

National Research Ethics
Service


Health Research Authority

NRES Committee South East Coast - Brighton and Sussex

Annual Report

01 April 2011 – 31 March 2012

Part 1 – Committee Membership and Training

Name of REC:	NRES Committee South East Coast - Brighton and Sussex
Type of REC:	Type 111
Type of Flag:	Paediatric
Chair:	Dr Simon Walton
Vice-Chair:	Mr Maurice Marchant & Dr John Bull
Alternate Vice-Char:	None
Co-ordinator:	Mrs Nischinth Cherodian
PRSC Co-ordinator:	None
Assistant Co-ordinator:	None
Committee Address:	Charing Cross Hospital REC Centre Room 4W/12, 4th Floor Charing Cross Hospital Fulham Palace Road, London W6 8RF
Telephone:	020 797 22565
Fax:	020 797 22592
Email:	nrescommittee.secoast-brightonandsussex@nhs.net

Chair's overview of the past year:

This is the first full year for the REC since it was formed from the merger of Brighton East and West RECs. Over this year the committee has successfully settled into its new membership and the depth of expert and lay membership has been significantly improved.

Despite relocation to London the committee has continued to be served excellently by its administrator. This is testament to her hard work and dedication despite the obvious difficulties relocation has caused.

NRES Committee South East Coast - Brighton and Sussex Membership:

Name	Occupation	Expert or Lay	Dates	
			Appointed	Resigned
Dr Jill Adams	GP	Expert	01/03/2011	
Dr Duncan Angus	Consultant Psychiatrist	Expert	01/03/2011	
Dr John Bull	Consultant Physician (retired)	Expert	01/03/2011	
Mr Gerard Cronin	Business Development Manager	Lay Plus	01/03/2011	
Dr Sue Eckstein	Lecturer in Clinical and Biomedical Ethics	Lay Plus	01/03/2011	
Prof Angie Hart	Professor of Child, Family & Community Health	Expert	01/03/2011	
Mr Stuart Heatherington	Mathematician	Lay Plus	01/03/2011	
Dr Puneet Kakar	Specialist Registrar in Medicine & Geriatrics	Expert	01/03/2011	
Mr Bill Kent	Retired Civil Servant	Lay Plus	01/03/2011	
Miss Samantha Lippett	Lead Microbial Pharmacist	Expert	01/03/2011	
Mr Maurice Marchant	Public Health Information Specialist	Lay Plus	01/03/2011	
Ms Nicola Mason	Specialist Midwife - Practice Development	Expert	01/03/2011	
Dr Martin Parry	Consultant Paediatric Anaesthetist	Expert	01/03/2011	
Dr Paul Seddon	Consultant Paediatrician	Expert	01/01/2007	
Mr Christopher Snowling	Retired Solicitor	Lay Plus	01/03/2011	06/06/2011
Mrs Kathy Stott	Pharmacist	Expert	01/03/2011	
Dr Simon Walton	Consultant in Anaesthesia and Intensive Care	Expert	01/03/2011	
Mrs Susan Waton	School Librarian	Lay Plus	01/03/2011	
Dr Stuart White	Consultant Anaesthetist	Expert	01/03/2011	
Ms Vanessa Wright	Nurse Consultant	Expert	01/03/2011	08/08/2011
Ms Debra Young	Head of Midwifery	Expert	01/03/2011	

Deputy Members

Name	Occupation	Expert or Lay	Meeting date attended
Miss Samantha Lippett	Lead Microbial Pharmacist	Expert	05/05/2011, 07/07/2011, 01/09/2011, 03/11/2011
Prof Angie Hart	Professor of Child, Family & Community Health	Expert	07/07/2011, 08/12/2011, 01/03/2012

Co-opted Members - none

Member Bank

Name	Occupation	Expert or Lay	Meeting date attended
Dr Puneet Kakar	Specialist Registrar in Medicine & Geriatrics	Expert	01/03/2012

