

NRES Committee South East Coast - Surrey

Annual Report

01 April 2011 – 31 March 2012

Part 1 – Committee Membership and Training

Name of REC:	NRES Committee South East Coast - Surrey
Type of REC:	Authorised
Type of Flag:	None
Chair:	Prof David Russell-Jones
Vice-Chair:	Dr JHP Powell
Alternate Vice-Chair:	Miss Elizabeth Cheshire
Co-ordinator:	Miss Georgina Marshall since April 2012, currently on maternity leave
PRSC Co-ordinator:	None
Assistant Co-ordinator:	Shevon Oxford
Committee Address:	HRA Research Ethics Committee (REC) London Centre Ground Floor 80 Skipton House London Road London SE1 6LH
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Chair's overview of the past year:

NRES Committee South East Coast - Surrey Membership:

Name	Occupation	Expert or Lay	Dates	
			Appointed	Resigned
Miss M Ayton	Infection Control Adviser	Expert	01/05/2005	July 2011
Dr Julia Boyle	Director Surrey CRC/Pharmacologist	Expert	12/01/2011	
Miss Elizabeth Cheshire	Consultant in Emergency Medicine	Expert	01/06/2010	
Dr Matthew Dickinson	Consultant Anaesthetist	Expert	01/03/2011	
Mrs Margaret Handyside	Lay Member	Lay Plus	18/01/2011	
Rev D Hobden	Senior Chaplain	Lay	01/07/2005	Leave of absence
Dr Stephen Houston	Consultant Medical Oncologist	Expert	01/05/2005	
Ms Wendy Joy	Lay Member	Lay	01/01/2011	
Mrs Chrissie Lawson	Nurse Specialist	Expert	01/05/2006	
Dr Charles Li	Consultant Physician	Expert	12/01/2011	
Mr Michael Morris	Lay Member	Lay	01/10/2007	
Dr JHP Powell	Consultant Physician	Expert	01/05/2005	
Prof David Russell-Jones	Professor of Diabetes and Endocrinology	Expert	01/04/2005	
Mrs Ann Sayer	Lay Member	Lay Plus	01/05/2006	
Dr Jane Stuart	Public Health Researcher	Expert	01/10/2011	
Dr L Selby	General Practitioner	Expert	01/06/2005	30/08/2012

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 - Surrey: Members' Declarations of Interest:

Name	Declaration of Interest	Date
Dr Charles Li	None declared (signed 20/3/12)	02/04/2011
Dr Stephen Houston	Have attended advisory board meetings for ROCHE Novartis, AMGEN and Bristol Myers Squibb (signed 28/12/11)	02/04/2011
Mrs Ann Sayer	None declared (signed 22/12/11)	02/04/2011
Mrs Margaret Handyside	None declared (signed 28/12/11)	02/04/2011
Miss Elizabeth Cheshire	Any connection, including any position of authority, in a charity or voluntary body in the field of health and social care involved in or possibly seeking to be involved in the conduct of research - Vice President of Leonard Cheshal Disability.	04/01/2012
Mr Michael Morris	none declared	08/01/2012
Dr Jane Stuart	None (as at 6.0.2011)	06/09/2011
Rev D Hobden	Shareholdings in Roche, Glaxo, Smith and Nephew (as at 4.2.2011)	02/04/2011
Dr Matthew Dickinson	None (as at 16.2.2011).	02/04/2011
Ms Wendy Joy	None (as at 5.2.2011).	02/04/2011
Mrs Chrissie Lawson	None (as at 8.2.2011)	02/04/2011
Prof David Russell-Jones	Has research grants, gives lectures and talks for a number of Pharmaceutical companies. Connections to charity/voluntary sector: Trustee of Sir Jules Thorn Trust (medical research charity); Cedar (charity supporting care and diabetes research)(as at 20.1.2011)	02/04/2011

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

Month	Date	Number of Members Present at Meeting
April	05/04/2011	10
May	03/05/2011	9
June	07/06/2011	12
July	05/07/2011	13
September	06/09/2011	11
December	06/12/2011	10
January	17/01/2012	10
February	07/02/2012	12
March	06/03/2012	8

9 full committee meetings were held during the reporting period.

