

NRES Committee London - Riverside

Annual Report

01 April 2011 – 31 March 2012

Part 1 – Committee Membership and Training

Name of REC:	NRES Committee London - Riverside
Type of REC:	RECs recognised to review CTIMPS in healthy volunteers - type i RECs recognised to review CTIMPS in patients - type iii
Type of Flag:	Phase 1 Studies in Healthy Volunteers
Chair:	Dr Sabita Uthaya
Vice-Chair:	Dr Mark Atkins
Alternate Vice-Chair:	n/a
Co-ordinator:	Miss Tina Cavaliere
PRSC Co-ordinator:	Miss Tina Cavaliere
Assistant Co-ordinator:	Miss. Christine Hobson
Committee Address:	South West Research Ethics Committee Level 3 Block B Whitefriars Lewins Mead Bristol BS1 2NT
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Chair's overview of the past year:

The Riverside NRES REC has had another busy year. We continue to receive a wide variety of applications from Phase 1 studies to industry sponsored clinical trials and investigator led research. The Committee has significant paediatric experience and it is my view that paediatric studies should be reviewed by a Committee with relevant experience of the issues relating to children. Currently this is not mandatory. We have also received positive feedback from researchers who have found their experience of dealing with the Committee a pleasant and helpful one. We were sad to see Anna Smajdor leave. Anna was Vice Chair and her input in to the Committee was particularly insightful. Graeme Moyle and Mike Stafford finished two very productive terms on the Committee and unfortunately rules about the maximum length of time allowed on a Committee meant that we were unable to extend their time on the Committee. Sharmista Appaya, a lay member, who also resigned from the Committee will be missed for her perceptive approach to ethical issues. I would like to thank all four for their contributions to the reviews. Unfortunately issues with moving the NRES offices and changes in co-ordinators had some impact the timelines of reviews. However, it is good to see that these have now been resolved and having Tina Cavaliere as the co-ordinator is welcome. Thank you to Stephanie Macpherson for bridging the gap between co-ordinators so seamlessly. It is a pleasure to welcome Mark Atkins as Vice Chair. Finally, I look forward to another term as Chair!

NRES Committee London - Riverside Membership:

Name	Occupation	Expert or Lay	Dates	
			Appointed	Resigned
Dr Mark Atkins	Consultant Virologist	Expert	18/05/2005	
Ms Anna Bischler	Pharmacist	Expert	17/11/2007	
Mr John Clifford	Lawyer	Lay Plus	18/05/2005	
Dr Julian Collinson	Consultant Cardiologist	Expert	01/03/2011	
Dr Matthew Hyde	Research Scientist	Expert	01/09/2009	
Dr Margaret Jones	General Practitioner	Expert	26/09/2007	
Miss Effie Katsarma	Consultant Plastic and Hand Surgeon	Expert	01/03/2011	
Ms Alexandra Mancini	Modern Matron	Expert	06/04/2009	
Ms Fanny Mitchell	Retired	Lay Plus	01/10/2009	
Dr Karen Phekoo	Researcher	Expert	01/10/2009	
Mr Kamen Shoylev	Medical Law	Lay Plus	01/12/2011	
Ms Fiona Slomovic	Advocacy and Mediation Consultant	Lay Plus	01/03/2011	
Dr Anna Smajdor	Lecturer	Lay	28/04/2005	01/10/2011
Mr Mike Stafford	Consultant Gynaecologist	Expert	24/09/2001	01/03/2012
Dr Sabita Uthaya	Consultant Neonatologist	Expert	01/07/2010	
Dr Daniel Wood	Clinical Psychologist	Expert	06/04/2009	

Deputy Members

Name	Occupation	Expert or Lay	Meeting date attended

Co-opted Members

Name	Occupation	Expert or Lay	Meeting date attended

Member Bank

Name	Occupation	Expert or Lay	Meeting date attended

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

Name	Declaration of Interest	Date
Dr Sabita Uthaya	None.	05/12/2011
Ms Anna Bischler	None.	05/12/2011
Dr Daniel Wood	None.	05/11/2011
Dr Margaret Jones	Shareholdings: Jointly with her husband they hold a few shares in Smith & Nephew.	05/12/2011
Ms Fanny Mitchell	None.	05/12/2011
Dr Karen Phekoo	None.	05/11/2011
Dr Matthew Hyde	None.	05/11/2011
Dr Julian Collinson	None.	05/12/2011
Miss Effie Katsarma	None.	05/12/2011
Mr Kamen Shoylev	None.	23/12/2011