NRES Committee South East Coast - Brighton and Sussex: Members' Declarations of

Name	Declaration of Interest	Date
Dr Paul Seddon	chair of MCRN Respiratory and CF Clinical sub-Group	07/06/2011
Dr Jill Adams	Involved in research that has been ethically approved elsewhere	11/01/2012
Mr Gerard Cronin	No interests declared	01/12/2011
Dr Simon Walton	No interests declared	08/12/2011
Mr Maurice Marchant	Secretary Royal Statistical Society	08/12/2011
Dr John Bull	No interests declared	08/12/2011
Dr Sue Eckstein	Faculty member of Brighton and Sussex Medical School	08/12/2011
Dr Martin Parry	No interests declared	08/12/2011
Mrs Kathy Stott	No interests declared	08/12/2011
Dr Duncan Angus	No interests declared	08/12/2011
Mr Bill Kent	Secretary Chronic Fatigue Society	08/12/2011
Dr Stuart White	No interests declared	08/12/2011
Mrs Susan Waton	No interests declared	08/12/2011
Ms Debra Young	No interests declared	08/12/2011
Mr Stuart Heatherington	No interests declared	08/12/2011
Dr Jill Adams	The GP practice is a member of the PCRN	08/12/2011
Ms Nicola Mason	None declared	08/12/2011
Dr Paul Seddon	The Chair of Respiratory and Cystic Fibrosis Society	08/12/2011
Prof Angie Hart	Supervisor for the students at the University of Brighton	08/12/2011
Miss Samantha Lippett	None declared	08/12/2011
Dr Puneet Kakar	None Declared	08/12/2011

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

Month	Date	Number of Members Present at Meeting
April	07/04/2011	13
May	05/05/2011	10
June	02/06/2011	11
July	07/07/2011	10
August	04/08/2011	14
September	01/09/2011	9
October	06/10/2011	11
November	03/11/2011	13
December	08/12/2011	12
February	02/02/2012	14
March	01/03/2012	12

11 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
Dr Simon Walton	11
Mr Bill Kent	9
Mr Maurice Marchant	9
Mr Stuart Heatherington	9
Dr Sue Eckstein	8
Dr John Bull	8
Dr Martin Parry	7
Dr Duncan Angus	7
Dr Stuart White	7
Mr Gerard Cronin	7
Ms Nicola Mason	7
Mrs Kathy Stott	6
Mrs Susan Waton	6
Dr Jill Adams	6
Dr Paul Seddon	6
Ms Vanessa Wright (resigned)	4
Prof Angie Hart (deputy to Debra Young)	3
Miss Samantha Lippett (deputy member to Kathy Stott)	4
Ms Debra Young	3
Mr Christopher Snowling (resigned)	2
Dr Puneet Kakar (Bank member)	1

Number of inquorate meetings held: None

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

Name	Number of Meetings Attended
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No proportionate review sub-committee meetings held

Training 01 April 2011 – 31 March 2012:

Name of Member	Date	Event(s) attended
Dr Simon Walton	27/05/2011 - 27/05/2011	Adults lacking capacity on-line tool kit, University of Leicester & NRES
Mr Bill Kent	26/06/2011 - 26/06/2011	NRES Medical Devices , NRES
Miss Samantha Lippett	07/12/2011 - 07/12/2011	NRES Statistics Training for NRES REC Members , NRES
Dr Duncan Angus	07/12/2011 - 07/12/2011	NRES Statistics Training for NRES REC Members, NRES
Mr Stuart Heatherington	06/09/2011 - 06/09/2011	Equality & Diversity, Core Learning Unit
Mr Gerard Cronin	11/09/2011 - 11/09/2011	Equality & Diversity, NRES
Dr Puneet Kakar	30/09/2011 - 30/09/2011	GCP training, Ashford and st Peter's Hospital NHS Trust
Dr Puneet Kakar	15/08/2011 - 15/08/2011	Mental Capacity Act 2005 Dissertation Review, Self direct learning
Dr John Bull	06/12/2011 - 06/12/2011	Chairing Skills, NRES
Mr Stuart Heatherington	14/03/2012 - 14/03/2012	NRES Members National Training Day - London, NRES
Mrs Susan Waton	14/03/2012 - 14/03/2012	NRES Members National Training Day - London, NRES
Dr Simon Walton	23/02/2012 - 23/02/2012	Reviewing Clinical Trials of Investigational Medicinal Products, NRES
Mr Maurice Marchant	08/11/2011 - 08/11/2011	Chairing Skills, NRES
Mrs Kathy Stott	12/12/2011 - 12/12/2011	E-learning package - Adults lacking capacity (completed SDL), University of Leicester - online
Mr Stuart Heatherington	29/12/2011 - 29/12/2011	Mental Capacity Act DVD by NRES, NRES provided MCA DVD
Ms Nicola Mason	18/01/2012 - 18/01/2012	Mental Capacity Act - DVD by NRES, NRES
Dr Sue Eckstein	30/01/2012 - 30/01/2012	MCA DVD and online MCA Training, NRES and online
Prof Angie Hart	08/12/2011 - 08/12/2011	NRES DVD, NRES DVD
Prof Angie Hart	16/09/2011 - 20/09/2011	Psychiatry Conference, not known
Mr Bill Kent	26/01/2012 - 26/01/2012	Mental Capacity Act DVD for NRES committee members, NRES
Mrs Susan Waton	01/12/2011 - 01/12/2011	MCA DVD provided by NRES, NRES DVD
Dr Paul Seddon	28/06/2011 - 28/06/2011	GCP training , NIHR
Dr Paul Seddon	11/03/2012 - 11/03/2012	NRES MCA DVD, NRES
Dr Jill Adams	07/03/2012 - 07/03/2012	NRES DVD, NRES provided DVD

