

National Research Ethics
Service


Health Research Authority

NRES Committee South East Coast - Brighton and Sussex

Annual Report

01 April 2013 – 31 March 2014

Part 1 – Committee Membership and Training

Name of REC:	NRES Committee South East Coast - Brighton and Sussex
Type of REC:	CTIMPS in patients – type iii
Type of Flag:	Research involving children
Chair:	Dr Simon Walton
Vice-Chair:	Dr John Bull and Mr Maurice Marchant
Alternate Vice-Chair:	Vacant
REC Manager:	Mr Danyal Enver
PRSC Co-ordinator:	Mr Danyal Enver
REC Assistant:	Mr Thomas McQuillan
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 has been a difficult year for the Brighton and Sussex NRES Committee. We have lost several long standing members of the committee as well as our long standing Committee manager. In addition our regional office has gone through a major restructure and this has led to several changes in personnel who help administer the committee. However our members and officers have remained committed to providing a high standard of ethical opinion and we are hoping with the appointment of new committee members and a new Committee manager, Brighton and Sussex will go from strength to strength.

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	06/09/2013
Prof Angie Hart	Professor of Child, Family & Community Health	Expert	01/03/2011	
Mr Stuart Heatherington	Mathematician	Lay Plus	01/03/2011	10/09/2013
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 (retired)	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	01/05/2011	
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	

Deputy Members

Name	Occupation	Expert or Lay	Meeting date attended
Prof Angie Hart	Professor of Child, Family & Community Health	Expert	01/08/2013 12/12/2013
Miss Samantha Lippett	Lead Microbial Pharmacist	Expert	06/06/2013 01/08/2013 03/10/2013 12/12/2013

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

Name	Declaration of Interest	Date
Dr Martin Parry	None declared	06/06/2013
Mr Gerard Cronin	None declared	30/01/2014
Dr Paul Seddon	Trustee of the Brighton wsalia NHS Health Line (registered charity). Active clinical researcher, chief investigator on 3 multicentre UK studies and on 2 single centre studies; local principal investigator on 3 multicentre studies.	04/02/2014
Ms Nicola Mason	Currently undertaking PHD at University of Brighton (final year).	31/01/2014
Mrs Susan Waton	None declared.	06/02/2014
Dr Stuart White	<ul style="list-style-type: none"> •Member of Brighton Anaesthetic Research Forum •National Director of Research, Hip Fracture Perioperative Network •Member Age Anaesthesia Association •Editor, Anaesthesia •AAGBI Grants Committee •Trust co-ordinator, Quality Audit and Research Co-ordination group of National Institute Academic Anaesthesia 	19/03/2014
Mr Bill Kent	Secretary - Chronic Fatigue Society	19/03/2014
Dr Jill Adams	General Practice is a member of the Primary Care Research Network and undertaking ethically approved research studies.	19/03/2014
Dr Duncan Angus	No interest declared	19/03/2014
Dr John Bull	No interests declared	19/03/2014
Dr Simon Walton	No interests declared	19/03/2014
Mr Maurice Marchant	Secretary of Primary Health Care Study Group and the Royal Statistical Society.	19/03/2014
Mrs Kathy Stott	No interests declared	19/03/2014
Prof Angie Hart	Co-director, Boingboing resilience research, social enterprise. Decision making panel for the Big Lottery Fund's resilience investment. University Researcher.	19/03/2014
Miss Samantha Lippett	Undertook consultancy work for Astella's relating to products with UK license (Fidaxomicin & Micafungin) – July 2014.	19/03/2014

Meetings for Full Ethical Review 01 April 2013 - 31 March 2014:

Month	Date	Number of Members Present at Meeting
April	04/04/2013	8
May	02/05/2013	12
June	06/06/2013	10
July	04/07/2013	8
August	01/08/2013	13
September	05/09/2013	11
October	03/10/2013	8
November	07/11/2013	8
December	12/12/2013	8
February	06/02/2014	7

10 full committee meetings were held during the reporting period.

