

**NRES Committee London -
Bloomsbury**

Annual Report

01 April 2011 – 31 March 2012

Part 1 – Committee Membership and Training

Name of REC:	NRES Committee London - Bloomsbury
Type of REC:	1 and 3
Type of Flag:	Paediatrics
Chair:	Dr Joe Brierley
Vice-Chair:	Reverend Jim Linthicum
Alternate Vice-Char:	n/a
Co-ordinator:	Ashley Totenhofer (since May 2012 previously Taki Austin)
PRSC Co-ordinator:	n/a
Assistant Co-ordinator:	n/a
Committee Address:	HRA NRES Centre Manchester Barlow House 3rd Floor 4 Minshull Street Manchester M1 3DZ
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Chair's overview of the past year:

A year of transition for the Bloomsbury (nee Institute of child health) REC in which our administrator for around 8 years, Taki Austin left. Many thanks to her, to Georgina our excellent interim administrator and a special welcome to Ashley Totenhofer our new administrator - who in a further change is based in sunny Manchester.

We have also lost some long-standing members such as Kate Khair and Mario Cortina Borja - many thanks to them, and welcomed some new and returning members such as Toni Hall and Rosa Piser.

Jim Linthicum plows on as an excellent vice chair and I am grateful to both him, and all our members for their excellent help in maintaining our standards in terms of feedback from researchers, and process targets.

The committee have also embraced Proportionate Review, and electronic subcommittees and have contributed to the RCPCH paediatric research ethics writing group and continue to review studies with complex paediatric ethical issues at HRA request.

NRES Committee London - Bloomsbury Membership:

Name	Occupation	Expert or Lay	Dates	
			Appointed	Resigned
Dr Joe Brierley	Consultant Intensivist	Expert	12/05/2005	
Dr Fiona Castell <i>[maternity leave from February 2012]</i>	Clinical Oncologist	Expert	17/05/2011	
Dr Mario Cortina Borja	Statistician	Expert	10/04/2007	
Ms Sally Doganis	Executive Producer and Media Consultant	Lay	23/03/2011	
Professor Faith Gibson	Clinical Professor of Children and Young People's Cancer Care	Expert	12/05/2005	
Ms Stacey Golding	Pharmacist	Expert	19/05/2011	30/09/2011
Mrs Toni Hall <i>[secondment from July 2011]</i>	Radiographer	Expert	25/07/2007	
Dr Michael Jacobs	Lay member - Retired Pharmacologist	Lay	01/09/2002	
K Khair	Consultant Nurse	Expert	01/06/2002	
Ms Claire Khalil	Pharmacist	Expert	31/07/2009	
Dr Rachel L Knowles	Clinical Research Fellow	Expert	17/10/2008	
Dr John Lamberty	Consultant in Pain Medicine	Expert	29/07/2009	
Reverend Jim Linthicum	Lay member, Hospital Chaplain	Lay	30/05/2007	
Mr Roger Selby	Lay member, Retired Solicitor	Lay Plus	04/08/2004	
Ms Nabila Youssouf	Cancer Research Practitioner	Lay	25/03/2011	
Mrs Sandra Shaw	Magistrate / Retired Special Needs Teacher	Lay Plus	15/01/2007	

Deputy Members

Name	Occupation	Expert or Lay	Meeting date attended

Co-opted Members

Name	Occupation	Expert or Lay	Meeting date attended
Mrs Rosa Pizer	Retired Teacher and Jewish Hospital Chaplain	Lay	06/04/2011 05/10/2011
Dr Lorraine Ludman	Retired Psychologist	Lay	07/12/2011
Dr Michael Schachter	Clinical Pharmacologist	Expert	07/12/2011

Member Bank

Name	Occupation	Expert or Lay	Meeting date attended

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

Name	Declaration of Interest	Date
Ms Claire Khalil	Clinical trial specialist at GOSH	01/03/2012
Dr Fiona Castell	None	01/03/2012
Mrs Rosa Pizer	Redbridge Friends of Cancer Research UK	18/10/2012
Mrs Sandra Shaw	None	19/10/2012
Mr Roger Selby	None (11/01/12)	01/03/2012
Dr Michael Jacobs	None (27.03.11)	30/03/2012
Mrs Toni Hall	None	19/10/2012

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

Month	Date	Number of Members Present at Meeting
April	06/04/2011	8
May	04/05/2011	10
June	01/06/2011	11
August	03/08/2011	10
September	07/09/2011	10
October	05/10/2011	10
November	02/11/2011	10
December	07/12/2011	8
January	11/01/2012	9
February	01/02/2012	11
March	07/03/2012	11

11 full committee meetings were held during the reporting period.