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

Month	Date	Number of Members Present at Meeting
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0 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
Ms Wendy Joy	9
Mrs Ann Sayer	8
Dr JHP Powell	8
Mrs Chrissie Lawson	7
Mrs Margaret Handyside	7
Prof David Russell-Jones	7
Mr Michael Morris	6
Dr Julia Boyle	6
Dr L Selby	6
Dr Charles Li	6
Miss Elizabeth Cheshire	5
Dr Matthew Dickinson	5
Rev D Hobden	5
Dr Stephen Houston	4
Miss M Ayton	3
Dr Jane Stuart	3

Number of inquorate meetings held:0

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

Name	Number of Meetings Attended
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Training 01 April 2011 – 31 March 2012:

Name of Member	Date	Event(s) attended
Mrs Margaret Handyside	22/06/2011 - 22/06/2011	NRES Members Induction Training, NRES
Dr Julia Boyle	11/10/2011 - 11/10/2011	Induction, NRES
Dr Matthew Dickinson	11/10/2011 - 11/10/2011	Induction, NRES
Dr Julia Boyle	30/06/2011 - 30/06/2011	Ethics Training Day Workshop, AREC
Rev D Hobden	11/10/2011 - 11/10/2011	Poor Supervision, AREC
Ms Wendy Joy	11/10/2011 - 11/10/2011	Poor Supervision, AREC
Mrs Margaret Handyside	28/02/2012 - 28/02/2012	Qualitative Research and Ethical Review, 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	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	51	100.00
Total Applications Reviewed	51	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	23
Number of paediatric applications reviewed	3
Number of device applications reviewed	0
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	3	5.88
Favourable Opinion with Additional Conditions	22	43.14
Unfavourable Opinion	1	1.96
Provisional Opinion	25	49.02
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	51	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	23	45.10
Further Information Favourable Opinion with Additional Conditions	1	1.96
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	3	5.88
Favourable Opinion with Additional Conditions	22	43.14
Unfavourable Opinion	1	1.96
Provisional Opinion	0	0.00
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	1.96
Total	51	100

Table 5: Other Management Information for the reporting period:

Average number of applications reviewed per full meeting	5.67
Number of applications for full ethical review over 60 days	5
Number of applications over 60 days as a % of total	9.80%
Number of days taken to final decision - average	31
Number of days taken to final decision - mode	16
Number of SSAs (non-Phase 1) reviewed	2
Number of applications for SSA review over 25 days	2
Number of applications for SSA review over 25 days as % of all non-Phase 1 (SSAs)	100.0%
Number of SSAs (Phase 1) reviewed	2
Number of applications for SSA review over 14 days	1
Number of applications for SSA review over 14 days as % of all Phase 1 (SSAs)	50.0%
Number of substantial amendments reviewed	22
Number of substantial amendments over 35 days	4
Number of substantial amendments over 35 days as a % of total substantial amendments	18.2%
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%

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/0298	Immune Responses in Hepatitis Delta Virus Infection v1	23
11/LO/0302	Stairs Negotiation in fallers versus non-fallers	29
11/LO/0348	Quality & Safety in European Hospitals by research(1)	24
11/LO/0393	MAIP Study_v1.0	24
11/LO/0444	Oxytocin in social and non-social decision-making	22
11/LO/0491	Epigenetics, biomarkers and colon cancer.	17
11/LO/0492	Magnetic Resonance Lymphangiography in Primary Lymphoedema	21
11/LO/0503	The effects of heat on skin transport	18
11/LO/0565	An IPA study exploring migrant Pakistani women's postnatal experiences	22
11/LO/0708	Ergocalciferol vs. Cholecalciferol Food Fortification Study - Vers1.0	20
11/LO/0720	Investigation into newly-qualified nurses'experiences of preceptorship	17
11/LO/0916	Healthcare professionals perspectives of interprofessional education	16
11/LO/0918	RESPONSE project: responding to service users'care concerns Version 1	17
11/LO/0931	The usefulness of the 6 Part Story Method as a diagnostic tool.	21
11/LO/1035	Can Immature Reticulocyte Fraction predict red cell recovery?	23
11/LO/1318	Maintaining Recovery (Version 1)	17
11/LO/1319	childrens cancer nurses experiences of providing palliative care	19
11/LO/1327	Training Provision for Community Associate Practitioners- version 1	17
11/LO/1459	Service User & Practitioner Experiences of Community Treatment Orders	43
11/LO/1922	Gait Analysis Following Proximal Medial Gastrocnemius Release	58
12/LO/0178	Gait analysis of Joint sparing knee Vs Limb salvaging operation	71
12/LO/0182	EUROASPIRE IV survey	117
12/LO/0348	Collection and processing of non-invasive respiratory specimens	125