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

Month	Date	Number of Members Present at Meeting
April	04/04/2011	13
June	06/06/2011	13
July	04/07/2011	13
August	01/08/2011	9
September	05/09/2011	13
October	03/10/2011	11
November	07/11/2011	11
December	05/12/2011	12
January	09/01/2012	9
February	06/02/2012	13
March	05/03/2012	10

11 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
March	20/03/2012	4

1 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
Ms Anna Bischler	11
Ms Alexandra Mancini	10
Dr Julian Collinson	10
Dr Matthew Hyde	10
Dr Sabita Uthaya	10
Dr Margaret Jones	9
Ms Fanny Mitchell	8
Dr Daniel Wood	8
Miss Effie Katsarma	7
Ms Sharmista Appaya	7
Dr Mark Atkins	7
Ms Fiona Slomovic	6
Mr John Clifford	6
Dr Karen Phekoo	6
Dr Graeme Moyle	4
Mr Mike Stafford	4
Dr Anna Smajdor	2
Mr Kamen Shoylev	2

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
Dr Mark Atkins	1
Dr Matthew Hyde	1
Dr Sabita Uthaya	1
Ms Fanny Mitchell	1

Training 01 April 2011 – 31 March 2012:

Name of Member	Date	Event(s) attended
Ms Anna Bischler	26/07/2011 - 26/07/2011	NRES Medical Devices training, NRES
Ms Anna Bischler	01/11/2011 - 01/11/2011	NRES Reviewing Clinical Trials of Investigational Medicinal Products , NRES
Miss Effie Katsarma	04/10/2011 - 04/10/2011	Induction, NRES
Dr Julian Collinson	22/06/2011 - 22/06/2011	Induction, NRES
Ms Fiona Slomovic	22/06/2011 - 22/06/2011	Induction, NRES
Dr Sabita Uthaya	26/09/2011 - 26/09/2011	NRES Update Session , NRES
Dr Sabita Uthaya	05/12/2011 - 05/12/2011	Shared Ethical Debate, NRES
Ms Anna Bischler	05/12/2011 - 05/12/2011	Shared Ethical Debate, NRES
Mr Mike Stafford	05/12/2011 - 05/12/2011	Shared Ethical Debate, NRES
Dr Daniel Wood	05/12/2011 - 05/12/2011	Shared Ethical Debate, NRES
Mr John Clifford	05/12/2011 - 05/12/2011	Shared Ethical Debate, NRES
Dr Margaret Jones	05/12/2011 - 05/12/2011	Shared Ethical Debate, NRES
Dr Graeme Moyle	05/12/2011 - 05/12/2011	Shared Ethical Debate, NRES
Ms Sharmista Appaya	05/12/2011 - 05/12/2011	Shared Ethical Debate, NRES
Ms Fanny Mitchell	05/12/2011 - 05/12/2011	Shared Ethical Debate, NRES
Dr Karen Phekoo	05/12/2011 - 05/12/2011	Shared Ethical Debate, NRES
Dr Matthew Hyde	05/12/2011 - 05/12/2011	Shared Ethical Debate, NRES
Ms Fiona Slomovic	05/12/2011 - 05/12/2011	Shared Ethical Debate, NRES
Dr Julian Collinson	05/12/2011 - 05/12/2011	Shared Ethical Debate, NRES
Miss Effie Katsarma	05/12/2011 - 05/12/2011	Shared Ethical Debate, NRES
Dr Matthew Hyde	07/12/2011 - 07/12/2011	statistics training , NRES
Ms Fanny Mitchell	31/01/2012 - 31/01/2012	Delegate Information - NRES Phase 1 Training 31 January 2012 - Manchester, NRES
Dr Daniel Wood	14/03/2012 - 14/03/2012	NRES Members National Training Day - London, 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	18	28.13
Phase 1	0	0.00
Gene Therapy	0	0.00
Research Tissue Bank	0	0.00
Research Database	0	0.00
Others	46	71.87
Total Applications Reviewed	64	100

Table 2: Other REC activity during the reporting period:

Number of applications made invalid by co-ordinator	1
Number of studies withdrawn prior to the meeting	7
Number of student applications reviewed	17
Number of paediatric applications reviewed	17
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	4	6.25
Favourable Opinion with Additional Conditions	8	12.50
Unfavourable Opinion	3	4.69
Provisional Opinion	46	71.88
Invalid	0	0.00
No Opinion Pending Consultation with Referee	3	4.69
Provisional Opinion Pending Consultation with Referee	0	0.00
Not Requiring Review by NHS REC	0	0.00
Total	64	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	38	59.38
Further Information Favourable Opinion with Additional Conditions	9	14.06
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	4	6.25
Favourable Opinion with Additional Conditions	8	12.50
Unfavourable Opinion	3	4.69
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	1	1.56
Not Requiring Review by NHS REC	0	0.00
No decision entered on RED	1	1.56
Number of studies withdrawn after the meeting	0	0.00
Total	64	100