Proportionate Review Sub Committee Meetings held during 01 April 2013 - 31 March 2014:

Month	Date	Number of Members Present at Meeting
April	23/04/2013	3
May	24/05/2013	3
June	25/06/2013	3
July	23/07/2013	4
August	27/08/2013	3
September	24/09/2013	3
October	29/10/2013	3
November	19/11/2013	3
December	03/12/2013	3
February	25/02/2014	3
March	11/03/2014	3
March	25/03/2014	3

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

Attendance of Members: 01 April 2013 – 31 March 2014:

Name	Number of Meetings Attended
Dr John Bull	9
Mrs Susan Waton	9
Mr Gerard Cronin	8
Dr Simon Walton	8
Dr Jill Adams	7
Ms Nicola Mason	6
Mr Maurice Marchant	6
Dr Duncan Angus	6
Dr Paul Seddon	5
Mr Stuart Heatherington	5
Mrs Kathy Stott	5
Mr Bill Kent	5
Dr Sue Eckstein	4
Miss Samantha Lippett	4
Dr Stuart White	3
Prof Angie Hart	2
Dr Martin Parry	1

Number of inquorate meetings held: None

**Attendance of Members at proportionate review sub-committee meetings:
01 April 2013 – 31 March 2014:**

Name	Number of Meetings Attended
Dr John Bull	7
Mr Maurice Marchant	6
Mr Bill Kent	5
Dr Paul Seddon	4
Mr Gerard Cronin	4
Dr Simon Walton	4
Mrs Susan Waton	3
Dr Duncan Angus	2
Dr Martin Parry	1
Mr Stuart Heatherington	1

Training 01 April 2013 – 31 March 2014:

Name of Member	Date	Event(s) attended
Dr Sue Eckstein	17/04/2013 - 17/04/2013	Ethical review of Mental Health/Psychiatric research, NRES
Dr Duncan Angus	17/04/2013 - 17/04/2013	Ethical review in Mental Health, NRES
Dr Jill Adams	25/04/2013 - 25/04/2013	Good Clinical Practice Update, Other
Dr John Bull	02/09/2013 - 02/09/2013	London Chair's Meeting, NRES
Ms Nicola Mason	15/05/2013 - 15/05/2013	Equality & Diversity, East Sussex Healthcare NHS Trust
Dr John Bull	11/12/2013 - 11/12/2013	National Training Day for NRES Committee Chairs, HRA
Dr Stuart White	01/12/2013 - 01/12/2013	Publication of article in Anaesthesia 2014

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	26.09
Phase 1	0	0.00
Gene Therapy	0	0.00
Research Tissue Bank	0	0.00
Research Database	0	0.00
Others	34	73.91
Total Applications Reviewed	46	100

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	10
Number of paediatric applications reviewed	10
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	1	2.17
Favourable Opinion with Additional Conditions	4	8.70
Unfavourable Opinion	7	15.22
Provisional Opinion	34	73.91
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	46	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	30	65.22
Further Information Favourable Opinion with Additional Conditions	4	8.70
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	1	2.17
Favourable Opinion with Additional Conditions	4	8.70
Unfavourable Opinion	7	15.22
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	0	0.00
Total	46	100

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

Total Applications Reviewed	26
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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	5	19.23
Favourable Opinion with Additional Conditions	5	19.23
No Opinion transfer to full committee for review	10	38.46
Provisional Opinion	6	23.08
Unfavourable Opinion	0	0.00
Total	26	100

Table 7: Other Management Information for the reporting period:

Average number of applications reviewed per full meeting	4.18
Number of applications for full ethical review over 60 days	4
Number of applications over 60 days as a % of total	8.70%
Number of days taken to final decision - average	42
Number of days taken to final decision - mode	35
Number of SSAs (non-Phase 1) reviewed	4
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	124
Number of substantial amendments over 35 days	16
Number of substantial amendments over 35 days as a % of total substantial amendments	12.9%
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	9
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	9
Number of proportionate review applications over 14 days as a % of total	56.3%

