

NRES Committee South East Coast - Kent

Annual Report

01 April 2011 – 31 March 2012

Part 1 – Committee Membership and Training

Name of REC:	NRES Committee South East Coast - Kent
Type of REC:	Authorised
Type of Flag:	Paediatric
Chair:	Dr Ray Godfrey
Vice-Chair:	Mr Mike Tatlow
Alternate Vice-Chair:	n/a
Co-ordinator:	Mrs Halina Pounds
PRSC Co-ordinator:	n/a
Assistant Co-ordinator:	n/a
Committee Address:	Health Research Authority Ground Floor, Skipton House 80 London Road London SE1 6LH
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Chair's overview of the past year:

This year started very well for the Committee. Although we had to say goodbye to some very long-serving members, whose experience and dedication was greatly valued, we gained a number of new members who quickly developed a very good understanding of the business of a REC and began to play a full part in our work.

NRES Committee South East Coast - Kent Membership:

Name	Occupation	Expert or Lay	Dates	
			Appointed	Resigned
Dr Jim Appleyard	Retired Paediatrician	Expert	01/12/2009	
Mrs Margaret Bell	Retired Nurse	Lay	01/12/2009	31/08/2011
Mrs Carole Brooks	Psychotherapist	Expert	01/12/2009	
Mrs Helen Burn	Head of Pharmacy	Expert	09/06/2011	
Mr Neal Clifton	Teacher	Lay Plus	01/12/2009	
Dr Beverly Donaldson	Midwife	Expert	01/10/2009	
Dr Ray Godfrey	Statistician	Lay Plus	01/12/2009	
Professor V M Mathew	Consultant Psychiatrist	Expert	01/12/2009	01/11/2011
Mrs Liz Moorut	Chief Biomedical Scientist	Expert	01/12/2009	
Ms Lynda Pearce	Membership Engagement Manager	Lay Plus	15/04/2011	
Dr Brijender Rana	Consultant in Public Health	Expert	01/12/2009	
Mrs Amanda Richardson	Neonatal Sister	Expert	09/06/2011	
Mrs Sue Harrison	Managing Director of a Trade Association	Lay Plus	01/05/2011	
Dr Amit Saha	Consultant Rheumatologist	Expert	09/06/2011	
Mrs Heather Salzer	Ultrasound Clinical Specialist I	Expert	09/06/2011	
Mr John Skilton	Senior Biomedical Scientist	Expert	01/12/2009	
Mr Mike Tatlow	Health Informaticist	Expert	01/12/2009	
Mrs Joyce Williams	Retired District Supplies Manager	Lay Plus	01/12/2009	02/10/2011
Mrs Maureen Williams	Senior Lecturer Midwifery	Expert	01/12/2009	

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 South East Coast - Kent: Members' Declarations of Interest:

Name	Declaration of Interest	Date
Mr John Skilton	None.	15/01/2012
Mrs Liz Moorut	None.	19/05/2012
Mrs Carole Brooks	May see a client who is actively involved in research, this would be declared at the appropriate committee meeting.	18/04/2011
Dr Jim Appleyard	Hon Secretary of International Association. Part of a wider share portfolio (ISAs and Pensions) Patron and Dyspraxia Foundation.	03/12/2010
Mrs Sue Harrison	Work closely with, but no formal link to, St George's, University of London. On a steering group for a Re-solve project (research) funded by big lottery. Director of a Trade Association involved in the chemistry industry, including consumer products such as cosmetics, household cleaning products.	07/05/2011
Dr Beverly Donaldson	Research Fellow in Academic Health Science	27/04/2011
Mrs Helen Burn	Involved with R&D at Maidstone Hospital specifically certain clinical trials.	13/06/2011
Dr Lynda Pearce	Employee by East Kent Hospitals University NHS Foundation Trust.	18/04/2011
Dr Brijender Rana	Consultant Public Health West Kent.	30/03/2011
Mr Neal Clifton	None.	28/12/2011
Mr Mike Tatlow	None.	30/03/2011

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

Month	Date	Number of Members Present at Meeting
April	27/04/2011	9
May	25/05/2011	12
June	29/06/2011	13
August	31/08/2011	13
September	28/09/2011	10
November	30/11/2011	10
January	25/01/2012	14
February	29/02/2012	11

8 full committee meetings were held during the reporting period.

