

NRES Committee London - Bromley

Annual Report

01 April 2011 – 31 March 2012

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:	N/A
Co-ordinator:	Miss Stephanie Macpherson
PRSC Co-ordinator:	N/A
Assistant Co-ordinator:	Miss Vicky Canfield
Committee Address:	South West REC Centre Whitefriars Level 3, Block B Lewins Mead Bristol BS1 2NT
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Chair's overview of the past year:

2011/12 Report of NRES Research and Ethics committee

Welcome to the annual report of the newly named London - Bromley Research Ethics Committee.. We were delighted to receive full accreditation of our committee in 2011.

This is due to a whole team effort but in no small part the excellent administration support we have had since our administration was moved from London to Bristol. Initially we were worried about the effect that this would have on the day to day running of our committee as Bristol feels a long way away but, I am delighted to report that our concerns were totally unfounded as not only has the service the committee receives from the administration team not weakened it has in fact strengthened and the quality of communication and standard of support is outstanding.

It has been another very busy and rewarding year for our Committee, We have seen an increase in the number of studies that we review and those that we review are of a more complex nature and take more debate. This has the downside of some really epic length meetings but we are addressing this by hopefully only having a maximum of six studies in the future. We have also seen some outstanding very well written applications from researchers who have clearly given a great deal of thought and put real effort into writing their applications and also they have given important consideration to the information required to be given to potential research participants. The committee has now commenced the proportionate review scheme for reviewing studies and this has been an enjoyable facet to our work.

The committee has continued to enjoy the interaction between itself and the researchers. This year we have decided to invite the researchers back into the room at the end of our discussions to inform them of our decisions This has been very well received by the researchers and has not to date caused any difficulties.

I am very sorry to have to report the untimely and sudden death of a valued and highly respected member of our committee Josephine Hammond. Josephine was a retired Paediatrician and her contribution to ethical debate was always outstanding. We will really miss her robust energy, ready smile and the diligence with which she approached everything she did.

On a much happier note I am very pleased to report that following the interviews for the vice chair post Jayne Steadman has been appointed. Jayne is a physiotherapist by training and has been a member of our ethics committee for 2 ½ years. She is a very welcome addition to our committee management structure.

Our training this year was focused on updating on the Mental Capacity Act.

The creation of the new Health Research Authority on the 1st December 2011 heralds a new dawn for NRES and as a committee we very much look forward to the year ahead and continuing to support NRES in delivering a very professional research and ethics service.

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	
Mrs Angela Clayton-Turner	Retired NHS Therapy Manager	Lay	01/08/2009	
Dr Josephine Hammond	Retired Paediatrician	Expert	01/08/2009	01/07/2011
Ms Carol Jones	Management Consultant	Lay	01/11/2009	
Mrs Kathryn Kinnear	Solicitor	Lay Plus	01/12/2010	
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	Staff Community Paediatrician	Expert	01/08/2009	
Mr C.V. Praveen	Associate Specialist in ENT	Expert	01/08/2009	23/3/2012
Mrs Christine Rumbelow	Retired Charity Organiser	Lay	01/08/2009	
Dr Mukesh Sahi	General Practitioner	Expert	01/08/2009	
Ms Jayne Steadman	Consultant Physiotherapist	Expert	01/08/2009	

Deputy Members

Name	Occupation	Expert or Lay	Meeting date attended
N/A			

Co-opted Members

Name	Occupation	Expert or Lay	Meeting date attended
N/A			

Member Bank

Name	Occupation	Expert or Lay	Meeting date attended
N/A			

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

Name	Declaration of Interest	Date
Ms Carol Jones	Partner of Oak Tree Management & Training Consultancy	16/02/2012
Ms Jayne Steadman	There are no declarations of interest.	23/01/2012
Rev Tim Mercer	Priest of the Church of England Member of the College of Healthcare Chaplains Clinical Ethics Committee - South London Healthcare NHS Trust.	23/01/2012
Dr Mukesh Sahi	Member of QoE Assessor team.GP Appraiser Bromley/South London	31/01/2012
Mrs Fran McMillan	There are no declarations of interest	24/01/2012
Dr David Osoba	There are no declarations of interest	27/01/2012
Mrs Susan Beer	Member of The Marfan Trust Member of International Glaucoma Association	15/12/2011
Mrs Christine Rumbelow	There are no declarations of interest	11/12/2011
Mrs Kathryn Kinnear	There are no declarations of interest	21/12/2011
Mrs Angela Clayton-Turner	Member of Alzheimer's Society research network of volunteers. Co-opted member of Alzheimer's Society Nomination and appointments committee (voluntary)Volunteer members of Oxleas NHS Foundations Trust R&D Committee for older people.	26/01/2012
Mr Munir Ahmed	There are no declarations of interest	31/03/2012
Dr Angela Orunta	There are no declarations of interest	31/03/2012

