



*National Patient Safety Agency*

National Research Ethics Service

**NRES Committee London - East**

**Annual Report**

**01 April 2011 – 31 January 2012**

## Part 1 – Committee Membership and Training

<b>Name of REC:</b>	NRES Committee London - East
<b>Type of REC:</b>	Authorised
<b>Type of Flag:</b>	MCA
<b>Chair:</b>	Revd Dr Joyce Smith
<b>Vice-Chair:</b>	Dr Elizabeth Webster
<b>Alternate Vice-Chair:</b>	Miss Elaine Mason
<b>Co-ordinator:</b>	Ms Laura Keegan (now left NRES contact Atul Patel)
<b>PRSC Co-ordinator:</b>	Mr Atul Patel
<b>Committee Address:</b>	REC Offices Room 10 4th Floor West Charing Cross Hospital Fulham Palace Road London W6 8RF
<b>Telephone:</b>	020 797 22587
<b>Fax:</b>	
<b>Email:</b>	atul.patel@nhs.net

### Chair's overview of the past year:

Committee closed on 31 January 2012

## NRES Committee London - East Membership:

Name	Occupation	Expert or Lay	Dates	
			Appointed	Resigned
Mr David Burbridge	Retired	Lay	13/10/2011	
Mrs Sylvia Clarke	Retired / Lay Member	Lay	01/12/2008	
Mr. David Fenton	Retired	Lay	01/12/2008	
Mr A Jabbari	Lay Member & Stastician	Lay	01/12/2008	
Ms Ros Levenson	Independent Consultant	Lay	09/06/2011	
Mrs Kathryn Lobb	Industry Liaison Manager	Lay	09/06/2011	
Miss Elaine Mason	Retired Pharmacist	Lay	31/12/2008	
Dr Rex Melville	Consultant Physician	Expert	01/12/2008	
Ms Lindsay Royan	Consultant Clinical Psychologist	Expert	01/12/2008	
Dr Shah-Jalal Sarker	Cancer Biostatistics Lecturer	Expert	01/09/2011	
Mr. Pieter Shaw	Chief Pharmacist	Expert	01/06/2009	17/11/2011
Revd Dr Joyce Smith	Chair - Clergy/Retired Consultant Dentist	Expert	01/12/2008	
Dr Sivasubramaniam Srikumar	Consultant Psychiatrist	Expert	01/12/2008	
Mr Leslie J. Stevens	Retired Lay Member	Lay	31/12/2008	
Dr Elizabeth Webster	General Practitioner	Expert	01/12/2008	
Mr Peter Wilson	Finance and Resource Manager (retired)	Lay	01/09/2011	

### Deputy Members

Name	Occupation	Expert or Lay	Meeting date attended

### Co-opted Members

Name	Occupation	Expert or Lay	Meeting date attended
Ms Lara Callaghan	Pharmacy Student	Lay	19/01/2012
Ralph White	Director-Pharmaceutical Consultancy	Lay	14 April 2011
Valerie Lang	Retired	Lay	14 April 2011

### Member Bank

Name	Occupation	Expert or Lay	Meeting date attended

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

<b>Month</b>	<b>Date</b>	<b>Number of Members Present at Meeting</b>
April	14/04/2011	7
May	12/05/2011	9
June	09/06/2011	10
July	14/07/2011	10
August	11/08/2011	10
September	08/09/2011	8
October	13/10/2011	7
November	10/11/2011	8
December	08/12/2011	11
January	19/01/2012	7

10 full committee meetings were held during the reporting period.