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

Total Applications Reviewed	2
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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	0	0.00
Favourable Opinion with Additional Conditions	2	100.00
No Opinion transfer to full committee for review	0	0.00
Provisional Opinion	0	0.00
Unfavourable Opinion	0	0.00
Total	2	100

Table 7: Other Management Information for the reporting period:

Average number of applications reviewed per full meeting	5.82
Number of applications for full ethical review over 60 days	1
Number of applications over 60 days as a % of total	1.56%
Number of days taken to final decision - average	34
Number of days taken to final decision - mode	25
Number of SSAs (non-Phase 1) reviewed	2
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	135
Number of substantial amendments over 35 days	11
Number of substantial amendments over 35 days as a % of total substantial amendments	8.1%
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	18
Number of modified amendments over 14 days	4
Number of modified amendments over 14 days as a % of total modified amendments	22.2%
Number of proportionate review applications for ethical review over 14 days*	0
Number of proportionate review applications over 14 days as a % of total	0.00%

***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/0265	ROMI-ADVM-004 dated 7 January 2011	43
11/LO/0284	Recovery Discourses - Version 1	36
11/LO/0288	Investigation into the effect of exercise on wheelchair users with MS	40
11/LO/0692	EORTC SWB36 Validation - Phase 4	57
11/LO/0712	FERTILITY OUTCOMES FOLLOWING LAPAROSCOPIC SURGERY FOR ENDOMETRIOSIS	28
11/LO/0717	Evaluating a 1 Day Skills Workshop for Supporters of clients with BPD	53
11/LO/0719	Stereoacuity and 3D television	51
11/LO/0727	Sensory thresholds and identification of the midline in pregnancy	39
11/LO/0782	Incremental exercise test in CF	34
11/LO/0804	ST10-021 for IDA in quiescent UC	46
11/LO/0929	Acceptance and Commitment Therapy for voice hearers: A case series	45
11/LO/0935	Personalised Medicine for Morbid Obesity	51
11/LO/0990	GS-0148: GS-5885 alone or with GS-9451 with PEG/RBV for Hepatitis C	25
11/LO/0998	The effect of Nicotinamide (Vitamin B3) in Friedreich's ataxia	21
11/LO/1166	Identifying patient's functional needs following hip joint replacement	30
11/LO/1333	Maraviroc in HIV post exposure prophylaxis (MiPEP) Trial Version 1.0	19
11/LO/1358	Echocardiography during endothermal ablation of varicose veins	29
11/LO/1359	Effects of sclerosing agents on white blood cells	26
11/LO/1376	Developing Interventions for Parents of Feeding Disordered Children	29
11/LO/1383	Human Biomonitoring for Europe a harmonised approach: The UK Study	40
11/LO/1591	TRansvaginal Ultrasonography versus Saline sonography Trial(TRUST-IVF)	30
11/LO/1744	Brain development in twins	28
11/LO/1753	Phase I study of modified dose of saquinavir and ritonavir in HIV	23
11/LO/1764	Are anxiety levels influenced by a probability of viability score	41
11/LO/1781	Medicines Reconciliation Research in Young patients Post Discharge V9	28
11/LO/1783	EEG assessment of anaesthesia depth during endoscopy in children (v1)	20
11/LO/1788	Evaluation of Safety and Efficacy of HHFNC in Acute Paediatric Illness	29
11/LO/1929	Laser Trabeculoplasty for Treatment of Ocular Hypertension or Glaucoma	46
12/LO/0017	PCS - Painful Channelopathies Study version 1	34

12/LO/0020	Does electrical stimulation affect spasticity in people with MS? V2	40
12/LO/0036	Phase 3 study of NS5a inhibitor in patients coinfectd with HIV & HCV	29
12/LO/0079	006: Oral CP-690,550 as an Induction Therapy for Ulcerative Colitis	46
12/LO/0161	VibraTip in the assessment of diabetic peripheral neuropathy	64
12/LO/0309	Habit formation and maintenance in Parkinson's Disease	59