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

No proportionate review sub-committee meetings were held during the reporting period.

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

Name	Number of Meetings Attended
Mr Neal Clifton	8
Mrs Liz Moorut	8
Ms Lynda Pearce	8
Mrs Carole Brooks	7
Dr Ray Godfrey	7
Mr John Skilton	7
Dr Brijender Rana	6
Dr Beverly Donaldson	5
Mrs Amanda Richardson	5
Mrs Heather Salzer	5
Mrs Helen Burn	5
Mrs Maureen Williams	5
Mrs Sue Harrison	4
Mrs Margaret Bell	4
Dr Amit Saha	4
Dr Jim Appleyard	3
Mrs Joyce Williams	1

Number of inquorate meetings held: 0

Training 01 April 2011 – 31 March 2012:

Name of Member	Date	Event(s) attended
Dr Ray Godfrey	12/04/2011 - 12/04/2011	Equality & Diversity, NRES
Mrs Amanda Richardson	11/10/2011 - 11/10/2011	NRES Members Induction Training, NRES
Ms Lynda Pearce	10/01/2012 - 10/01/2012	NRES Members Induction Training, NRES
Dr Amit Saha	10/01/2012 - 10/01/2012	NRES Members Induction Training, NRES
Mrs Heather Salzer	10/01/2012 - 10/01/2012	NRES Members Induction Training, NRES
Mrs Helen Burn	10/01/2012 - 10/01/2012	NRES Members Induction Training, NRES
Mrs Sue Harrison	28/02/2012 - 28/02/2012	NRES Qualitative Research and Ethical Review, NRES
Mrs Amanda Richardson	30/07/2011 - 30/07/2011	Equality and Diversity, Maidstone and Tunbridge Wells NHS Trust
Mrs Amanda Richardson	06/08/2011 - 06/08/2011	Introduction to Information Governance E-Learning Module Introductory Level, Department of Health, Informatics Directorate, Information Governance Policy Team
Dr Ray Godfrey	02/02/2012 - 02/02/2012	HTA, NRES
Mrs Sue Harrison	20/03/2012 - 20/03/2012	Induction, NRES
Mrs Heather Salzer	15/02/2012 - 15/02/2012	Equality & Diversity, Queen Mary's Hospital Sidcup

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	1	2.44
Research Database	0	0.00
Others	40	97.56
Total Applications Reviewed	41	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	2
Number of student applications reviewed	18
Number of paediatric applications reviewed	5
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	2	4.88
Favourable Opinion with Additional Conditions	5	12.20
Unfavourable Opinion	3	7.32
Provisional Opinion	31	75.61
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	41	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	28	68.29
Further Information Favourable Opinion with Additional Conditions	2	2.44
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	2	4.88
Favourable Opinion with Additional Conditions	5	12.20
Unfavourable Opinion	3	7.32
Provisional Opinion	0	4.88
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	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	1	0.00
Total	41	100

Table 5: Other Management Information for the reporting period:

Average number of applications reviewed per full meeting	5.13
Number of applications for full ethical review over 60 days	7
Number of applications over 60 days as a % of total	17.07%
Number of days taken to final decision - average	44
Number of days taken to final decision - mode	29
Number of SSAs (non-Phase 1) reviewed	1
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	19
Number of substantial amendments over 35 days	5
Number of substantial amendments over 35 days as a % of total substantial amendments	26.3%
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	3
Number of modified amendments over 14 days	0
Number of modified amendments over 14 days as a % of total modified amendments	0.0%