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

<b>Month</b>	<b>Date</b>	<b>Number of Members Present at Meeting</b>
April	28/04/2011	3
May	26/05/2011	3
June	23/06/2011	3
July	28/07/2011	3
August	25/08/2011	4
September	29/09/2011	3
October	27/10/2011	5
November	24/11/2011	5
January	16/01/2012	3

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

**Attendance of Members: 01 April 2011 – 31 January 2012:**

<b>Name</b>	<b>Number of Meetings Attended</b>
Dr Elizabeth Webster	10
Mr A Jabbari	10
Revd Dr Joyce Smith	10
Mr Leslie J. Stevens	8
Miss Elaine Mason	6
Ms Lindsay Royan	6
Ms Ros Levenson	6
Mr. David Fenton	5
Mrs Sylvia Clarke	5
Mr. Pieter Shaw	4
Mrs Kathryn Lobb	3
Dr Shah-Jalal Sarker	3
Dr Sivasubramaniam Srikumar	3
Dr Rex Melville	2
Mr David Burbridge	2
Mr Ralph White (Co-opted)	1
Mr Peter Wilson	1
Ms Lara Callaghan (Co-opted)	1
Ms Valerie Lang (Co-opted)	1

**Number of inquorate meetings held: 0**

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

<b>Name</b>	<b>Number of Meetings Attended</b>
Dr Elizabeth Webster	8
Elaine Mason	6
Ms Lindsay Royan	6
Revd Dr Joyce Smith	6
Mrs Sylvia Clarke	4
Mrs Gillian Rimington	1
Ms Margaret Vince	1

**Training 01 April 2011 – 31 January 2012:**

<b>Name of Member</b>	<b>Date</b>	<b>Event(s) attended</b>
Revd Dr Joyce Smith	15/04/2011 - 15/04/2011	Equality and Diversity, NRES
Miss Elaine Mason	11/04/2011 - 11/04/2011	Self Directed Learning - equality and diversity training, NRES
Mr A Jabbari	03/06/2011 - 03/06/2011	Self Directed Learning - equality and diversity training, NRES
Dr Elizabeth Webster	17/10/2011 - 17/10/2011	Self Directed Learning - EQUALITY AND DIVERSITY TRAINING, NRES
Dr Rex Melville	11/04/2011 - 11/04/2011	Self Directed Learning - EQUALITY AND DIVERSITY TRAINING, NRES
Mr. Pieter Shaw	11/04/2011 - 11/04/2011	Self Directed Learning - EQUALITY AND DIVERSITY TRAINING, NRES
Mr. Pieter Shaw	22/06/2011 - 22/06/2011	NRES Members Induction Training (code OP1 001), NRES
Dr Elizabeth Webster	06/12/2011 - 06/12/2011	NRES Chair's National Training Day, NRES
Revd Dr Joyce Smith	17/06/2011 - 17/06/2011	Dementia Awareness, Kaye Partnership
Revd Dr Joyce Smith	19/01/2012 - 19/01/2012	MCA training DVD, NRES
Dr Elizabeth Webster	19/01/2012 - 19/01/2012	MCA Training DVD, NRES
Miss Elaine Mason	19/01/2012 - 19/01/2012	MCA Training DVD, NRES
Mr A Jabbari	19/01/2012 - 19/01/2012	MCA Training DVD, NRES
Mr Leslie J. Stevens	19/01/2012 - 19/01/2012	MCA Training DVD, NRES
Mr David Burbridge	19/01/2012 - 19/01/2012	MCA Training DVD, 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:**

<b>Applications for full ethical review – Study Type</b>	<b>Number</b>	<b>%</b>
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	60	100.00
<b>Total Applications Reviewed</b>	<b>60</b>	<b>100.0</b>

**Table 2: Other REC activity during the reporting period:**

Number of applications made invalid by co-ordinator	4
Number of studies withdrawn prior to the meeting	7
Number of student applications reviewed	28
Number of paediatric applications reviewed	8
Number of device applications reviewed	0
Number of prisoner applications reviewed	0
Number of reviewed applications involving adults unable consent reviewed	11
Number of applications reviewed funded by the US DHHS	0