Further Information Favourable Opinion with Additional Conditions		
REC Reference	Application Short Title	Number of Days on Clock
11/LO/0263	ROMI-ADVM-002 amendment 2 dated 07 January 2011 re submission	43
11/LO/0264	ROMI-ADVM-001 amendment 2 dated 07 January 2011 re submission	43
11/LO/0920	Macrophage polarization in Graft-versus-Host Disease v.1	27
11/LO/1159	GENA-13 (follow-up study to REC reference number 10/H0706/48)	42
11/LO/1179	Central blood pressure with and without kidney disease	51
11/LO/1526	Measuring Placental Transfusion in Premature Infants	24
11/LO/1941	Study of Icatibant in Idiopathic Angioedema	30
11/LO/2063	Effect of apelin on cardiopulmonary performance in IPAH	53
12/LO/0015	The HeartSpare Study (Stage I)	35

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

Favourable Opinion with Standard Conditions		
REC Reference	Application Short Title	Number of Days on Clock
11/LO/0286	The Advanced Renal Care (ARC) project	39
11/LO/0951	Non Invasive Prenatal diagnosis: Sickle and Thalassemia	32
11/LO/1162	Non-Hodgkin's Lymphoma in Young Adults	15
11/LO/1583	Small Bowel Bacterial Overgrowth in Oesophagogastric Cancer Patients	32

Favourable Opinion with Additional Conditions		
REC Reference	Application Short Title	Number of Days on Clock
11/LO/1047	Socio-demographic Correlates and Predictors of Drug-Related Mortality	9
11/LO/1183	EWTD and the Quality of Life of Senior Vascular Trainees	15
11/LO/1437	Pediatric CINV Trial MK-0869 Protocol 208	25
11/LO/1490	NO25390 Phase I Paed Melanoma	25

11/LO/1570	CHEMO-T	25
11/LO/1579	DNA methylation patterns in children with and without asthma. V1.	25
11/LO/1602	Antenatal renal pelvis dilatation observational study	18
11/LO/1951	Head and Neck Cancer Patients' Experiences of Chemo-Radiation - 1	21
12/LO/0519	Impact of small vessel disease (SVD) on acute stroke 6-month outcomes	13
12/LO/0520	HAT score for stroke thrombolysis	14

Unfavourable Opinion

REC Reference	Application Short Title	Number of Days on Clock
11/LO/0940	Laser Trabeculoplasty for Treatment of Ocular Hypertension or Glaucoma	20
11/LO/0991	Sustainability in Nursing Education	16
11/LO/1445	Patient preferences towards surgery for oesophagogastric cancer	15

Provisional Opinion

REC Reference	Application Short Title	Number of Days on Clock
12/LO/0307	Improving glycaemic profiles in obese pregnancies (IG-POP)	N/A
12/LO/0312	Secondary bacterial infections in asthma	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
12/LO/0161	VibraTip in the assessment of diabetic peripheral neuropathy	64

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
11/LO/0264/AM01	ROMI-ADVM-001 amendment 2 dated 07 January 2011 re submission	Amendment 1	37
07/H0706/72/AM13	Viewpoint Survey	Amendment 9	37
11/LO/0263/AM01	ROMI-ADVM-002 amendment 2 dated 07 January 2011 re submission	Amendment 1	38
11/LO/0265/AM02	ROMI-ADVM-004 dated 7 January 2011	Amendment 2	37
10/H0706/67/AM10	GSK1349572 v Raltegravir in HIV infected, treatment experienced adults	Amendment 8	37
10/H0706/58/AM01	Attitudes towards recruitment and participation in a clinical biobank	Substantial Amendment 1	38
10/H0706/65/AM14	ARISTOTLE	Amendment 10	46
08/H0706/108/AM04	CIN-E Study	Amendment 4:	55
11/LO/0804/AM06	ST10-021 for IDA in quiescent UC	Substantial Amendment 3 28/02/2012	42

09/H0706/41/AM07	The impact of interval cancers in FOBt screening on cancer adjustment	Substantial Amendment 5 28.02.2012	51
07/Q0401/20/AM10	Cellular, DNA and Protein changes in breast cancer	Substantial amendment 2 (controls) 21.02.2012	48

Modified Amendments over 14 day timeline

Amendment Reference	Application Short Title	Amendment Title	Number of Days on Clock
10/H0706/7/AM05/1	GS-9256 and GS-9190 in Patients with Hepatitis C Virus Infection.	Modified Amendment 4.1	22
09/H0706/40/AM01/1	Corticomuscular coherence and the factors that modulate it	Modified Substantial Amendment 1	25
11/LO/0805/AM01/1	ST10-021 for IDA in quiescent CD	Modified Amendment for AM01	26
11/LO/0804/AM01/1	ST10-021 for IDA in quiescent UC	Modified Amendment to AM01	26

Section 30 application over 60 day timeline

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