

**NRES Committee London -
Wandsworth**

Annual Report

01 April 2011 – 31 March 2012

Part 1 – Committee Membership and Training

Name of REC:	NRES Committee London - Wandsworth
Type of REC:	Type I & III
Type of Flag:	CTIMP, Phase I & Paediatrics
Chair:	Ms Stephanie Ellis (for September, October and November 2012)
Vice-Chair:	Mr Colin Stanfield
Alternate Vice-Char:	n/a
Co-ordinator:	Mr Janhoi MacGregor (from February 2012 until REC closed 31 March 2012). Previously Miss Kristy Randall
Assistant Co-ordinator:	n/a
Committee Address:	Health Research Authority Ground Floor, Skipton House, 80 London Road, London SE1 6LH
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Chair's overview of the past year:

REC Closed 31 March 2012

NRES Committee London - Wandsworth Membership:

Name	Occupation	Expert or Lay	Dates	
			Appointed	Resigned
Dr Lisa Anderson	Consultant Cardiologist	Expert	01/02/2009	
Dr Murray Bain	Senior Lecturer / Consultant Paediatrician	Expert	01/12/2000	
Mr Paul Carter	Consultant Obstetrician & Gynaecologist	Expert	01/09/2009	
Dr. Adrian Draper	Consultant Chest Physician	Expert	01/03/2010	
Mrs Eileen Duff	Lay Member	Lay Plus	01/07/2009	
Ms Stephanie Ellis	Retired Civil Servant	Lay	16/09/2011	
Miss Ruth Gerrard	Clinical Nurse Specialist	Expert	20/08/2004	
Mrs Simone Grinyer	Lay Member	Lay Plus	28/05/2008	
Professor George Hall	Professor of Anesthesia	Expert	01/07/2006	
Dr Christine Heron	Consultant Radiologist	Expert	01/06/2006	
Dr Helen Lucas	General Practitioner	Expert	25/07/2005	
Mr David Melville	Consultant Surgeon	Expert	01/01/2004	11/10/2011
Dr Philip Sedgwick	Senior Lecturer in Medical Statistics	Expert	01/06/2003	
Mr Roy Sinclair	Pharmacist	Expert	01/05/2001	
Mr Colin Stanfield	Lay Member	Lay	01/10/2011	
Reverend Robert Wall	Chaplain	Lay	02/12/2009	
Mrs Alexandra Williamson	Lay Member	Lay Plus	01/07/2009	

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 - Wandsworth: Members' Declarations of Interest:

Name	Declaration of Interest	Date
	Not known	

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

Month	Date	Number of Members Present at Meeting
April	27/04/2011	10
May	25/05/2011	11
June	22/06/2011	12
July	27/07/2011	10
September	28/09/2011	10
October	26/10/2011	9
November	23/11/2011	9
December	14/12/2011	9

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
May	11/05/2011	4
June	15/06/2011	4
July	13/07/2011	4
August	17/08/2011	3
September	07/09/2011	4

5 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
Miss Ruth Gerrard	8
Dr Murray Bain	6
Mr Paul Carter	6
Mr Roy Sinclair	7
Mrs Alexandra Williamson	7
Dr Helen Lucas	6
Dr Lisa Anderson	6
Dr Philip Sedgwick	5
Dr. Adrian Draper	4
Mr David Melville	4
Dr Christine Heron	3
Mrs Simone Grinyer	3
Ms Stephanie Ellis	4
Reverend Robert Wall	4
Professor George Hall	2
Mrs Eileen Duff	2
Colin Stanfield	3

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 Murray Bain	5
Mr Roy Sinclair	5
Mrs Alexandra Williamson	5
Dr. Adrian Draper	3
Dr Adrian Draper	1

Training 01 April 2011 – 31 March 2012:

Name of Member	Date	Event(s) attended
Mrs Alexandra Williamson	26/07/2011 - 26/07/2011	Medical Devices, NRES
Dr Philip Sedgwick	22/09/2011 - 22/09/2011	NRES Informed Consent and Explaining Risk in randomised Trials, NRES
Mr Roy Sinclair	19/05/2011 - 19/05/2011	NRES - Research with Adolescents, NRES
Ms Stephanie Ellis	26/10/2011 - 26/10/2011	Shared Ethical Debate, NRES
Colin Stanfield	26/10/2011 - 26/10/2011	Shared Ethical Debate, NRES
Dr Murray Bain	26/10/2011 - 26/10/2011	Shared Ethical Debate, NRES
Mr Paul Carter	26/10/2011 - 26/10/2011	Shared Ethical Debate, NRES
Miss Ruth Gerrard	26/10/2011 - 26/10/2011	Shared Ethical Debate, NRES
Dr Philip Sedgwick	26/10/2011 - 26/10/2011	Shared Ethical Debate, NRES
Mr Roy Sinclair	26/10/2011 - 26/10/2011	Shared Ethical Debate, NRES
Dr Helen Lucas	26/10/2011 - 26/10/2011	Shared Ethical Debate, NRES
Mrs Simone Grinyer	26/10/2011 - 26/10/2011	Shared Ethical Debate, NRES
Mrs Alexandra Williamson	26/10/2011 - 26/10/2011	Shared Ethical Debate, NRES
Mrs Eileen Duff	26/10/2011 - 26/10/2011	Shared Ethical Debate, NRES
Reverend Robert Wall	26/10/2011 - 26/10/2011	Shared Ethical Debate, 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	11	22.45
Phase 1	2	4.08
Gene Therapy	0	0.00
Research Tissue Bank	2	4.08
Research Database	0	0.00
Others	34	69.39
Total Applications Reviewed	49	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	11
Number of student applications reviewed	12
Number of paediatric applications reviewed	4
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	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	3	6.12
Favourable Opinion with Additional Conditions	2	4.08
Unfavourable Opinion	2	4.08
Provisional Opinion	42	85.71
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	49	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	36	73.47
Further Information Favourable Opinion with Additional Conditions	1	2.04
Further Information Unfavourable Opinion	2	4.08
Favourable Opinion with Standard Conditions	3	6.12
Favourable Opinion with Additional Conditions	2	4.08
Unfavourable Opinion	2	4.08
Provisional Opinion	2	4.08
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	2.04
Total	49	100

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

Total Applications Reviewed	19
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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	5.26
Favourable Opinion with Additional Conditions	1	5.26
No Opinion transfer to full committee for review	8	42.11
Provisional Opinion	9	47.37
Unfavourable Opinion	0	0.00
Total	19	100

Table 7: Other Management Information for the reporting period:

Average number of applications reviewed per full meeting	6.13
Number of applications for full ethical review over 60 days	17
Number of applications over 60 days as a % of total	34.69%
Number of days taken to final decision - average	56
Number of days taken to final decision - mode	56
Number of SSAs (non-Phase 1) reviewed	10
Number of applications for SSA review over 25 days	7
Number of applications for SSA review over 25 days as % of all non-Phase 1 (SSAs)	70.0%
Number of SSAs (Phase 1) reviewed	8
Number of applications for SSA review over 14 days	5
Number of applications for SSA review over 14 days as % of all Phase 1 (SSAs)	62.5%
Number of substantial amendments reviewed	72
Number of substantial amendments over 35 days	32
Number of substantial amendments over 35 days as a % of total substantial amendments	43.8%
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	1
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*	11
Number of proportionate review applications over 14 days as a % of total	100.00%

