

NRES Committee London - Bromley

Annual Report

01 April 2013 – 31 March 2014

Part 1 – Committee Membership and Training

Name of REC:	NRES Committee London - Bromley
Type of REC:	Authorised REC
Type of Flag:	Research Involving Adults Lacking Capacity
Chair:	Ms Carol Jones
Vice-Chair:	Ms Jayne Steadman
Alternate Vice-Chair:	Mrs Heather Salzer
REC Manager:	Miss Lauren Allen
REC Assistant:	Mrs Sarah Payne
Committee Address:	Bristol Research Ethics Committee Centre Whitefriars Level 3, Block B Lewins Mead Bristol BS1 2NT
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Chair's overview of the past year:

This year we have seen a rise in the complexity of studies to be considered which may reflect the slight increase in the number of unfavourable opinions this year. However, we have also seen an increase in the number of studies that have had a favourable opinion this is due to an improvement in the quality of the completed applications and researchers producing excellent Participation information sheets.

This year we have appreciated the guidance received from the HRA on specific issues examples of this have been the advice on registering of studies on a public data base and the guidance on the signing of consent forms.

We continue to be one of the few committees that do not use the lead reviewer system but we trialled the process this year and the committee decided to continue using its' current reviewing style. We may need to review this again when the new system for the taking and recording of minutes comes into force.

It is pleasing to note that the committee only breached one deadline this year and that was only by one day so thanks to the whole team especially Lauren and Sarah our administrators on achieving that.

The committee was very sad to hear of the relatively sudden death of one of our members this year Mrs Christine Rumbelow, A wonderful wise and yet pragmatic member of our committee, we will really miss her.

We welcome two new members this year, Mr Abdulzahra Hussain and Dr Joanne Brooke. Our year has ended on a real high this year as we had an outstanding training day this year looking at medical devices, philosophical ethics, and the Human Tissue Act. The speakers were exceptional and gave us the opportunity as a committee to explore these issues in real depth.

NRES Committee London - Bromley Membership:

Name	Occupation	Expert or Lay	Dates	
			Appointed	Resigned
Mr Munir Ahmed	Consultant Urologist	Expert	01/09/2009	
Mrs Susan Beer	Retired Project Manager	Lay Plus	01/08/2009	
Dr Joanne Brooke	Senior Lecturer and Nurse Consultant in Dementia	Expert	21/02/2014	
Mrs Angela Clayton-Turner	Retired NHS Therapy Manager	Lay	01/08/2009	
Mr Abdulzahra Hussain	Speciality Doctor in general surgery/senior lecturer	Expert	21/02/2014	
Ms Carol Jones	Management Consultant	Lay	01/08/2009	
Mrs Kathryn Kinnear	Solicitor	Lay Plus	01/08/2009	
Mrs Fran McMillan	Retired	Lay Plus	01/08/2009	
Rev Tim Mercer	Hospital Chaplain	Lay Plus	01/08/2009	
Dr Angela Orunta	Consultant Anaesthetist	Expert	01/08/2009	
Dr David Osoba	Associate Specialist in Paediatrics	Expert	01/08/2009	
Mrs Christine Rumbelow	Retired Charity Organiser	Lay	01/08/2009	14/06/2013
Dr Mukesh Sahi	General Practitioner	Expert	01/08/2009	14/11/2013
Mrs Heather Salzer	Ultrasound Clinical Specialist	Expert	17/07/2013	
Ms Jayne Steadman	Consultant Physiotherapist	Expert	01/08/2009	

Co-opted Members

Name	Occupation	Expert or Lay	Meeting date attended
Miss Stephanie Ellis	Formal Civil Servant	Lay Plus	21/11/2013, 12/12/2013,
Ms Alison Higgs	Lecturer- Social Work, Faculty of HSC	Lay Plus	20/02/2014, 20/03/2014

NRES Committee London - Bromley: Members' Declarations of Interest:

Name	Declaration of Interest	Date
Mrs Heather Salzer	None	02/09/2013
Ms Carol Jones	None	25/02/2014
Dr Angela Orunta	None	25/02/2014
Mrs Fran McMillan	None	25/02/2014
Mrs Kathryn Kinnear	None	25/02/2014
Mrs Heather Salzer	None	25/02/2014
Dr David Osoba	None	25/02/2014
Mr Abdulzahra Hussain	Member of European Association of Endoscopic surgery. Editorial board member of WJES. Editorial board member of journal of gastroenterology and hepatology.	25/02/2014
Mrs Susan Beer	Sits on a steering committee for a clinical trial at Moorfields as the patient representative.	25/02/2014
Dr Jo Brooke	Senior Lecturer at University of Greenwich. Nurse Consultant in Dementia- Kent Community Health NHS Trust. Applied for grant from Marie Curie and General Nursing Council to complete research within my two roles. Member of Dementia Friends Champion Alzheimer's Society. Completion of research with in my two roles and as head for the Dementia Cluster within the Centre of Positive Aging, University of Greenwich.	10/03/2014
Ms Jayne Steadman	Occasionally asked for advice on matters relating to the conduct of research by my quality department.	10/03/2014
Rev Tim Mercer	Trustee The Dalehill Trust Charity to support spiritual Care. Trustee The Friends of the Priests Royal University Hospital. Chaplaincy Training- Rochester Diocese, Church of England	24/03/2014
Mr Munir Ahmed	Consultant and Urological surgeon/Senior Lecturer and Sub Dean, King's College. Director – Urology Health Care Ltd. Reviewer of Journals. Researcher as part of employment	31/03/2014
Mrs Angela Clayton-Turner	Alzheimers society research network volunteer and occasional lay reviewer for NIHR proposals seeking funding. Member of OXLEAS NHS Trust older peoples R&D group.	31/03/2014

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

Month	Date	Number of Members Present at Meeting
April	18/04/2013	12
May	16/05/2013	9
June	20/06/2013	9
August	15/08/2013	7
September	19/09/2013	11
October	17/10/2013	8
November	21/11/2013	9
December	12/12/2013	7
January	16/01/2014	8
February	20/02/2014	9
March	20/03/2014	8

11 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	02/04/2013	3
May	28/05/2013	3
July	01/07/2013	3
September	30/09/2013	3
October	28/10/2013	3
December	02/12/2013	3
January	23/01/2014	3
March	18/03/2014	3

8 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 Angela Orunta	10
Mrs Susan Beer	10
Ms Carol Jones	9
Ms Jayne Steadman	9
Mrs Kathryn Kinnear	9
Mrs Angela Clayton-Turner	9
Mrs Fran McMillan	9
Rev Tim Mercer	8
Mr Munir Ahmed	6
Mrs Heather Salzer	6
Dr Mukesh Sahi	5
Dr David Osoba	3
Mr Abdulzahra Hussain	1
Dr Jo Brooke	1
Mrs Christine Rumbelow	1

Number of inquorate meetings held: 0

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

Name	Number of Meetings Attended
Ms Carol Jones	7
Mrs Kathryn Kinnear	3
Dr Angela Orunta	3
Mrs Angela Clayton-Turner	2
Mrs Heather Salzer	2
Ms Jayne Steadman	2
Rev Tim Mercer	2
Mrs Fran McMillan	1
Dr David Osoba	1
Mr Munir Ahmed	1

Training 01 April 2013 – 31 March 2014:

Name of Member	Date	Event(s) attended
Ms Carol Jones	11/12/2013 - 11/12/2013	National Day for NRES Committee Chairs, HRA
Mr Munir Ahmed	15/01/2014 - 15/01/2014	Equality & Diversity
Mrs Angela Clayton-Turner	13/02/2014 - 13/02/2014	Assessing the Consequences of Research, HRA
Mrs Angela Clayton-Turner	10/03/2014 - 10/03/2014	London and South East Coast NREAP/ Chairs Network Meeting , HRA
Mr Abdulzahra Hussain	11/03/2014 - 11/03/2014	Equality & Diversity, HRA
Mrs Fran McMillan	01/05/2013 - 01/05/2013	Self-Directed Learning
Ms Carol Jones	31/03/2014 - 31/03/2014	Bromley REC Annual Training Meeting, REC Manager
Ms Jayne Steadman	31/03/2014 - 31/03/2014	Bromley REC Annual Training Day, REC Manager
Mrs Heather Salzer	31/03/2014 - 31/03/2014	Bromley REC Annual Training Day, REC Manager
Rev Tim Mercer	31/03/2014 - 31/03/2014	Bromley REC Annual Training Day, REC Manager
Mrs Fran McMillan	31/03/2014 - 31/03/2014	Bromley REC Annual Training Day, REC Manager
Mrs Susan Beer	31/03/2014 - 31/03/2014	Bromley REC Annual Training Day, REC Manager
Mrs Kathryn Kinnear	31/03/2014 - 31/03/2014	Bromley REC Annual Training Day, REC Manager
Mrs Angela Clayton-Turner	31/03/2014 - 31/03/2014	Bromley REC Annual Training Day, REC Manager
Mr Munir Ahmed	31/03/2014 - 31/03/2014	Bromley REC Annual Training Day, REC Manager
Mr Abdulzahra Hussain	31/03/2014 - 31/03/2014	Bromley REC Annual Training Day, REC Manager
Dr Jo Brooke	31/03/2014 - 31/03/2014	Bromley REC Annual Training Meeting, REC Manager