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
13/LO/0374	Pre U7-53 Study	30
13/LO/0422	ICG clearance in patients randomised to FOLFOX or FOLFIRI	35
13/LO/0499	SARIL-RA-ASCERTAIN - SFY13370 (CCRN 1085)	47
13/LO/0567	CBT for psychosis	54
13/LO/0572	Phase III of Two Single tablet regimens in HIV-1 Positive Adults	53
13/LO/0574	Phase 3 of Two Single tablet regimens in HIV-1 Positive Adults	53
13/LO/0577	The introduction of Petra Running-bikes: a pilot study	56
13/LO/0652	Imiquimod chemotherapy adjuvant periocular BCC	69
13/LO/0806	Lipomodelling of peri-stomal symptomatic skin contour abnormalities	34
13/LO/1024	AFFIRM- COPD Acclidinim and Formoterol Findings in Respiratory Medicine	25
13/LO/1029	HIV Bioresource	56
13/LO/1082	RINCAL Trial	38
13/LO/1108	UPBEAT TEMPO	38
13/LO/1115	PIVOTAL	36
13/LO/1177	Minoritised womens' narratives of recovering from an eating disorder	46
13/LO/1185	Pilot Study of White Matter in Early Psychosis Version 93838-1	42
13/LO/1199	Long Term Safety and Efficacy of Baricitinib in Patients with RA	35
13/LO/1261	DECAN Study	35
13/LO/1302	Dolutegravir/abacavir/lamivudine vs a standard HIV regimen in females	43
13/LO/1421	Transliminality and interpersonal difficulties	33
13/LO/1426	Dobutamine in haemodynamic insufficiency of extreme prematurity (v1)	33
13/LO/1441	Self-sampled HPV testing for cervical screening non-attenders v 1.0	54
13/LO/1450	Pregnancy lifestyle intervention & childhood cardiovascular function	47
13/LO/1528	Quality of Life in Survivors of Out of Hospital Cardiac Arrest V1	18
13/LO/1532	Impact of middle ear and mastoid surgery on quality of life	16
13/LO/1553	Experiences of young people with neuromuscular diseases	53
13/LO/1587	The Restless Mind	55
13/LO/1622	A GT study of engagement with an adolescent sex offender group v.1	61
13/LO/1727	Inhaler technique: Does counselling by pharmacists have a benefit?	21

13/LO/1806	Seizures and arousal: epileptiform activity and autonomic control	37
13/LO/1866	Cardiac Control of Fear in Brain: relationship to anxiety symptoms	50
13/LO/1911	Comparison of Lantus, Lixisenatide and Lixilan in Type 2 diabetes	44
14/LO/0069	A study of XEN-0103 in patients with Atrial Fibrillation	31
14/LO/0375	Patient based questionnaire for screening LUTS related to BPE/BPO	26
14/LO/0382	Effects of shoes in individuals with intermittent claudication	18
14/LO/0384	Haemato-oncology patients' perceptions of quality of life post ICU v.2	57

Further Information Favourable Opinion with Additional Conditions

REC Reference	Application Short Title	Number of Days on Clock
13/LO/0740	A5481008	47
13/LO/0801	Dapagliflozin Effect on Cardiovascular Events	38
14/LO/0137	A review of Frontal Fibrosing Alopecia	56
14/LO/0168	Impact of bariatric surgery on cardiorespiratory function	64

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
13/LO/0841	Blood compatibility studies for basic research	14
13/LO/1058	i4i ADEPT Version 1.1	14
13/LO/1381	Observational study describing the culture of hospital visiting time.	24
13/LO/1388	Retrospective notes review of patients on DUODOPA	19
13/LO/1721	Does chronic intermittent hypoxia affect hematocrit level?	6
13/LO/1912	Group B Streptococcal disease in infants less than 90 days of age	31

Favourable Opinion with Additional Conditions

REC Reference	Application Short Title	Number of Days on Clock
13/LO/0660	Mothers' views of a webcam service for children who stammer	11
13/LO/0662	IMPACCT: health economics survey of patients with cancer pain	11
13/LO/0959	Investigating Vitreous Oxygenation in CRVO & DR Using MRI - Pilot	21
13/LO/1111	eSTI2 chlamydia clinical care pathway pilot study	50

13/LO/1178	MRI study of nerve inflammation in whiplash	29
13/LO/1380	I-Scan a novel endoscopic tool for identification of mucosal lesions	24
13/LO/1870	Exploring influences on physical activity levels in stroke survivors.	31
13/LO/1915	Clinical Follow-up of ASR Patients Post-Recall v.2-0	13
13/LO/1920	A qualitative interview study to evaluate patient's experience on pain	13

