

National Research Ethics
Service


Health Research Authority

NRES Committee London - South East

Annual Report

01 April 2013 – 31 March 2014

Part 1 – Committee Membership and Training

Name of REC:	NRES Committee London - South East
Type of REC:	RECs recognised to review CTIMPS in patients - type iii
Type of Flag:	Establishing Research Databases Research Involving Adults Lacking Capacity Research Involving Prisoners or Prisons
Chair:	Professor David Caplin
Vice-Chair:	Mrs Vera Hughes
Alternate Vice-Chair:	Dr Alan Fishtal
REC Manager:	Mr Rajat Khullar
PRSC Manager:	Mr Rajat Khullar
Assistant Co-ordinator:	Mr. Wai Yeung
Committee Address:	Bristol Research Ethics Committee Centre Level 3, Block B Whitefriars, Lewins Mead, Bristol BS1 2NT
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Chair's overview of the past year:

I am pleased to say that the Committee found itself in a stable environment for 2013-2014; the Bristol office continued to serve us well, and the REC Manager, Mr Rajat Khullar and REC Assistant, Mr. Wai Yeung, have not only worked hard and effectively, but also used their initiative with the REC members, who are now well-known to them.

As previously, the workload has been heavy, almost invariably with the full complement of 6 studies at each meeting. It is worth commenting that with rare exceptions, the studies for which we have given "Unfavourable" decisions have had worthy research objectives, but have faced complex or demanding ethical issues; in those cases the REC has endeavoured to be constructive and to ensure that their reasoning is totally clear to the applicant.

At the beginning of the year, the membership numbers were already low, and during the year our hard-working and invaluable pharmacist member, Mr Roy Sinclair, came to the end of his term. We have now recruited successfully, including some members with previous REC experience. However, for some months we had a dearth of members able to serve on sub-Committees for Substantial Amendments; given the large numbers of SAs that the REC receives, this put a heavy burden on those that were able to do the work.

NRES Committee London - South East Membership:

Name	Occupation	Expert or Lay	Dates	
			Appointed	Resigned
Dr Ashok Bhiman	Consultant Psychiatrist	Expert	01/07/2007	
Professor David Caplin	Physicist	Lay	01/10/2003	
Ms Stephanie Cooper	Retired Solicitor	Lay Plus	23/01/2013	
Mr Ron Driver	University Lecturer/Statistician	Lay	01/06/2009	
Professor John Eastwood	Consultant Renal Physician	Expert	01/01/2008	
Dr Alan Fishtal	GP	Expert	01/01/2008	
Dr Ann Gallagher	Reader in Nursing Ethics (Nurse Member)	Expert	01/06/2007	
Mr Guy Gardener	Retired Assistant Chief Constable	Lay Plus	01/10/2007	
Mrs Vera Hughes	Training Consultant	Lay Plus	01/10/2003	
Professor Robin MacKenzie	Director Medical Law & Ethics	Lay Plus	01/01/2007	
Mr Roy Sinclair	Former Pharmacist	Expert	01/01/2002	31/12/2013
Mr Graham Smith	Business Consultant	Lay Plus	14/01/2013	
Ms Vanda Taylor	Senior Cancer Information Nurse	Expert	14/01/2013	
Professor Zahur Zaman	Retired Clinical Pathologist	Expert	24/02/2014	

Co-opted Members

Name	Occupation	Expert or Lay	Meeting date attended
Mr Roy Sinclair	Former Pharmacist	Expert	12/03/2014

NRES Committee London - South East: Members' Declarations of Interest:

Name	Declaration of Interest	Date
Professor David Caplin	Shareholding in Smith and Nephew (joint implants etc) (Medical Device manufacturer)	27/02/2014
Mrs Vera Hughes	None	27/02/2014
Dr Alan Fishtal	None	27/02/2014
Professor Robin MacKenzie	None	27/02/2014
Dr Ann Gallagher	None	27/02/2014
Dr Ashok Bhiman	None	27/02/2014
Mr Guy Gardener	None	27/02/2014
Professor John Eastwood	Hon. Consultant Physician, St George's Hospital London. Emeritus Professor, St George's University of London, SW17 0RE Shares in AstraZeneca, held in 1996 The Kathleen Valles Charitable Trust, Chairman since 1999	27/02/2014
Mr Ron Driver	None	27/02/2014
Ms Stephanie Cooper	None	27/02/2014
Ms Vanda Taylor	Works as a cancer information nurse for Cancer Research UK.	27/02/2014
Mr Graham Smith	None	27/02/2014
Professor Zahur Zaman	None	01/03/2014

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

Month	Date	Number of Members Present at Meeting
April	10/04/2013	11
May	08/05/2013	9
June	12/06/2013	12
July	10/07/2013	11
August	14/08/2013	8
October	09/10/2013	12
November	13/11/2013	9
December	11/12/2013	8
January	08/01/2014	11
February	12/02/2014	9
March	12/03/2014	11

11 full committee meetings were held during the reporting period.