**Table 3: Decisions given at meetings held within the reporting period:**

<b>Decisions taken at meetings following review of applications</b>	<b>Number</b>	<b>%</b>
Favourable Opinion with Standard Conditions	0	0.00
Favourable Opinion with Additional Conditions	22	36.07
Unfavourable Opinion	6	9.84
Provisional Opinion	32	52.46
Invalid	1	1.64
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
<b>Total</b>	<b>61</b>	<b>100%</b>
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	23	37.70%
Further Information Favourable Opinion with Additional Conditions	7	11.48%
Further Information Unfavourable Opinion	0	0.00%
Favourable Opinion with Standard Conditions	0	0.00%
Favourable Opinion with Additional Conditions	22	36.07%
Unfavourable Opinion	6	9.83%
Provisional Opinion	1	1.64%
Invalid	1	1.64%
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%
<b>Total</b>	<b>61</b>	<b>100%</b>

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

<b>Total Applications Reviewed</b>	<b>31</b>	<b>100.0</b>
------------------------------------	-----------	--------------

**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	6	19.35
Favourable Opinion with Additional Conditions	14	45.16
No Opinion transfer to full committee for review	4	12.90
Provisional Opinion	7	22.58
Unfavourable Opinion	0	0.00
<b>Total</b>	<b>31</b>	<b>100%</b>



**Table 7: Other Management Information for the reporting period:**

<b>Average number of applications reviewed per full meeting</b>	6.10
<b>Number of applications for full ethical review over 60 days</b>	8
<b>Number of applications over 60 days as a % of total</b>	13.11%
<b>Number of days taken to final decision - average</b>	38
<b>Number of days taken to final decision - mode</b>	19
<b>Number of SSAs (non-Phase 1) reviewed</b>	6
<b>Number of applications for SSA review over 25 days</b>	0
<b>Number of applications for SSA review over 25 days as % of all non-Phase 1 (SSAs)</b>	0.0%
<b>Number of SSAs (Phase 1) reviewed</b>	0
<b>Number of applications for SSA review over 14 days</b>	0
<b>Number of applications for SSA review over 14 days as % of all Phase 1 (SSAs)</b>	0%
<b>Number of substantial amendments reviewed</b>	30
<b>Number of substantial amendments over 35 days</b>	4
<b>Number of substantial amendments over 35 days as a % of total substantial amendments</b>	13.3%
<b>Number of Section 30 applications reviewed</b>	0
<b>Number of Section 30 applications over 60 days</b>	0
<b>Number of Section 30 applications over 60 days as a % of total Section 30 applications</b>	0%
<b>Number of modified amendments reviewed</b>	2
<b>Number of modified amendments over 14 days</b>	1
<b>Number of modified amendments over 14 days as a % of total modified amendments</b>	50.0%
<b>Number of proportionate review applications for ethical review over 14 days*</b>	17
<b>Number of proportionate review applications over 14 days as a % of total</b>	62.96%