Dr Jill Adams	22/02/2012 - 22/02/2012	Morals and Medicine - a changing landscape, BMA
Mr Gerard Cronin	29/02/2012 - 29/02/2012	NRES MCA DVD and on line MCA, NRES
Dr John Bull	15/02/2012 - 15/03/2012	NRES MCA DVD, NRES
Dr John Bull	20/03/2012 - 20/03/2012	Equality & Diversity, online
Ms Debra Young	25/11/2011 - 25/01/2011	Attending NPEU launch of Birthplace in England research, London, Inhouse training
Mr Maurice Marchant	29/03/2012 - 29/03/2012	Equality & Diversity, online
Dr Stuart White	30/10/2011 - 30/10/2011	AAGBI 'Law and the Anaesthetist', not known

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	12	21.43
Phase 1	0	0.00
Gene Therapy	0	0.00
Research Tissue Bank	1	1.79
Research Database	0	0.00
Others	43	76.79
Total Applications Reviewed	56	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	10
Number of student applications reviewed	18
Number of paediatric applications reviewed	7
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	6	10.71
Favourable Opinion with Additional Conditions	5	8.93
Unfavourable Opinion	11	19.64
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	11	19.64
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	6	10.71
Favourable Opinion with Additional Conditions	5	8.93
Unfavourable Opinion	11	19.64
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	1	1.79
Not Requiring Review by NHS REC	0	0.00
No decision entered on RED	0	00.00
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	0
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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	0	0.00
Provisional Opinion	0	0.00
Unfavourable Opinion	0	0.00
Total	0	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	1
Number of applications over 60 days as a % of total	1.79%
Number of days taken to final decision - average	29
Number of days taken to final decision - mode	21
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	56
Number of substantial amendments over 35 days	1
Number of substantial amendments over 35 days as a % of total substantial amendments	1.8%
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	0
Number of modified amendments over 14 days as a % of total modified amendments	0.0%
Number of proportionate review applications for ethical review over 14 days*	0
Number of proportionate review applications over 14 days as a % of total	0%

***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/0296	An evaluation of organisational change within merging trusts	21
11/LO/0358	Treponema pallidum clearance as a marker of antimicrobial efficacy	45
11/LO/0399	18F-Fluoride PET-CT for Detecting Bone Metastases in RCC	28
11/LO/0509	Developmental cognitive trajectory of the 22q11.2 Deletion	28
11/LO/0512	Biomarkers in Childhood Cancer and Blood Disorders	41
11/LO/0740	Post operative neurophysiological assessment of the median nerve.	41
11/LO/0747	Physical Activity Advice in Diabetics at Annual Review	31
11/LO/0751	GS 0118 Open label cobicistat regimens in HIV	42
11/LO/0961	PERFORM Prospective Observational Study of Functioning in Depression	37
11/LO/1006	Service users experiences of initial help seeking	31
11/LO/1068	A pilot study of the use of peripheral nerve block in forefoot surgery	45
11/LO/1182	Study of avoidable variations in weekday hospital mortality	50
11/LO/1320	Inflammation & Fatigue in Rheumatoid Arthritis	29
11/LO/1341	Letrozole plus Oral CDK4/6 inhibitor in Advanced Breast Cancer	30
11/LO/1511	Effect of donor skin type on nipple reconstruction (version 1).	27
11/LO/1588	MARCH study	21
11/LO/1789	MODE	47
11/LO/1950	NKTR-118 vs Placebo in Patients with Non-Cancer-Related Pain & OIC	28
12/LO/0055	Ranolazine & Dronedaronone in Patients with Atrial Fibrillation	64
12/LO/0171	IVIM DW-MR imaging in colorectal liver metastasis	35
12/LO/0277	LAAPITUP 2 1.0	29