Further Information Favourable Opinion with Additional Conditions		
REC Reference	Application Short Title	Number of Days on Clock
11/LO/0718	Project PEPSE (version 1)	16

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
11/LO/1336	Evaluation of a portable IR camera for measuring core temperature	15
11/LO/1451	Carriage of Staphylococcus aureus amongst ICU staff	15
12/LO/0073	Arterial spin labelling MRI in HIV (pilot)	39

Favourable Opinion with Additional Conditions		
REC Reference	Application Short Title	Number of Days on Clock
11/LO/0514	Prevention of aggressive radiotherapy induced dental decay	16
11/LO/0539	The Characteristics of Compassionate Care in an Acute Care Trust	14
11/LO/0563	Nurses' readiness to implement preceptorship framework-04/11,version 1	16
11/LO/0738	Supportive care needs survey amongst men with prostate cancer	16
11/LO/0739	Myelin Mapping in Primary Progressive Multiple Sclerosis	23
11/LO/0943	Glycaemic Variability in Stress Hyperglycaemia	24
11/LO/0960	Simulation Training vs Observed Workplace Supervision in Psychiatry	21
11/LO/1321	Staff experiences and attitudes of discussing sexual issues v1	15
11/LO/1382	PrOstate CAncer in Men Over Seventy (POCAMOS)	28
11/LO/1926	EN2 in seminal fluid	29
11/LO/1990	Variability of cephalic vein diameters in renal patients - version 1	29
12/LO/0053	Carer Involvement in Obsessive Compulsive Disorder (OCD)	28
12/LO/0064	Intradialytic Hypertension Incidence, Prevalence and Risk Factors	40
12/LO/0106	Agreement between people with dementia and their carers	28
12/LO/0170	Studies of Hereditary Stomatocytosis	29
12/LO/0180	Physiotherapy in Pregnancy related pelvic girdle pain.	36
12/LO/0181	Does the WiiFit improve outcomes for patients with lower limb injuries	36
12/LO/0189	An Exploration of Short hospital stay following mastectomy	30
12/LO/0323	USS assessment of TVT-O position & correlation with outcome in SUI	36
12/LO/0345	The Lung Clearance Index (LCI) in Non CF Bronchiectasis (nCFBx)	28
12/LO/0349	Anxiety related to discharge from inpatient neurorehabilitation	36
12/LO/0356	Simultaneous PET-MRI of Alzheimer disease and frontotemporal dementia	28

Unfavourable Opinion		
REC Reference	Application Short Title	Number of Days on Clock
11/LO/2034	Effect of Stimulant Medication and Neurofeedback on Children With ADHD	63
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
11/LO/2004	Donation of Mouth Air and Oral HBS for Oral Health Research	73
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/2004	Donation of Mouth Air and Oral HBS for Oral Health Research	73
11/LO/2034	Effect of Stimulant Medication and Neurofeedback on Children With ADHD	63
12/LO/0178	Gait analysis of Joint sparing knee Vs Limb salvaging operation	71
12/LO/0182	EUROASPIRE IV survey	117
12/LO/0348	Collection and processing of non-invasive respiratory specimens	125

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
11/LO/2035	Sleep efficiency assessed by PSG in advanced Parkinson's disease	45
12/LO/0445	Evaluating interventions to improve pain relief during day surgery	35

SSAs (Phase 1) over 14 days timeline		
REC Reference	Application Short Title	Number of Days on Clock
12/LO/0390	In-house evaluation an experimental mouthwash on oral bacteria (V1.0)	22

Substantial Amendments over 35 day timeline			
Amendment Reference	Application Short Title	Amendment Title	Number of Days on Clock
09/H1109/98/AM01	HistoScanning™ in diagnosing, assessing & following up prostate cancer	Amendment 1	40
09/H1109/62/AM01	HistoScanning™ in diagnosing localised prostate cancer	Amendment 1	39
08/H1109/183/AM03	effectiveness of intensive MBT outpatient psychotherapy for BPD	Amendment 2	37
11/H1109/12/AM03	Vitamin D therapy, left ventricular	changes to PIS and invite letter	58

	mass in predialysis CKD		
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Modified Amendments over 14 day timeline			
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Amendment Reference	Application Short Title	Amendment Title	Number of Days on Clock
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Section 30 application over 60 day timeline			
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Amendment Reference	Application Short Title	Amendment Title	Number of Days on Clock
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