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

Name	Number of Meetings Attended
Mr Ron Driver	11
Ms Stephanie Cooper	11
Professor David Caplin	10
Mr Roy Sinclair	10
Mrs Vera Hughes	10
Dr Alan Fishtal	9
Mr Guy Gardener	9
Professor Robin MacKenzie	9
Professor John Eastwood	8
Ms Vanda Taylor	8
Mr Graham Smith	7
Dr Ann Gallagher	6
Dr Ashok Bhiman	2
Professor Zahur Zaman	1

Number of inquorate meetings held: 0

Training 01 April 2013 – 31 March 2014:

Name of Member	Date	Event(s) attended
Ms Vanda Taylor	04/07/2013 - 04/07/2013	Induction, HRA
Mr Graham Smith	04/07/2013 - 04/07/2013	Induction, HRA
Ms Vanda Taylor	04/09/2013 - 04/09/2013	Research Involving Adults Who Lack Capacity, HRA
Mrs Vera Hughes	04/11/2013 - 04/11/2013	Training Material on Human Tissues Act, Mental Capacity Act and Qualitative Research, NRES
Mrs Vera Hughes	07/11/2013 - 07/11/2013	Prison Visit - Elmley Prison - HMP Rochester, David Caplin
Professor David Caplin	01/11/2013 - 01/11/2013	Training Material on Human Tissues Act, Mental Capacity Act and Qualitative Research, NRES
Professor David Caplin	07/11/2013 - 07/11/2013	Prison Visit - Elmley Prison - HMP Rochester, David Caplin
Dr Alan Fishtal	07/11/2013 - 07/11/2013	Prison Visit - Elmley Prison - HMP Rochester, David Caplin
Dr Alan Fishtal	01/11/2013 - 01/11/2013	Training Material on Human Tissue Act, Mental Capacity Act and Qualitative Research, NRES
Professor Robin MacKenzie	07/11/2013 - 07/11/2013	Prison Visit - Elmley Prison - HMP Rochester, David Caplin
Professor Robin MacKenzie	30/10/2013 - 30/10/2013	Training Material on Human Tissues Act, Mental Capacity Act and Qualitative Research, NRES
Dr Ann Gallagher	07/11/2013 - 07/11/2013	Prison Visit - Elmley Prison - HMP Rochester, David Caplin
Dr Ann Gallagher	01/11/2013 - 01/11/2013	Training Material on Human Tissues Act, Mental Capacity Act and Qualitative Research, NRES
Mr Ron Driver	07/10/2013 - 07/10/2013	Equality & Diversity, NRES, HRA
Mr Ron Driver	07/10/2013 - 07/10/2013	HRA Members Training Day, NRES, HRA
Dr Ashok Bhiman	30/10/2013 - 30/10/2013	Training Material on Human Tissues Act, Mental Capacity Act and Qualitative Research, NRES
Mr Guy Gardener	06/11/2013 - 06/11/2013	Training Material on Human Tissues Act, Mental Capacity Act and Qualitative Research, NRES
Professor John Eastwood		Equality & Diversity, NRES, HRA (Online)

Professor John Eastwood	21/11/2013 - 21/11/2013	Prison Visit - Elmley Prison - HMP Rochester, David Caplin
Professor John Eastwood	01/11/2013 - 01/11/2013	Training Material on Human Tissues Act, Mental Capacity Act and Qualitative Research, NRES
Ms Stephanie Cooper	01/11/2013 - 01/11/2013	Training Material on Human Tissues Act, Mental Capacity Act and Qualitative Research, NRES
Ms Stephanie Cooper	21/11/2013 - 21/11/2013	Prison Visit - Elmley Prison - HMP Rochester, David Caplin
Ms Stephanie Cooper	27/01/2014 - 27/01/2014	Equality & Diversity, NRES, HRA (Online)
Ms Vanda Taylor	11/12/2013 - 11/12/2013	Training Material on Human Tissues Act, Mental Capacity Act and Qualitative Research, NRES
Mr Graham Smith	11/12/2013 - 11/12/2013	Training Material on Human Tissues Act, Mental Capacity Act and Qualitative Research, NRES
Mrs Vera Hughes		Equality & Diversity, NRES, HRA (Online)
Mr Graham Smith	31/01/2014 - 01/02/2014	Equality & Diversity, NRES, HRA (Online)
Professor Robin MacKenzie	04/02/2014 - 04/02/2014	Equality & Diversity, HRA-NRES Online
Mr Graham Smith	21/11/2013 - 21/11/2013	Prison Visit - Elmley Prison - HMP Rochester, David Caplin
Dr Ann Gallagher	06/02/2014 - 07/02/2014	Equality & Diversity, NRES
Dr Alan Fishtal	19/02/2014 - 19/02/2014	Equality & Diversity, 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	14	22.22
Phase 1	0	0.00
Gene Therapy	0	0.00
Research Tissue Bank	0	0.00
Research Database	5	7.94
Others	44	69.84
Total Applications Reviewed	63	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	8
Number of student applications reviewed	17
Number of paediatric applications reviewed	7
Number of device applications reviewed	2
Number of prisoner applications reviewed	7
Number of applications involving adults unable consent reviewed	12
Number of applications reviewed funded by the US DHHS	1