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	1.70
Research Database	0	0.00
Others	58	98.30
Total Applications Reviewed	59	100

Table 2: Other REC activity during the reporting period:

Number of applications made invalid by co-ordinator	7
Number of studies withdrawn prior to the meeting	9
Number of student applications reviewed	24
Number of paediatric applications reviewed	7
Number of device applications reviewed	4
Number of prisoner applications reviewed	0
Number of applications involving adults unable consent reviewed	1
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	5	8.47
Favourable Opinion with Additional Conditions	20	33.90
Unfavourable Opinion	1	1.69
Provisional Opinion	32	54.24
Invalid	0	0.00
No Opinion Pending Consultation with Referee	0	0.00
Provisional Opinion Pending Consultation with Referee	1	1.69
Not Requiring Review by NHS REC	0	0.00
Total	59	100
Number of studies sent back to full committee meeting for final opinion	0	0.00

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	29	49.15
Further Information Favourable Opinion with Additional Conditions	3	5.08
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	4	6.78
Favourable Opinion with Additional Conditions	21	35.60
Unfavourable Opinion	1	1.69
Provisional Opinion	1	1.69
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	59	100

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

Total Applications Reviewed	15
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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	6	42.86
Favourable Opinion with Additional Conditions	8	50.00
No Opinion transfer to full committee for review	0	0.00
Provisional Opinion	1	7.14
Unfavourable Opinion	0	0.00
Total	15	100

Table 7: Other Management Information for the reporting period:

Average number of applications reviewed per full meeting	5.36
Number of applications for full ethical review over 60 days	1
Number of applications over 60 days as a % of total	1.69%
Number of days taken to final decision - average	31
Number of days taken to final decision - mode	20
Number of SSAs (non-Phase 1) reviewed	6
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	44
Number of substantial amendments over 35 days	1
Number of substantial amendments over 35 days as a % of total substantial amendments	2.3%
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	2
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	3
Number of proportionate review applications over 14 days as a % of total	20.0%

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/0452	Brain Magnetic Resonance Spectroscopy in Heart Failure	24
13/LO/0512	Family meals in families with an adolescent with anorexia nervosa	38
13/LO/0513	Parental Uncertainty and Family Functioning in Anorexia Nervosa	35
13/LO/0519	Comparison of horizontal reference lines in orthognathic patients	30
13/LO/0640	The Addiction Recovery Clinic (ARC)	32
13/LO/0643	ElectroCore - GC 003	24
13/LO/0703	Fetal Alcohol Spectrum Disorders: UK Birth Mothers' Experiences.	34
13/LO/1169	Study of the electroarchitectural substrate in atrial fibrillation	60
13/LO/1219	A laboratory based functional assessment course for amputees (v1)	36
13/LO/1246	Consent for research in primary care.	43
13/LO/1249	Uveitic ADS Study	35
13/LO/1348	Lutonix Global SFA Registry	47
13/LO/1376	Investigating the Impact of Group Work on Homicide	39
13/LO/1549	Increasing physical activity in older adults v1	31
13/LO/1726	User Evaluation of the MiniMed 640G Insulin Pump	22
13/LO/1738	Novel biomarkers in cooled newborns (Oct 2013)	21
13/LO/1745	STRATEGIC	24
13/LO/1748	UK national platform for Spinal Muscular Atrophy (SMA)	30
13/LO/1836	Mapping the development of the use of metaphor in therapeutic groups.	40
13/LO/1865	Short telomeres and pathogenesis of pulmonary fibrosis	30
13/LO/1897	The neural basis of treatment-resistance in depression	21
13/LO/1904	The role of Gastroesophageal Reflux in Scleroderma Pulmonary Fibrosis	32
13/LO/1946	Pulseboot Pilot Safety and Tolerability Study (V1)	41
14/LO/0077	Validation of the ApneaScan algorithm in sleep disordered breathing	54
14/LO/0078	The effect of CRT on the hypercapnic ventilatory response	57
14/LO/0086	Experiences of intravenous drug users with leg ulceration	32
14/LO/0300	Genetic analysis of oesophageal and head and neck cancers (version 1)	21
14/LO/0424	Online CBT for Type 1 diabetes	23
08/H0810/67+5	TransATAC tissue core and DNA research bank	36