Attendance of Members: 01 April 2011 – 31 March 2012:

Name	Number of Meetings Attended
Reverend Jim Linthicum	11
Dr Michael Jacobs	10
Dr Mario Cortina Borja	9
Professor Faith Gibson	9
Dr Rachel L Knowles	8
Ms Nabila Youssouf	7
Dr Joe Brierley	7
Dr John Lamberty	7
K Khair	6
Dr Fiona Castell	5
Ms Claire Khalil	5
Mr Roger Selby	5
Mrs Sandra Shaw	5
Mrs Toni Hall	4
Ms Sally Doganis	4
Ms Stacey Golding	2
Mrs Rosa Pizer	2
Dr Lorraine Ludman	1
Dr Michael Schachter	1

Number of inquorate meetings held: 0

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

Training 01 April 2011 – 31 March 2012:

Name of Member	Date	Event(s) attended
K Khair	19/05/2011 - 19/05/2011	Research with Adolescents, Joe Brierley/Jim Linthicum
Dr Joe Brierley	19/05/2011 - 19/05/2011	Research with Adolescents, Joe Brierley/Jim Linthicum
Reverend Jim Linthicum	19/05/2011 - 19/05/2011	Research with Adolescents, Joe Brierley/Jim Linticum
Dr Michael Jacobs	19/05/2011 - 19/05/2011	Research with Adolescents, Joe Brierley/Jim Linthicum
Mr Roger Selby	19/05/2011 - 19/05/2011	Research with Adolescents, Joe Brierley/Jim Linthicum
Professor Faith Gibson	19/05/2011 - 19/05/2011	Research with Adolescents, Joe Brierley/JimLinthicum
Dr Mario Cortina Borja	19/05/2011 - 19/05/2011	Research with Adolescents, Joe Brierley/Jim Linthicum
Mrs Sandra Shaw	19/05/2011 - 19/05/2011	Research with Adolescents, Joe Brierley/Jim Linthicum
Dr Rachel L Knowles	22/06/2011 - 22/06/2011	Induction, NRES
Dr John Lamberty	19/05/2011 - 19/05/2011	Research with Adolescents, Joe Brierley/Jim Linthicum
Mrs Toni Hall	19/05/2011 - 19/05/2011	Research with Adolescents, Joe Brierley/Jim Linthicum
Ms Nabila Youssouf	22/06/2011 - 22/06/2011	Induction, NRES
Ms Sally Doganis	22/06/2011 - 22/06/2011	Induction, NRES
Dr Fiona Castell	22/06/2011 - 22/06/2011	Induction, NRES
Dr Fiona Castell	28/09/2011 - 28/09/2011	NRES Phase 1 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	19	30.16
Phase 1	0	0.00
Gene Therapy	0	0.00
Research Tissue Bank	0	0.00
Research Database	0	0.00
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	3
Number of student applications reviewed	18
Number of paediatric applications reviewed	20
Number of device applications reviewed	1
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	12	19.05
Favourable Opinion with Additional Conditions	11	17.46
Unfavourable Opinion	0	0.00
Provisional Opinion	40	63.49
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	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	39	61.90
Further Information Favourable Opinion with Additional Conditions	0	0.00
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	12	19.05
Favourable Opinion with Additional Conditions	11	17.46
Unfavourable Opinion	0	0.00
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	1	1.59
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	5
Number of applications over 60 days as a % of total	7.94%
Number of days taken to final decision - average	43
Number of days taken to final decision - mode	28
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	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	78
Number of substantial amendments over 35 days	12
Number of substantial amendments over 35 days as a % of total substantial amendments	15.4%
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	3
Number of modified amendments over 14 days	2
Number of modified amendments over 14 days as a % of total modified amendments	66.7%