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	0	0.00
Favourable Opinion with Additional Conditions	8	12.70
Unfavourable Opinion	5	7.94
Provisional Opinion	49	77.78
Invalid	0	0.00
No Opinion Pending Consultation with Referee	0	0.00
Provisional Opinion Pending Consultation with Referee	1	1.59
Not Requiring Review by NHS REC	0	0.00
Total	63	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	44	69.84
Further Information Favourable Opinion with Additional Conditions	2	3.17
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	0	0.00
Favourable Opinion with Additional Conditions	8	12.70
Unfavourable Opinion	5	7.94
Provisional Opinion	3	4.76
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	1	1.59
Number of studies withdrawn after the meeting	0	0.00
Total	63	100

Table 5: Other Management Information for the reporting period:

Average number of applications reviewed per full meeting	5.73
Number of applications for full ethical review over 60 days	0
Number of applications over 60 days as a % of total	0.00%
Number of days taken to final decision - average	40
Number of days taken to final decision - mode	43
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	122
Number of substantial amendments over 35 days	12
Number of substantial amendments over 35 days as a % of total substantial amendments	9.3%
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	5
Number of modified amendments over 14 days	2
Number of modified amendments over 14 days as a % of total modified amendments	40.0%

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
13/LO/0470	Predicting destabilisation: The family's response to alcohol treatment	43
13/LO/0520	OCTAVE, Ranibizumab in neovascular age-related macular degeneration	39
13/LO/0522	Alexithymia in prisoners	46
13/LO/0529	Electra Registry	44
13/LO/0533	Open Label MM-111 in patients with HER2	43
13/LO/0569	Foot position and muscle strength in the child with JDM	54
13/LO/0612	Cancer Patient Experience	49
13/LO/0663	FIAsp versus insulin aspart in type 1 diabetes - onset 1	34
13/LO/0669	MINIMISE STEMI trial version 1	38
13/LO/0695	TRIPHIC project	43
13/LO/0722	Supporting the health and social care needs of older prisoners	58
13/LO/0831	Aerosure for airway clearance in patients with cystic fibrosis	43
13/LO/0860	Remember to Dance: evaluating creative dance for people with dementia	37
13/LO/0884	A retrospective analysis of a patient observation database	49
13/LO/0895	Norovirus Infection in Healthcare Settings	42
13/LO/0909	Mental state inference in Borderline Personality Disorder	36
13/LO/0939	ALTO: Antipsychotic Long acTing injection in schizophrenia	36
13/LO/1035	Impulsivity and addictive behaviours in prisoners	46
13/LO/1036	Real-world reasoning and attachment in offenders	48
13/LO/1096	MID-FRAIL Study - version 01	43
13/LO/1121	LY2875358 plus Erlotinib versus Erlotinib in NSCLC (JTBB)	37
13/LO/1154	Ph.1b/II study of buparlisib with docetaxel in squamous NSCLC patients	55
13/LO/1182	Functional imaging in the assessment of mRCC response to sunitinib	60
13/LO/1317	Patient acceptance of the Implantable Cardioverter Defibrillator (ICD)	55
13/LO/1339	A palliative care intervention for people with dementia in care homes	39
13/LO/1384	Retinal oximetry after treatment for macular oedema in Vein Occlusion	34
13/LO/1407	The Role of the Circadian Clock in Alzheimer's Disease	56
13/LO/1485	Phase2/Proof of concept,Ponezumab treatment in participants with CAA	57
13/LO/1660	Impact of "telecoaching program" on physical activity in COPD patients	41

13/LO/1692	A Study of LFB-IGSC in Patients with Primary-Immunodeficiency	48
13/LO/1757	Reversible hypoxia in lung cancer (REPLICA) (version 1.0)	53
13/LO/1814	EMR200061-005: Phase III Pergoveris in ART	27
13/LO/1834	Is it right to mock - An RCT	34
13/LO/1835	Can seminal plasma injected into the uterus improve pregnancy rate	38
13/LO/1857	Physiology of Schizophrenia Spectrum Disorders	23
13/LO/1881	OPUS - A Cross-Over Study Of BCX4161 in the Prevention of HAE Attacks	52
14/LO/0004	Acceptability of intrauterine contraception: a mixed methods study v1	50
14/LO/0013	CAPPS Study, Version 1 26th of November 2013	33
14/LO/0173	An IPA of BPD prisoners experiences of DBT	38
14/LO/0195	Application of "NODDI" in Motor Neurone Disease	42
14/LO/0203	CLARITY Version 1.0	42
14/LO/0289	young people's views on the effectiveness of group CBT for depression	39
14/LO/0335	Volasertib in paediatric patients with leukaemia or solid tumour.	52
14/LO/0383	ASSERT 2 Database (Version 1)	32