***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/0340	Women's experiences of wearing hospital gowns. Version one.	104
11/LO/0378	Pilot study of combined movements and facet joint injection responses	73
11/LO/0380	Radio-ligands for TSPO and IL-2 in Crohn's Disease	117
11/LO/0459	Cervico-vaginal CN54gp140-hsp70 conjugate vaccine	41
11/LO/0471	Using a modified Chester Step test as a measure of fitness	67
11/LO/0612	PROMISSE - Predictors of pregnancy outcome in Lupus and APS	53
11/LO/0661	SOLUTION UC	76
11/LO/0670	Imaging test preference	21
11/LO/0685	Use of contractual mechanisms in commissioning	97
11/LO/0869	Validation of the Hypoglycaemia Symptom Rating Questionnaire Version 1	52
11/LO/0874	Seeing Orthopaedic Surgery Through The Child's Eyes: version 1	47
11/LO/0880	Malaria chemoprophylaxis and HIV positive travellers	49
11/LO/0889	Psychological impact of ICDs in patients with congenital heart disease	47
11/LO/0893	Exploring child HIV testing decisions in mothers with HIV	116
11/LO/0894	Peripartum determinants of left ventricular function	76
11/LO/0895	Study of the Safety and PK of TT30 in Subjects with PNH	47
11/LO/0897	Nonadherence to tyrosine kinase inhibitors in CML - v1.1	56
11/LO/0899	Debrase Scar Formation and Quality of Life Study	40
11/LO/1123	VANGUARD-ROCC Knee Prosthesis Surveillance Study	60
11/LO/1130	BMN 673 in Patients with Advanced Hematological Malignancies	55
11/LO/1135	Skull base tumour quality of life measure	65
11/LO/1136	MO22982 PrefHer Study Version 1.0 dated 30th May 2011	64
11/LO/1139	CCSVI in MS	52
11/LO/1142	The clinical utility of Automated 3D Ultrasound in Breast disease	41
11/LO/1151	To assess safety/tolerability and PK/PD of inhaled AZD8683	44
11/LO/1154	A survey of egg donors in Europe	56
11/LO/1334	Exploring the associations between diabetes and cancer	19
11/LO/1338	Measuring Lumbar Spine Motion Using Ultrasound Imaging	16
11/LO/1457	Promotional Interview Project	31
11/LO/1464	Timing of pelvic inflammatory disease development	15

11/LO/1538	COMPARE study: COMparing treatment options for ProstAte canceR	60
11/LO/1539	Patient preferences for Thrombolytic treatments. tPA-PP Version 1.0	68
11/LO/1546	Evaluating an eMAR System in Care Homes version 1	63
11/LO/1733	Blinatumomab (MT103) in adult patients with relapsed/refractory ALL	33
11/LO/1735	Assessment of Repolarisation Abnormalities in Black Athletes	72
11/LO/1737	CEPROTIN Registry	30
11/LO/1739	NV27779 Quad therapy in Hep C prior null responder patients	34
11/LO/1821	Efficacy and safety of delayed release prednisolone in GCA	56
11/LO/1823	Extension study of Migalastat HCl in subjects with Fabry disease	64
11/LO/1839	Hysteroscopic management of persistent pregnancy of unknown location	53
11/LO/1857	NEOMERO2 - PK and Safety of Meropenem in Infants with Meningitis (V1)	65
11/LO/2049	An electronic tool for the management of child overweight	35

Further Information Favourable Opinion with Additional Conditions

REC Reference	Application Short Title	Number of Days on Clock
11/LO/0656	Sickle Cell Disease: A Lived Experience	29
11/LO/0664	Clinico-radiological correlation of shoulder US findings	19
11/LO/1385	The boceprevir and sildenafil PK study	72

Further Information Unfavourable Opinion

REC Reference	Application Short Title	Number of Days on Clock
11/LO/1738	Muslim Therapists working with Muslim Clients.1	36
11/LO/1840	Lonza Biologics	30

Favourable Opinion with Standard Conditions

REC Reference	Application Short Title	Number of Days on Clock
11/LO/0872	Factors Predicting Preoperative Decompensation in Neonates with HLHS	17
11/LO/1536	The rilpivirine CSF study	65
11/LO/1552	Cumulus cell gene expression in normal and aneuploid human oocytes	31
11/LO/1555	The effectiveness of Collaborative Care feasibility study	37

Favourable Opinion with Additional Conditions

REC Reference	Application Short Title	Number of Days on Clock
11/LO/0662	Issues to adult with CLP and the delivery of care - Version 1.0	49

11/LO/0684	Effects of Pulmonary Hypertension on ability of paid work.	42
11/LO/0907	Hypertensive patients' beliefs about cardiovascular risk - version 1	16

Unfavourable Opinion		
REC Reference	Application Short Title	Number of Days on Clock
11/LO/1545	Lonza Biologics	32
11/LO/1668	(duplicate) researching maternal anxiety from a psychoanalytic perspec	16

Provisional Opinion		
REC Reference	Application Short Title	Number of Days on Clock
11/LO/2003	Valacyclovir in Delaying Antiretroviral Treatment Entry (VALIDATE)	N/A
11/LO/2047	Seamguard vs Duet TRS	N/A