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
11/LO/0292	Spectral domain anterior segment optical coherence v1.0	42
11/LO/0293	Safety and Efficacy of GS-9451 with/out Tegobuvir in Patients with HCV	47
11/LO/0295	iPS cells from keratinocytes	54
11/LO/0324	Provider and Patient Experiences - Rapid HIV Testing in Primary Care	49
11/LO/0351	A study evaluating IPI-926 in patients with Chondrosarcoma	40
11/LO/0420	IELSG 32	47
11/LO/0455	Hedrin Once versus Lyclear against head lice	47
11/LO/0496	Multiple time point 18F-FDG PET/CT imaging in Head and Neck Tumours	147
11/LO/0711	PROactive WP4 Version 1.1/Final	48
11/LO/0724	Psychological questionnaire of orthognathic patients	58
11/LO/0771	Sorafenib in NF2	60
11/LO/1161	Measurement of B6 vitamers in dried blood spots	60
11/LO/1164	Ecuzumab in antibody-mediated rejection in LD kidney transplant	56
11/LO/1167	The Phenotype of The Infant of The Diabetic Mother (Version 1/260611)	74
11/LO/1177	iscovering the effect of non IgE mediated gastrointestinal food allerg	57
11/LO/1178	Randomised controlled trial of 2 techniques for lumbar fusion surgery	59
11/LO/1312	RVWF TREATMENT OF BLEEDS	39
11/LO/1322	Evaluation of paediatric airways after prolonged tracheal intubation	63
11/LO/1371	Clinical application of a novel biomarker of aspirin resistance	49
11/LO/1455	Gilead HCV Registry 0122 - Responders	46
11/LO/1456	Gilead HCV Registry 0123 - Non-Responders	46
11/LO/1540	GWAS in children with DDH	48
11/LO/1566	Calcium balance on dialysis	55
11/LO/1599	Social processing & empathy in children referred for assessments	27
11/LO/1612	Global thrombotic status in atrial arrhythmias	54
11/LO/1680	A1481283 follow up investigation for pts completing the A1481276 study	51
11/LO/1760	IMMUNOLOGICAL AND VIROLOGICAL EVALUATION OF ME/CFS - version 1	55
11/LO/1889	Measuring normal and impaired walking in children version 1.0	35
11/LO/1910	Patient-specific modelling of complex cardiovascular mechanics	74
12/LO/0009	RAFFAELLO - Ranolazine in AF following an electrical cardioversion	32

12/LO/0022	ADHD treatment outcomes some years on: a simple question.	53
12/LO/0030	The Practicality of a Virtual Reality based Rehabilitation System	42
12/LO/0132	Intraoperative Decision Making Training & Evaluation Using Simulation	36
12/LO/0140	Anorectal dysfunction in scleroderma	39
12/LO/0144	Mitochondrial Research Biobank [MitoBank], Version 1	57
12/LO/0169	Subcutaneous Levodopa infusion in Parkinson's Disease. V1,19Dec2011	33
12/LO/0331	ACE-EPIC: Enhancing the effects of pulmonary rehabilitation in COPD	28
12/LO/0339	The experience of mothers diagnosed antenatally with HIV	35
12/LO/0355	192024-041D Bimatoprost PF Intracameral Drug Delivery System	61

Further Information Favourable Opinion with Additional Conditions

REC Reference	Application Short Title	Number of Days on Clock
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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/0285	Histology of normal anorectum and anorectal malformations	26
11/LO/0704	Intelligent Handwashing Monitor (IHM) Ward Entrance Study	37
11/LO/0710	Parents' Experiences of ACP for Children and Young People. Version 1	40
11/LO/1188	Care Station version 1	53
11/LO/1373	Corneal Biomechanics: a biomarker for glaucoma?	41
11/LO/1512	Gender Identity Disorder Study	27
11/LO/1716	Intelligent Handwashing Monitor (IHM) Patient Zone Study	28
11/LO/1718	The 2012 TYA Cancer Cohort Study	28
11/LO/1898	Huntington's Phenocopy Genetics Study	29
11/LO/1983	GC33 in Patients with Unresectable Advanced or Metastatic HCC	28
12/LO/0041	HIV and Later Life	35
12/LO/0175	BMS790052 vs Telaprevir + Peg+RBV in Treatment-naive Hepatitis C Pts	26