Further Information Favourable Opinion with Additional Conditions		
REC Reference	Application Short Title	Number of Days on Clock
11/LO/0364	Cricothyroid membrane in infants and children	29
11/LO/0454	ABE4869g-Phase II study of MABT5102A vs Placebo in Alzheimer's Disease	34
11/LO/0745	Chlamydia testing in MSM	36
11/LO/0937	Patient perception of dietary salt intake	37
11/LO/1189	Peri-operative haemodynamic optimisation in hepatobiliary surgery	27

11/LO/1196	HIV Antigen Testing in Urine	35
11/LO/1379	Allergen challenge Phase IIa Study	32
11/LO/1724	Exploring the experience and impact of family therapy.	37
11/LO/1978	Lung function testing in HIV-infected individuals	35
12/LO/0164	Effects of coronary and aortic valve therapy in severe AS v2.1	24
12/LO/0166	Molecular Markers of Breast Tumours	28

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/0317	Use and impact of the pre-hospital electrocardiogram: MINAP	21
11/LO/0502	EPOCH	20
11/LO/0513	IDO in paediatric cancer	20
11/LO/1169	HIV testing in an outpatient setting	22
11/LO/1330	Mindfulness-based groups for people distressed by hearing voices	21
11/LO/1366	Patient views on experimental research in the context of MND and PD	16

Favourable Opinion with Additional Conditions

REC Reference	Application Short Title	Number of Days on Clock
11/LO/1190	Exploring back pain; Patients' perceptions of important Change (EPIC)	22
11/LO/1394	Health Professional views on the cancer attitudes of ethnic minorities	22
11/LO/1516	CPET variables in unexplained breathlessness	21
11/LO/1741	Understanding the meaning of integration from stroke survivors.	23
12/LO/0145	Survey of Care at Preterm Birth	27

Unfavourable Opinion

REC Reference	Application Short Title	Number of Days on Clock
11/LO/0528	Attitudes to cancer among ethnic minority women – version 1	20
11/LO/0725	Mindfulness-based groups for people distressed by hearing voices	24
11/LO/0750	Can Immature Reticulocyte Fraction predict red cell recovery?	23
11/LO/0924	Nephrotoxicity in patients with psoriasis receiving ciclosporin	22

11/LO/1060	Non-compliance in people aged 16-20 with Type 1 Diabetes Mellitus	16
11/LO/1224	NKTR-118 vs Placebo in Patients with Non-Cancer-Related Pain & OIC	25
11/LO/1544	Ageism in the management of Cardiovascular disease	15
11/LO/1727	Survey of Care at Preterm Birth	35
11/LO/1734	The influence of a open purge line on micro-bubbles generation	21
12/LO/0276	ACTUAL study 1.0	28
12/LO/0350	Cook MyoSite Incorporated AMDC Female SUI Clinical Study-10-019-02_EU	22

Provisional Opinion - none

REC Reference	Application Short Title	Number of Days on Clock
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Provisional Opinion Pending Consultation with Referee - None

REC Reference	Application Short Title	Number of Days on Clock
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Further information response not complete - none

REC Reference	Application Short Title	Number of Days on Clock
12/LO/0285	Associative memory in early dementia	N/A

Withdrawn after the meeting - None

REC Reference	Application Short Title	Number of Days on Clock
11/LO/1199	Nursing Personality Disorders: Innovations to the nursing process- v1	24

Invalid Application - none

REC Reference	Application Short Title	Number of Days on Clock
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No Opinion Pending Consultation with Referee - none

REC Reference	Application Short Title	Number of Days on Clock
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Not Requiring Review by NHS REC - none

REC Reference	Application Short Title	Number of Days on Clock
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Table 9: Items exceeding timelines:

Full applications for ethical review over 60 day timeline		
REC Reference	Application Short Title	Number of Days on Clock
12/LO/0055	Ranolazine & Dronedaronone in Patients with Atrial Fibrillation	64

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
09/H1107/107/AM10	Sorafenib vs Placebo in Thyroid Cancer	09-H1107-107-Am05 (incorporating Am7)	36

Modified Amendments over 14 day timeline - None			
Amendment Reference	Application Short Title	Amendment Title	Number of Days on Clock

Section 30 application over 60 day timeline - None			
Amendment Reference	Application Short Title	Amendment Title	Number of Days on Clock