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Further Information Favourable Opinion with Additional Conditions		
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REC Reference	Application Short Title	Number of Days on Clock
13/LO/1527	Microbiota & Radiotherapy (M & RT) Study	47
13/LO/1742	Piloting a Family Carer Support Programme V.1	27
13/LO/1905	Health assessment of sexual torture experienced by women refugees	21
13/LO/1907	Determining physical activity levels in young cystic fibrosis patients	13

Further Information Unfavourable Opinion		
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REC Reference	Application Short Title	Number of Days on Clock
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Favourable Opinion with Standard Conditions		
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REC Reference	Application Short Title	Number of Days on Clock
13/LO/0540	Predictive and prognostic biomarkers in bladder cancer	11
13/LO/0696	Glycaemic Index of foods	28
13/LO/0715	A prospective case series of patients with functional visual loss	25
13/LO/1569	Usefulness of patient-specific 3D models during clinical consultations	15
13/LO/1710	How unpleasant is endoscopy?	12
13/LO/1718	Fatty liver disease and diabetes	8
13/LO/1909	Effect of SVR post laryngopharyngoesophagectomy with gastric pull-up-1	7
14/LO/0206	Validation of brain:thymus weight ratio as a marker of fetal stress	7
14/LO/0291	ICECAP-O version 1.0	20
14/LO/0412	People with Learning Disabilities: Perceptions of the IAPT Programme	19

Favourable Opinion with Additional Conditions		
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REC Reference	Application Short Title	Number of Days on Clock
13/LO/0692	Patient Pathways & NHS Resource Use in IBS Management	14
13/LO/0848	The psychological impact of adverse drug reactions - CF adults V1	12
13/LO/0852	Qualitatively exploring the experiences of men with RA	13
13/LO/0897	NeoHIEC (V1.0)	30
13/LO/0901	Medication Acceptability and Adherence Study; MAAS	65

13/LO/0904	Amygdala neural responses in depression and bipolar disorder	27
13/LO/0915	Neuro-anatomical correlates of visuo-vestibular processing	27
13/LO/0943	EMMU	22
13/LO/1062	Investigating the relationship between social anxiety & paranoia.	8
13/LO/1064	Parent attitude	6
13/LO/1221	High Intensity Focused Ultrasound for Fibroadenomata (HIFU-F)	33
13/LO/1222	GV28855 Biomarker study in Chronic Hepatitis B	28
13/LO/1347	PROMPT	45
13/LO/1355	Small area profiles of health needs	25
13/LO/1379	Eustachian tube dysfunction in sinonasal disease	41
13/LO/1543	Prevention of Type 2 Diabetes in HIV - Version 1	36
13/LO/1551	WEM_Qual v1	15
13/LO/1561	Non-Attendance at AS clinics	17
13/LO/1571	FUTURE 4 Non-drug-interventional extension study	35
13/LO/1879	LDL receptor function in Familial Hypercholesterolaemia	20
14/LO/0090	Mascot v12	38
14/LO/0193	Brain Networks in Focal Epilepsy	20
14/LO/0207	BUCCS 2 (version 1)	7
14/LO/0213	Anxiety, periodontal therapy & salivary α -amylase	20
14/LO/0279	CAPRELSA	20
14/LO/0286	Intra-aortic haemodynamics in aortic dissection	21
14/LO/0436	Community intervention for acquired brain injury: A case series	21
14/LO/0445	Study of [^{11}C]PBR28 TSPO PET as a disease marker in MS patients	19
14/LO/0531	Reflux and quality of life in idiopathic pulmonary fibrosis	6

Unfavourable Opinion

REC Reference	Application Short Title	Number of Days on Clock
13/LO/1736	Anxiety, non-surgical periodontal therapy & salivary α -amylase	20

Provisional Opinion

REC Reference	Application Short Title	Number of Days on Clock
14/LO/0423	STR1DE: type 1 diabetes and eating disorder	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
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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
13/LO/0901	Medication Acceptability and Adherence Study; MAAS	65

Proportionate review applications for ethical review over 14 days timeline		
REC Reference	Application Short Title	Number of Days on Clock
13/LO/1561	Non-Attendance at AS clinics	17
13/LO/1569	Usefulness of patient-specific 3D models during clinical consultations	15
13/LO/1551	WEM_ Qual v1	15

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
12/LO/0104/AM05	Outcome of treatment options for Dupuytren's contracture	Amendment 3	38

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