Further Information Favourable Opinion with Additional Conditions

REC Reference	Application Short Title	Number of Days on Clock
13/LO/1508	Immediate coronary angiography after out of hospital cardiac arrest	55
14/LO/0019	Bone healing in osteoporotic and non-osteoporotic women	30

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
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Favourable Opinion with Additional Conditions

REC Reference	Application Short Title	Number of Days on Clock
13/LO/0594	Exploring the role of faith & spirituality for the QOL of PWID.	26
13/LO/0873	Evaluating the Integrate Model for socially excluded young people	32
13/LO/0979	BPV and Stroke: Its Measurement, Natural History and Prognosis	29
13/LO/1656	The LIXI study	28

13/LO/1775	The PRAETORIAN trial: Subcutaneous ICD versus Transvenous ICD	26
14/LO/0171	British Childhood Cancer Survivor Study - Case-Control Studies (v1.0)	28
14/LO/0347	Music Therapy Rehabilitation for Disorders of Consciousness	29
14/LO/0373	Older homeless people, memory problems and service use	29

Unfavourable Opinion

REC Reference	Application Short Title	Number of Days on Clock
13/LO/0655	Long-term psychosocial impact of severely burned patients	27
13/LO/0828	Charcot Marie Tooth Disease - International Database	26
13/LO/1659	Neuropsychiatric complications and QOL in adult patients with IMD	55
13/LO/1852	Measuring functional outcome following treatment for leg spasticity v1	23
14/LO/0007	young people's views on the effectiveness of group CBT for depression	49

Provisional Opinion

REC Reference	Application Short Title	Number of Days on Clock
14/LO/0116	Longitudinal study of quality of life in dementia	N/A
14/LO/0236	High Vs Low Starting dose of OAB medication:A patient preference study	N/A
14/LO/0402	How is clinical decision making enacted? A pilot study.	N/A

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 7: Items exceeding timelines:

Full applications for ethical review over 60 day timeline			
REC Reference	Application Short Title	Number of Days on Clock	
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
10/H1102/66/AM02	Airway disease optimisation of pharmaco-therapy in lung cancer	AM02: CCR3480, Protocol version 2.0 dated 05.04.20	48
12/LO/0787/AM04	CIAO project	Substantial Amendment 2 dated 20 May 2013	66
07/H1102/73/AM22	LaMB	Substantial Amendment 15 dated 1st July 2013	52
10/H1102/44/AM04	Registry for Patients with Niemann-Pick Type C Disease	Substantial Amendment 3 (N Ireland) dated 16 July	44
12/LO/1297/AM04	ACT12339 - SAR100842 in Diffuse Cutaneous Systemic Sclerosis	Substantial Amendment 4 dated 18 July 2013	43
10/H1102/16/AM18	BIBW 2992 and Paclitaxel versus Chemotherapy in NSCLC	Substantial Amendment 14: IB version 14 dated 4 Ju	48
13/LO/0188/AM02	The DIME Study - Lucentis in Ischaemic Diabetic Macular Oedema	Substantial Amendment 2 dated 1 August 2013	43
12/LO/1090/AM04	MetMab combined with mFOLFOX6 in	Substantial Amendment 4 dated 5	40

	HER2 negative Met Positive GEC	September 2013	
10/H1102/16/AM19	BIBW 2992 and Paclitaxel versus Chemotherapy in NSCLC	Substantial Amendment 19 dated 7 Oct 2013	72
13/LO/0669/AM03	MINIMISE STEMI trial version 1	Substantial Amendment- Proposed protocol amendment	37
13/LO/0669/AM04	MINIMISE STEMI trial version 1	AM04 Substantial Amendment 3 dated 08/11/2013	37
13/LO/0214/AM02	GLiSten: 5-ALA in Bowel Cancer Surgery - Development Phase	AM02: Substantial Amendment dated 21 November 2013	43

Modified Amendments over 14 day timeline

Amendment Reference	Application Short Title	Amendment Title	Number of Days on Clock
12/LO/1076/AM02/1	Denosumab in Patients with Newly Diagnosed Multiple Myeloma	Modified Amendment 2 - PA2 11 Feb 13, PIS&IC v2.0	18
12/LO/0787/AM04/2	CIAO project	2nd Modified A to SA 2 dated October 2013	18

Section 30 application over 60 day timeline

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