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

Month	Date	Number of Members Present at Meeting
May	19/05/2011	11
June	16/06/2011	9
July	21/07/2011	10
August	18/08/2011	10
November	17/11/2011	9
January	19/01/2012	8
February	16/02/2012	9
March	15/03/2012	10

8 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
February	01/02/2012	3
March	03/03/2012	3

2 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 Angela Orunta	8
Mrs Angela Clayton-Turner	8
Ms Carol Jones	8
Rev Tim Mercer	7
Mrs Kathryn Kinnear	7
Dr Mukesh Sahi	7
Mrs Susan Beer	6
Ms Jayne Steadman	6
Mrs Fran McMillan	5
Mr C.V. Praveen	5
Mr Munir Ahmed	3
Mrs Christine Rumbelow	3
Dr Josephine Hammond	2
Dr David Osoba	1

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
Ms Carol Jones	2
Ms Jayne Steadman	1
Dr Mukesh Sahi	1
Mrs Fran McMillan	1
Mrs Kathryn Kinnear	1

Training 01 April 2011 – 31 March 2012:

Name of Member	Date	Event(s) attended
Mr Munir Ahmed	26/07/2011 - 26/07/2011	Medical Devices, NRES
Mr Munir Ahmed	07/12/2011 - 07/12/2011	Statistics Training, NRES
Dr David Osoba	06/10/2011 - 06/10/2011	NRES Researcher Training Day, NRES
Dr Angela Orunta	15/09/2011 - 15/09/2011	NRES Tissue Act training, NRES
Dr Angela Orunta	07/12/2011 - 07/12/2011	NRES Statistics Training for NRES REC Members, NRES
Mr C.V. Praveen	17/01/2012 - 17/01/2012	Adults Lacking Capacity (including research in emergency situations) workshop for RECS, NRES
Dr Angela Orunta	28/02/2012 - 28/02/2012	Qualitative Research and Ethical Review, NRES
Ms Jayne Steadman	14/04/2011 - 14/04/2011	Bespoke Ethics Committee Training, NRES
Mrs Angela Clayton-Turner	14/04/2011 - 14/04/2011	Bespoke Ethics Committee Training, NRES
Mrs Susan Beer	14/04/2011 - 14/04/2011	Bespoke Ethics Committee Training, NRES
Mrs Fran McMillan	14/04/2011 - 14/04/2011	Bespoke Ethics Committee Training, NRES
Rev Tim Mercer	14/04/2011 - 14/04/2011	Bespoke Ethics Committee Training, NRES
Ms Carol Jones	14/04/2011 - 14/04/2011	Bespoke Ethics Committee Training, NRES
Mrs Kathryn Kinnear	14/04/2011 - 14/04/2011	Bespoke Ethics Committee Training, NRES
Dr Angela Orunta	14/04/2011 - 14/04/2011	Bespoke Ethics Committee Training, NRES
Mrs Christine Rumbelow	14/04/2011 - 14/04/2011	Bespoke Ethics Committee Training, NRES
Dr Mukesh Sahi	14/04/2011 - 14/04/2011	Bespoke Ethics Committee Training, 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	45	100.00
Total Applications Reviewed	45	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	21
Number of paediatric applications reviewed	5
Number of device applications reviewed	0
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	8	17.39
Favourable Opinion with Additional Conditions	14	30.43
Unfavourable Opinion	4	8.70
Provisional Opinion	19	41.30
Invalid	0	0.00
No Opinion Pending Consultation with Referee	0	0.00
Provisional Opinion Pending Consultation with Referee	1	2.17
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	18	39.13
Further Information Favourable Opinion with Additional Conditions	0	0.00
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	8	17.39
Favourable Opinion with Additional Conditions	14	30.43
Unfavourable Opinion	4	8.70
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	1	2.17
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	8
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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	1	12.50
Favourable Opinion with Additional Conditions	2	25.00
No Opinion transfer to full committee for review	2	25.00
Provisional Opinion	3	37.50
Unfavourable Opinion	0	0.00
Total	8	100

Table 7: Other Management Information for the reporting period:

Average number of applications reviewed per full meeting	5.63
Number of applications for full ethical review over 60 days	2
Number of applications over 60 days as a % of total	4.44%
Number of days taken to final decision - average	36
Number of days taken to final decision - mode	27
Number of SSAs (non-Phase 1) reviewed	1
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	1
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)	0.0%
Number of substantial amendments reviewed	30
Number of substantial amendments over 35 days	1
Number of substantial amendments over 35 days as a % of total substantial amendments	3.3%
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	4
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	50.00%

