Opinion		
REC Reference	Application Short Title	Number of Days on Clock
11/LO/1551	P3-GLR: Glaritus compared to Lantus in patients with Type 1 diabetes	N/A
12/LO/0136	Oxygen saturation in infants at home with bronchiolitis	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
11/LO/0944	The affect of diet on blood glucose in women with PCOS (Version 1)	50
11/LO/1174	(duplicate) The impact of an intervention programme on service user mo	27
12/LO/0223	Phase 3 IGIV, 10% in AD	41

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
11/LO/0584	Evaluating National Developments in Service User involvement Englandv1	62
11/LO/0701	Automation bias in clinical decision support systems	72
11/LO/0726	HIV Reverse Cholesterol Transport Study	69
11/LO/0731	Hand Hygiene Monitoring System	67
11/LO/0835	VELVET	66
11/LO/0938	Parents of Children with Gender Identity issues	78
11/LO/0952	Cognitive and emotional processing in eating disorders: brain imaging	68
11/LO/1016	Endothelial Progenitor Cells in Diabetic eye disease	67
11/LO/1163	NGF and TRPV1 after intra-detrusor BoNT/A injections in DO	68
11/LO/1600	aMASE: advancing Migrant Access to health Services in Europe	78
11/LO/1608	BLVR for heterogeneous emphysema with intact interlobar fissures	68
12/LO/0066	AXMUS-C	61

Proportionate review applications for ethical review over 14 days timeline		
REC Reference	Application Short Title	Number of Days on Clock
12/LO/0246	Views of type 2 diabetic patients on clinical trial participation	38

SSAs (non Phase 1) over 25 days timeline		
REC Reference	Application Short Title	Number of Days on Clock
11/LO/0877	Hypocalcaemic Seizures Due To Vitamin D Deficiency In Children	29
11/LO/0818	Phase 2 Study of CAL-101 in Indolent B-Cell Non-Hodgkin Lymphoma	37
11/LO/1449	ATX-101-08-12: Long Term Follow-Up Study	40

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
05/Q0505/57/AM11	Biomarkers for cancer	substantial amendment 8	42
10/H0715/52/AM01	The Impact of an Antenatal Group Intervention on Attachment	substantial amendment 1	40
05/Q0505/73/AM17	A Phase III Study of Oral SAHA versus Placebo in Advanced Mesothelioma	substantial amendment 17	41
10/H0715/58/AM03	Cabazitaxel Expanded Access Program for mHRPC patients	Substantial Amendment 3	42
98/0090/AM07	The role of diet and lifestyle in breast cancer survival	Amendment 7, Substantial	36
10/H0715/50/AM02	Metabolic impact of Darunavir monotherapy vs Atripla in HIV patients	substantial amendment 2	47
07/Q0502/15/AM01	MR method development on normal volunteers	Amendment to Information sheet and ICF	38
08/H0715/91/AM12	BOSS (Barrett's Oesophagus Surveillance Study)	Amendment 8, Substantial	36
10/H0715/66/AM02	Myotrace: study to validate a critical illness monitoring system	substantial amendment 2	42
09/H0715/95/AM01	Genetic testing for Familial Hypercholesterolaemia in high risk group	REC Form changes	64
06/Q0505/10/AM02	A study of the influence of pheromones on superosmia	Amendment 2, substantial	380
10/H0715/52/AM02	The Impact of an Antenatal Group Intervention on Attachment	Substantial Amendment 2	51
10/H0715/48/AM01	ART DECO	substantial amendment 1	50
11/LO/0278/AM03	WV21913 Study in Hepatitis C Patients who failed previous therapy	substantial amendment 3	39
08/H0715/18/AM01	B cells role in autoimmune rheumatic diseases - version 1	Amendment 1	181

05/Q0502/101/AM08	Magnetic Resonance technique development	Amendment 8	57
04/Q0505/59/AM05	Genetics Variations in Tyrosine Kinase Signalling in Cancers	Substantial Amendment 1.3	36
09/H0714/34/AM07	Extension Study of AT1001 in Fabry Disease	Substantial Amendment 6	88
11/H0715/2/AM02	PADDINGTON Imaging Biomarker Study - Work Package 2	Substantial amendment 2 21/11/2011	77
01/0128/AM05	Myocardial preconditioning in patients undergoing cardiac surgery	Amendment 5, Substantial Amendment 3	49
10/H0714/8/AM07	BREATHER(PENTA 16) Trial: Short-Cycle Therapy(SCT)	Substantial Amendment 6	39
10/H0714/3/AM01	Preferences for new genetic tests in pregnancy	Substantial Amendment 1	36
10/H0715/30/AM01	REVEAL	Substantial Amendment 2	36
11/LO/0278/AM04	WV21913 Study in Hepatitis C Patients who failed previous therapy	Substantial Amendment 4	54
10/H0715/19/AM01	Effects of the nervous system on cardiac conduction	Substantial Amendment 1	49
10/H0715/58/AM05	Cabazitaxel Expanded Access Program for mHRPC patients	Amendments to Protocol	43
06/Q0502/92/AM05	PBMC derived macrophages and DC	Removal of the restriction on recruitment of older	37
10/H0714/9/AM02	Comparing MANTRA with SSCM in outpatients with anorexia nervosa - 1.	Substantial Amendment 2	70

Modified Amendments over 14 day timeline

Amendment Reference	Application Short Title	Amendment Title	Number of Days on Clock
10/H0715/5/AM01/1	The experience of suicidal feelings 1	Modified Substantial Amendment 1	69

Section 30 application over 60 day timeline

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