Unfavourable Opinion

REC Reference	Application Short Title	Number of Days on Clock
13/LO/0397	Frozen Shoulder: Manipulation versus Arthroscopic Capsular Release	28
13/LO/0474	What are the interpersonal mechanisms of change in IPT for depression?	33
13/LO/0794	Prolong™ Climax	35
13/LO/1068	Service utilisation in people with high CPM scores	61
13/LO/1103	Abbreviated Mentalization Based Therapy in Borderline Crises(AMBIC)	34
13/LO/1657	Mechanisms of Primary Lymphoedema	38
14/LO/0166	Achalasia: mechanisms underlying persistent symptoms after treatment	37

Provisional Opinion

REC Reference	Application Short Title	Number of Days on Clock
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Provisional Opinion Pending Consultation with Referee

REC Reference	Application Short Title	Number of Days on Clock
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Further information response not complete

REC Reference	Application Short Title	Number of Days on Clock
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Withdrawn after the meeting

REC Reference	Application Short Title	Number of Days on Clock
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Invalid Application

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

REC Reference	Application Short Title	Number of Days on Clock
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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
13/LO/0652	Imiquimod chemotherapy adjuvant periocular BCC	69
13/LO/1068	Service utilisation in people with high CPM scores	61
13/LO/1622	A GT study of engagement with an adolescent sex offender group v.1	61
14/LO/0168	Impact of bariatric surgery on cardiorespiratory function	64

Proportionate review applications for ethical review over 14 days timeline		
REC Reference	Application Short Title	Number of Days on Clock
13/LO/1380	I-Scan a novel endoscopic tool for identification of mucosal lesions	24
13/LO/1381	Observational study describing the culture of hospital visiting time.	24
13/LO/1388	Retrospective notes review of patients on DUODOPA	19
13/LO/1528	Quality of Life in Survivors of Out of Hospital Cardiac Arrest V1	18
13/LO/1532	Impact of middle ear and mastoid surgery on quality of life	16
13/LO/1727	Inhaler technique: Does counselling by pharmacists have a benefit?	21
14/LO/0375	Patient based questionnaire for screening LUTS related to BPE/BPO	26
14/LO/0382	Effects of shoes in individuals with intermittent claudication	18
14/LO/0384	Haemato-oncology patients' perceptions of quality of life post ICU v.2	57

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
13/LO/0107/AM01	The immunological basis of preterm delivery	Substantial amendment 1 (AM01)	55

13/LO/0244/AM04	Pilot Study investigating Cortisol and Behaviour in Fragile X Syndrome	Amendment 4; 25/9/13	46
09/H1103/40/AM01	SYMPPLICITY HTN-2 (TP-058, ver. 1.0)	Addendum: Protocol Number: TP-058. Revision: 1.0.	41
13/LO/1177/AM01	Minoritised womens' narratives of recovering from an eating disorder	Substantial Amendment 1	37
13/LO/1441/AM01	Self-sampled HPV testing for cervical screening non-attenders v 1.0	Amendment 1 - 21 Nov 2013	39
13/LO/0411/AM01	BMRI- CAM 1	Substantial Amendment 1	36
13/LO/1302/AM04	Dolutegravir/abacavir/lamivudine vs a standard HIV regimen in females	Substantial Amendment 3	38
12/LO/1942/AM01	Joint Hypermobility	1, 26/11/2013	36
10/H1101/69/AM03	Non-invasive physiological biomarkers in health and disease	V5; 04 FEB 2014	52
13/LO/1177/AM02	Minoritised womens' narratives of recovering from an eating disorder	Version 4 February 2014	48
13/LO/0244/AM08	Pilot Study investigating Cortisol and Behaviour in Fragile X Syndrome	AMO6 22/01/2014	46
08/H1107/35/AM08	e-Biomatrix	7.0 10th February 2014	46
13/LO/1587/AM01	The Restless Mind	New documents: 1) Invitation to take part Version 1	52
12/LO/1954/AM01	Maraviroc Switch Renal Substudy	2.0 18th December 2013	55
13/LO/1302/AM05	Dolutegravir/abacavir/lamivudine vs a standard HIV regimen in females	Amendment 4	55
13/LO/1302/AM06	Dolutegravir/abacavir/lamivudine vs a standard HIV regimen in females	Substantial Amendment 5	52

Modified Amendments over 14 day timeline

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

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