Favourable Opinion with Additional Conditions

REC Reference	Application Short Title	Number of Days on Clock
11/LO/0489	A molecular and genetic analysis of otosclerosis	28

11/LO/0495	Immunophenotyping using tissue arrays (version 1)	34
11/LO/0497	Vasomotor symptoms (HF/NS) in men with prostate cancer [Version 1.5]	33
11/LO/0779	AZithromycin Against pLacebo in Exacerbations of Asthma (AZALEA)	30
11/LO/1175	Ultrastructural features of neuroblastic tumours (Version 1.2)	32
11/LO/1313	Cetuximab with chemoradiotherapy in bladder cancer (TUXEDO)	21
11/LO/1446	CTC enumeration and analysis in gynaecological malignancies v1.1	21
11/LO/1749	Exploring the experiences of women with COPD and urinary incontinence	28
11/LO/1943	MISOP study	30
12/LO/0059	DEFERASIROX GASTROINTESTINAL TOLERABILITY STUDY	35
12/LO/0150	Ultrasound findings in patients with moderate disease activity RA	26

Unfavourable Opinion

REC Reference	Application Short Title	Number of Days on Clock
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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
11/LO/0494	FDG-PET vs MUGA in measuring LVEF	33

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 7: Items exceeding timelines:

Full applications for ethical review over 60 day timeline		
REC Reference	Application Short Title	Number of Days on Clock
11/LO/0496	Multiple time point 18F-FDG PET/CT imaging in Head and Neck Tumours	147
11/LO/1167	The Phenotype of The Infant of The Diabetic Mother (Version 1/260611)	74
11/LO/1322	Evaluation of paediatric airways after prolonged tracheal intubation	63
11/LO/1910	Patient-specific modelling of complex cardiovascular mechanics	74
12/LO/0355	192024-041D Bimatoprost PF Intracameral Drug Delivery System	61

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
05/Q0508/46/AM01	Orthopaedic Surgery for spastic diplegia: time to functional recovery	Version 1, 15 March 2011	48
09/H0713/77/AM10	Evaluation of edoxaban vs. warfarin in subjects with symptomatic VTE	substantial amendment 10	43
10/H0713/76/AM04	GSK1349572 + ABC/3TC v Atripla in HIV infected, treatment naive adults	Protocol Amendment 3	41
10/H0713/35/AM06	Xenon - Post Operative Delirium	Substantial Amendment 2	36
10/H0713/88/AM04	Phase II Ponatinib in Refractory CML and Ph+ALL Version 2.0 27Oct2010	Substantial Amendment 3	36
11/LO/0711/AM01	PROactive WP4 Version 1.1/Final	Substantial Amendment 1	41

05/Q0508/6/AM05	Identification of genes involved in renal and electrolyte disorders	Substantial Amendment 2	113
11/H0713/12/AM02	IDEA	Amendment 2 - 2/2/2012 - Protocol Change	49
10/H0713/53/AM04	A single-blind, randomized, 3-arm proof of concept study in PMR v1.0	Substantial Amendment 2	39
11/LO/0420/AM06	IELSG 32	Amendment 5	49
08/H0713/44/AM04	GCaPPS Version-1_20_April-2008	Substantial Amendment 3	41
09/H0713/12/AM07	Bringing markers of transplantation tolerance into the clinic	Substantial Amendment 3	39

Modified Amendments over 14 day timeline

Amendment Reference	Application Short Title	Amendment Title	Number of Days on Clock
10/H0713/28/AM03/1	The fracture healing study	Modified Amendment 3 April 20, 2011	15
10/H0713/8/AM02/1	Risk factors in hip dysplasia	amendment 2 24/01/2011 - modified 25/07/2011	28

Section 30 application over 60 day timeline

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