**\*NB – Proportionate Review Service is currently in pilot phase – 14 day review is an aim not a target**

**Table 8: Breakdown of current status of applications reviewed within the reporting period:**

<b>Further Information Favourable Opinion with Standard Conditions</b>		
<b>REC Reference</b>	<b>Application Short Title</b>	<b>Number of Days on Clock</b>
11/LO/0059	Implementation and Evaluation of Two Different CST Training Approaches	59
11/LO/0088	Sleep apnoea and inflammatory markers	59
11/LO/0108	Pathophysiology, Histology & Pharmacology of OAB UTI & Cystitis	92
11/LO/0192	Recovery mechanisms of shoulder movements after a stroke.	85
11/LO/0300	Training parameters for optimal resistance exercise after stroke.	33
11/LO/0381	Treatment priorities	27
11/LO/0428	Safety of patients with learning disabilities in NHS hospitals	39
11/LO/0486	The Micro-Circulation In Trauma Patients	41
11/LO/0587	Parental experience of anaesthetic induction: a qualitative study	40
11/LO/0596	The development and evaluation of MT outcome measures	32
11/LO/0699	Autism Education Trust Outcomes Research	10
11/LO/0759	Anxiety Symptoms Prevention Investigation (ASPI)	12
11/LO/0766	Vocal Attack Time of Edematous Vocal Folds	49
11/LO/0975	An Exploratory Study: The Effect Of Therapy On Self-Compassion	39
11/LO/0986	Exploring nursing experience of ambulance triage.	20
11/LO/0987	Periodontitis and disease progression in Alzheimer's Disease	53
11/LO/1061	Improving occupational performance post discharge (phase 2)	53
11/LO/1168	Bio impedance characteristics of brain tissue with nano particles v1	23
11/LO/1202	Muscle function and gait patterns in young people with haemophilia -V1	36
11/LO/1223	Caring for patients who are hoping for a miracle	55
11/LO/1229	Phenotyping Achromatopsia patients in Preparation for Gene Therapy	32
11/LO/1354	Mindfulness for Coping with Chronic Illness	33
11/LO/1674	Inflammatory/microbial translocation biomarker panel to diagnose SBP	37
11/LO/1758	Chromatic sensitivity for monitoring and diagnosis of glaucoma	26
11/LO/1759	Early detection of visual loss in age related macular degeneration	23
11/LO/1784	Genetics of child anxiety (version 1)	26
11/LO/1954	The Role of Contact Force Sensing in Atrial Fibrillation Ablation	71
12/LO/0112	The polymicrobial nature of STI syndromes: MRC eSTI2 Investigation	68
12/LO/0100	The Diabetes MyQuest Consultation Tool	74
12/LO/0127	Relapse triggers and recovery among mentally ill substance misusers	155

<b>Further Information Favourable Opinion with Additional Conditions</b>		
<b>REC Reference</b>	<b>Application Short Title</b>	<b>Number of Days on Clock</b>
11/LO/0476	Minitub:Prospective Registration Study on Sentinel Node (SN) Positive	51
11/LO/0767	Comparison of CQ and Fx parameters for semi-occluded exercises	49
11/LO/0776	Factors that affect rehabilitation of dual diagnosis patients	48
11/LO/1194	A new programme for people with alcohol-related brain injury	31
11/LO/1404	Upper Airway Function during Exercise in Patients with Asthma	40
11/LO/1406	Enhanced outcomes from simulation training for acute appendicitis	48
11/LO/1801	Brain TSPO Function	17
11/LO/1948	Vision and quality of life in pituitary disease	17

<b>Further Information Unfavourable Opinion</b>		
<b>REC Reference</b>	<b>Application Short Title</b>	<b>Number of Days on Clock</b>

<b>Favourable Opinion with Standard Conditions</b>		
<b>REC Reference</b>	<b>Application Short Title</b>	<b>Number of Days on Clock</b>
11/LO/0773	Analyses of OmniHeart specimens	15
11/LO/1181	Brain specific proteins	21
11/LO/1629	Assessment of digital microscopy for diagnosis of Malaria	13
11/LO/1761	Comparison of 23 vs 25 gauge tract for glaucoma tube implant insertion	16
11/LO/1945	Analysis of tumour microenvironment in paediatric cancers.	16
12/LO/0129	The Ipswich Touch Test (IpTT): screening for diabetic neuropathy	18

<b>Favourable Opinion with Additional Conditions</b>		
<b>REC Reference</b>	<b>Application Short Title</b>	<b>Number of Days on Clock</b>
11/LO/0109	Pathophysiological signals of urine in lower urinary tract symptoms	63
11/LO/0186	The assessment of CMR guided LV lead placement during CRT implantation	63
11/LO/0257	Understanding young peoples decision making about bariatric surgery	54
11/LO/0308	Attentional expectancies and cholinergic neurotransmission	28
11/LO/0363	Immune responses in BCG vaccinated UK infants	19
11/LO/0366	Biomarkers of radiation and chemotherapy response	19
11/LO/0531	Haemophilia, Experiences, Results, Opportunities: a psychosocial study	23
11/LO/0532	Motivation for wearing elastics bands with orthodontic braces	21
11/LO/0576	Do DBT and CBT for BPD enhance mentalization?	27