***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/0610	Patient perspectives on multidisciplinary teams in urology	41
11/LO/0623	Emotional processing in prodromal psychosis	73
11/LO/0837	A pilot study comparing post-op pain control after axillary dissection	49
11/LO/0881	DH PRP PRE PREGNANCY HEALTH & CARE (V.1)	51
11/LO/0888	Computerised decision support (CDS) for bowel cancer (adjuvant)	49
11/LO/1070	Is the IPAQ an effective prognostic tool to assess cardiac risk	55
11/LO/1091	Liberating the NHS, at what cost?	55
11/LO/1234	Implicit Theories of Firesetters [V2]	34
11/LO/1264	An evaluation of RNIB's Community Engagement Projects v1	55
11/LO/1266	Age-related changes in immunity	40
11/LO/1279	Cross-sectional irradiated carotid IMT study v2.1	54
11/LO/1280	Prospective carotid IMT study v2.1	54
11/LO/1875	Treatment for sleep in adults with ID	38
12/LO/0104	OUTCOME OF TREATMENT OPTIONS FOR DUPUYTREN'S CONTRACTURE	27
12/LO/0114	Fabry Imaging and Neuropsychology Observational Study (FINO study)	28
12/LO/0202	Surviving cardiac arrest: patients' experiences.	13
12/LO/0205	INCENTIVE:Improving the organisation & delivery of dental health care	49
12/LO/0206	Physical activity in patients with critical limb ischaemia (CLI).	12
12/LO/0210	Cognitive Profiling in OCD: Version 1	13
12/LO/0385	Exploring the stories of parents from care backgrounds(version 1).	28
12/LO/0442	Outcome Measures In Duchenne Muscular Dystrophy	28

Further Information Favourable Opinion with Additional Conditions		
REC Reference	Application Short Title	Number of Days on Clock

Further Information Unfavourable Opinion		
REC Reference	Application Short Title	Number of Days on Clock

Favourable Opinion with Standard Conditions		
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REC Reference	Application Short Title	Number of Days on Clock
11/LO/0468	Measuring Quality of Life in Children with Sickle Cell Anaemia.	48
11/LO/1089	Retinal oximetry after treatment of diabetic maculopathy. version 1	19
11/LO/1101	(duplicate) (duplicate) The experience of caring during a mental health	27
11/LO/1122	Self-modelled action observation in stroke rehabilitation Version 1	25
11/LO/1126	Psychological Therapy & Primary Antibody Deficiency Syndrome	27
11/LO/1871	Prevalence of PTSD and Psychological Distress post Facial Injury	20
11/LO/1887	Family Interview pilot (Relationship episode interview). Version 1.	18
11/LO/1890	The repeatability of preoperative CPET	18
12/LO/0421	Initial evaluation of CC-GCS: a novel consultation rating scale	17

Favourable Opinion with Additional Conditions		
REC Reference	Application Short Title	Number of Days on Clock
11/LO/0583	laryngeal reinnervation versus type I thyroplasty	27
11/LO/0611	The role of religion for people with dementia living in care homes.	36
11/LO/0622	Intracranial effects of iv Mg and pilot study of effects on EEG - v1	62
11/LO/0840	Academic award and recontextualising knowledge	33
11/LO/0853	Genome wide association study for primary open angle glaucoma.	27
11/LO/0878	Evaluation of a beta-lactam suspected allergy card	22
12/LO/0065	Mentalization in the art therapy triangular relationship	38
12/LO/0230	Using TMS to predict treatment effectiveness in epilepsy	34
12/LO/0243	Communication about hereditary cancer	33
12/LO/0248	A description of MS management pathways in UK clinical practice	34
12/LO/0252	A prospective RCT of surgical techniques for extraction of third molar	37
12/LO/0258	PB visual exploration MRL stroke	36
12/LO/0422	Role of Epicardial Adipose Tissue Adipokines	21
12/LO/0423	Using the levonogestrel intrauterine system for menorrhagia	21
12/LO/0428	MASTER Cancer	19
12/LO/0468	Investigating aberrant metacognition in schizophrenia	19

Unfavourable Opinion		
REC Reference	Application Short Title	Number of Days on Clock

11/LO/0694	Implicit Theories of Firesetters [V1]	19
11/LO/0702	Mindapples: 5-a-day for your mind (v1)	55
11/LO/0876	An investigation of the causes of failures in postoperative care	26
11/LO/1104	What is the Impact on Professionalism of Band 7 Nurses Plagiarising?	27

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
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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
11/LO/0622	Intracranial effects of iv Mg and pilot study of effects on EEG - v1	62
11/LO/0623	Emotional processing in prodromal psychosis	73

Proportionate review applications for ethical review over 14 days timeline		
REC Reference	Application Short Title	Number of Days on Clock
12/LO/0421	Initial evaluation of CC-GCS: a novel consultation rating scale	17
12/LO/0422	Role of Epicardial Adipose Tissue Adipokines	21
12/LO/0423	Using the levonogestrel intrauterine system for menorrhagia	21

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
07/H0809/49/AM08	Patient contributions to the evidence base	AM08 Substantial Amendment 6	49

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