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
11/LO/0403	Scoping the assessment needs of child carers Version 2	40
11/LO/0411	Stigmatisation of children receiving mental health treatment	56
11/LO/0628	Judgement and Decision Making in Nodal Irradiation for Breast Cancer	24
11/LO/0642	The effect of different proteins on satiety and gut hormones	61
11/LO/0644	Effect of a wholegrain diet on measures of vascular compliance	35
11/LO/0648	Evaluation of a Lean Improvement Programme	26
11/LO/0653	A study into the effectiveness of a postural care education program	39
11/LO/0672	Mental Health and Justice: Making it a Reality	29
11/LO/0847	Comparison of NCEMRA vs CEMRA in diagnosis of RAS	53
11/LO/0900	Evaluation of Lean Six Sigma in Kent Community Health NHS Trust (V1)	29
11/LO/0911	Effect of different meals on glycaemic response	37
11/LO/0941	Motor recovery from acute stroke: functional imaging	33
11/LO/0958	FAST-Forward	41
11/LO/1290	Insight and quality of life following cognitive stimulation therapy	41
11/LO/1304	Biological variation of biomarkers of kidney damage	31
11/LO/1357	Triggers to assess the needs of COPD patients and their carers	34
11/LO/1370	Testing a software application encouraging louder Parkinsons speech	29
11/LO/1372	Reading Skills Version 1	60
11/LO/1472	Pre-operative exercise training	86
11/LO/1576	Carpal Tunnel Syndrome (CTS) Ultrasound Therapy clinical Trial 1.0	47
11/LO/1582	Does Video feedback improve the performance of Exam students ?	114
11/LO/1605	A pilot RCT of CBT for adolescents with body dysmorphic disorder	53
12/LO/0089	Personality disorder, community art projects, interpersonal relations	61
12/LO/0135	The National Birdshot Biobank Project	58
12/LO/0151	MBT for Adolescents with BPD Features in an Outpatient Setting.	77
12/LO/0280	Evaluating interventions to improve pain relief during day surgery	68
12/LO/0302	Investigation into the treatment barriers of dually diagnosed patients	62
12/LO/0303	Mucograft and Subepithelial Connective Tissue Grafts for Root Coverage	42

Further Information Favourable Opinion with Additional Conditions		
REC Reference	Application Short Title	Number of Days on Clock
11/LO/0413	Understanding the Experiences of UK Cancer Treatment for Kuwaiti's	60
12/LO/0304	In-patient perceptions of psychologists in secure settings.	48

Further Information Unfavourable Opinion		
REC Reference	Application Short Title	Number of Days on Clock

Favourable Opinion with Standard Conditions		
REC Reference	Application Short Title	Number of Days on Clock
11/LO/0942	Biomechanical Testing of HAGL Lesions in Cadaveric Shoulders	37
11/LO/1649	Describing Acute Kidney Injury in the Community.	27

Favourable Opinion with Additional Conditions		
REC Reference	Application Short Title	Number of Days on Clock
11/LO/0414	Compassionate Nursing Care - a concept analysis and focus group study.	44
11/LO/0421	Immune responses in chronic viral hepatitis	28
11/LO/0643	Insulin Validation	37
11/LO/1486	OKCSIB versus convention in stroke physiotherapy: Case Control Series	30
11/LO/1497	Factors that influence womens experiences of vaginal breech birth	42

Unfavourable Opinion		
REC Reference	Application Short Title	Number of Days on Clock
11/LO/0946	Fetofit pilot trial (protocol version 7)	27
11/LO/1368	Non-neurological sexual dysfunction in patients with chronic backpain	29
11/LO/1736	Wound irrigation- is sterile saline better than tap water?	21

Provisional Opinion		
REC Reference	Application Short Title	Number of Days on Clock

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
12/LO/0299	Accidental nut exposure in nut allergic patients	27

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 7: Items exceeding timelines:

Full applications for ethical review over 60 day timeline		
REC Reference	Application Short Title	Number of Days on Clock
11/LO/0642	The effect of different proteins on satiety and gut hormones	61
11/LO/1472	Pre-operative exercise training	86
11/LO/1582	Does Video feedback improve the performance of Exam students ?	114
12/LO/0089	Personality disorder, community art projects, interpersonal relations	61
12/LO/0151	MBT for Adolescents with BPD Features in an Outpatient Setting.	77
12/LO/0280	Evaluating interventions to improve pain relief during day surgery	68
12/LO/0302	Investigation into the treatment barriers of dually diagnosed patients	62

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/Q1803/28/AM04	Quality of Life in Preschool Wheezy Children	Substantial Amendment 2 - September 2011	46
09/H1101/75/AM05	Evaluation of Pilgrims Hospices Rapid Response Service	Substantial Amendment 21 November 2011	46
11/LO/0672/AM02	Mental Health and Justice: Making it a Reality	Substantial amendment December 2012	55
11/LO/1472/AM01	Pre-operative exercise training	Amendment 1	64
08/H1101/114/AM04	EEG-NF to improve neglect in stroke patients	Substantial Amendment 27 February 2012	52

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

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