11/LO/0577	Quality of Life Survey Comparing Vitala vs Traditional Pouch System	27
11/LO/0589	Assessing Consciousness with AVPU (version 1)	34
11/LO/0752	Flexible Working Study Project	10
11/LO/0770	Developing a high performance support workforce in acute care (v1)	10
11/LO/0930	The Late Effects of Treatment Amongst Colorectal Cancer Patients.	12
11/LO/0959	Occupational stress and job satisfaction in mental health nurses (1)	21
11/LO/0974	Middle leaders perceptions of their role: a comparison	8
11/LO/1155	The Effects of Music Therapy with Low Awareness States	25
11/LO/1185	Measuring the size of back muscle contractions with ultrasound imaging	18
11/LO/1230	Assessment of ankle strength in CMT1A v1.0	27
11/LO/1352	The role of digital brachial pressure index in HASS	19
11/LO/1365	A study of personal goals and emotions	7
11/LO/1387	Incontinence preoccupation in anxiety disorders_Version1	14
11/LO/1395	Parents' Understanding of Conduct Disorder.	16
11/LO/1396	A study of major system reconfiguration in stroke services	24
11/LO/1476	Assessing clot formation and stability using a flow chamber system	14
11/LO/1550	Psychosocial factors in patient adherence with periodontal treatment	19
11/LO/1646	Quantifying exercise intensity and capacity in ICU patients	19
11/LO/1672	Functional Assessment in early Breast cancer in Older patients	22
11/LO/1673	Biomarkers in Early Breast Cancer in Older People	22
11/LO/1681	FXIII Activation Assay	19
11/LO/1755	Psychosocial factors predicting outcome in sciatica injection patients	17
11/LO/1814	Well-being Interventions for Social and Health needs (The WISH study)	15
11/LO/1946	Patients' experiences of a Colorectal Enhanced Recovery Programme. V1	13
11/LO/1957	Social Communication Skills Assessment Group - 1	22
11/LO/1997	Development of a simple tool for diagnosis of water-loss dehydration.	22
12/LO/0130	Surplus tissue from patients undergoing eye surgery	14

<b>Unfavourable Opinion</b>		
<b>REC Reference</b>	<b>Application Short Title</b>	<b>Number of Days on Clock</b>
11/LO/0988	Psychosocial factors & patient adherence with periodontal treatment v1	42
11/LO/1140	Dental Plaque Control in the Intensive Care Unit v1.0	34
11/LO/1222	Comprehensive geriatric assessment of early breast cancer (GAMBIT)	28
11/LO/1225	Evaluate the effectiveness of the iFriend initiative	24

11/LO/1461	Quality control of in vivo tape stripping	16
11/LO/1798	Clinical research of developmental disorders	15

<b>Provisional Opinion</b>		
<b>REC Reference</b>	<b>Application Short Title</b>	<b>Number of Days on Clock</b>
11/LO/1557	Electrophysiological study of neurological dysfunction in neonates	N/A

<b>Further information response not complete</b>		
<b>REC Reference</b>	<b>Application Short Title</b>	<b>Number of Days on Clock</b>

<b>Withdrawn after the meeting</b>		
<b>REC Reference</b>	<b>Application Short Title</b>	<b>Number of Days on Clock</b>

<b>Invalid Application</b>		
<b>REC Reference</b>	<b>Application Short Title</b>	<b>Number of Days on Clock</b>
11/LO/1817	Social Communication Skills Assessment Group - 1	18

<b>No Opinion Pending Consultation with Referee</b>		
<b>REC Reference</b>	<b>Application Short Title</b>	<b>Number of Days on Clock</b>

<b>Not Requiring Review by NHS REC</b>		
<b>REC Reference</b>	<b>Application Short Title</b>	<b>Number of Days on Clock</b>

**Table 9: Items exceeding timelines:**

<b>Full applications for ethical review over 60 day timeline</b>		
<b>REC Reference</b>	<b>Application Short Title</b>	<b>Number of Days on Clock</b>
11/LO/0108	Pathophysiology, Histology & Pharmacology of OAB UTI & Cystitis	92
11/LO/0109	Pathophysiological signals of urine in lower urinary tract symptoms	63
11/LO/0192	Recovery mechanisms of shoulder movements after a stroke.	85
11/LO/0186	The assessment of CMR guided LV lead placement during CRT implantation	63
11/LO/1954	The Role of Contact Force Sensing in Atrial Fibrillation Ablation	71
12/LO/0112	The polymicrobial nature of STI syndromes: MRC eSTI2 Investigation	68
12/LO/0100	The Diabetes MyQuest Consultation Tool	74
12/LO/0127	Relapse triggers and recovery among mentally ill substance misusers	155

<b>Proportionate review applications for ethical review over 14 days timeline</b>		
<b>REC Reference</b>	<b>Application Short Title</b>	<b>Number of Days on Clock</b>
11/LO/0531	Haemophilia, Experiences, Results, Opportunities: a psychosocial study	23
11/LO/0532	Motivation for wearing elastics bands with orthodontic braces	21
11/LO/0773	Analyses of OmniHeart specimens	15
11/LO/0959	Occupational stress and job satisfaction in mental health nurses (1)	21
11/LO/0986	Exploring nursing experience of ambulance triage.	20
11/LO/1168	Bio impedance characteristics of brain tissue with nano particles v1	23
11/LO/1181	Brain specific proteins	21
11/LO/1185	Measuring the size of back muscle contractions with ultrasound imaging	18
11/LO/1352	The role of digital brachial pressure index in HASS	19
11/LO/1354	Mindfulness for Coping with Chronic Illness	33
11/LO/1755	Psychosocial factors predicting outcome in sciatica injection patients	17
11/LO/1758	Chromatic sensitivity for monitoring and diagnosis of glaucoma	26
11/LO/1759	Early detection of visual loss in age related macular degeneration	23
11/LO/1761	Comparison of 23 vs 25 gauge tract for glaucoma tube implant insertion	16
11/LO/1945	Analysis of tumour microenvironment in paediatric cancers.	16
11/LO/1948	Vision and quality of life in pituitary disease	17
12/LO/0129	The Ipswich Touch Test (IpTT): screening for diabetic neuropathy	18

<b>SSAs (non Phase 1) over 25 days timeline</b>		
<b>REC Reference</b>	<b>Application Short Title</b>	<b>Number of Days on Clock</b>

<b>SSAs (Phase 1) over 14 days timeline</b>		
<b>REC Reference</b>	<b>Application Short Title</b>	<b>Number of Days on Clock</b>

<b>Substantial Amendments over 35 day timeline</b>			
<b>Amendment Reference</b>	<b>Application Short Title</b>	<b>Amendment Title</b>	<b>Number of Days on Clock</b>
07/H0701/71/AM07	Investigation of colonic motor activity in health and disease	substantial amendment 7	39
11/LO/0059/AM01	Implementation and Evaluation of Two Different CST Training Approaches	Substantial Amendment 1	42
11/LO/0759/AM01	Anxiety Symptoms Prevention Investigation (ASPI)	11/LO/0759/AM1/25 OCT 2011	38
11/LO/0428/AM01	Safety of patients with learning disabilities in NHS hospitals	Substantial Amendment 1	55
07/H0701/48/AM01	An Investigation of an A&E radiographer comment system	Change in protocol	36
08/H0701/30/AM05	Anatomical and functional MRI of the cleft palate	Amendment to the PIS	47
10/H0701/128/AM07	Safety and Appropriateness of Growth Hormone treatments in Europe	Amendment 7, Substantial	63

<b>Modified Amendments over 14 day timeline</b>			
<b>Amendment Reference</b>	<b>Application Short Title</b>	<b>Amendment Title</b>	<b>Number of Days on Clock</b>
10/H0701/122/AM01/1	Genetic predictors for treatment response of psychological treatment	Substantial Amendment 1, Modified	21

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