Provisional Opinion Pending Consultation with Referee		
REC Reference	Application Short Title	Number of Days on Clock

Further information response not complete		
REC Reference	Application Short Title	Number of Days on Clock

Withdrawn after the meeting		
REC Reference	Application Short Title	Number of Days on Clock
11/LO/0382	Preparing to leave high security: a group for Leavers	34
11/LO/1111	Factors affecting autologous HPC transplant outcome in Myeloma	126

Invalid Application		
REC Reference	Application Short Title	Number of Days on Clock

No Opinion Pending Consultation with Referee		
REC Reference	Application Short Title	Number of Days on Clock

Not Requiring Review by NHS REC		
REC Reference	Application Short Title	Number of Days on Clock

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/0378	Pilot study of combined movements and facet joint injection responses	73
11/LO/0380	Radio-ligands for TSPO and IL-2 in Crohn's Disease	117
11/LO/0340	Women's experiences of wearing hospital gowns. Version one.	104
11/LO/0471	Using a modified Chester Step test as a measure of fitness	67
11/LO/0661	SOLUTION UC	76
11/LO/0685	Use of contractual mechanisms in commissioning	97
11/LO/0894	Peripartum determinants of left ventricular function	76
11/LO/0893	Exploring child HIV testing decisions in mothers with HIV	116
11/LO/1136	MO22982 PrefHer Study Version 1.0 dated 30th May 2011	64
11/LO/1135	Skull base tumour quality of life measure	65
11/LO/1385	The boceprevir and sildenafil PK study	72
11/LO/1536	The rilpivirine CSF study	65
11/LO/1539	Patient preferences for Thrombolytic treatments. tPA-PP Version 1.0	68
11/LO/1546	Evaluating an eMAR System in Care Homes version 1	63
11/LO/1735	Assessment of Repolarisation Abnormalities in Black Athletes	72
11/LO/1823	Extension study of Migalastat HCl in subjects with Fabry disease	64
11/LO/1857	NEOMERO2 - PK and Safety of Meropenem in Infants with Meningitis (V1)	65

Proportionate review applications for ethical review over 14 days timeline		
REC Reference	Application Short Title	Number of Days on Clock
11/LO/0670	Imaging test preference	21
11/LO/0656	Sickle Cell Disease: A Lived Experience	29
11/LO/0664	Clinico-radiological correlation of shoulder US findings	19
11/LO/0872	Factors Predicting Preoperative Decompensation in Neonates with HLHS	17
11/LO/0874	Seeing Orthopaedic Surgery Through The Child's Eyes: version 1	47
11/LO/0907	Hypertensive patients' beliefs about cardiovascular risk - version 1	16
11/LO/1111	Factors affecting autologous HPC transplant outcome in Myeloma	126
11/LO/1334	Exploring the associations between diabetes and cancer	19

11/LO/1338	Measuring Lumbar Spine Motion Using Ultrasound Imaging	16
11/LO/1457	Promotional Interview Project	31
11/LO/1464	Timing of pelvic inflammatory disease development	15

SSAs (non Phase 1) over 25 days timeline

REC Reference	Application Short Title	Number of Days on Clock
11/LO/0549	Vitamin D therapy, left ventricular mass, immune regulation in CKD	41
11/LO/1176	Acute effects of exercise on tobacco withdrawal during pregnancy	28
11/LO/1458	Activity of anti-HIV agents in genital secretions v1	39
11/LO/1587	Non-invasive evaluation of endothelial function in angina patients	39
11/LO/1829	In-House Chlorhexidine Salivary Retention Study	28
11/LO/1905	Phase IIa Study to Investigate the Biological Activity of Oral FX125L	62
11/LO/1906	Phase IIa Study to Investigate the Biological Activity of Oral FX125L	27

SSAs (Phase 1) over 14 days timeline

REC Reference	Application Short Title	Number of Days on Clock
11/LO/1148	Cross-over study with fentanyl patch in healthy Japanese volunteers	26
11/LO/1149	The effect of food content and insulin on QTc interval	26
11/LO/1854	EuroNeut-41: Safety & immunogenicity of immunisations with HIV vaccine	20
11/LO/1956	Fentanyl patch dose proportionality study in Japanese volunteers	21
11/LO/1960	Fentanyl patch dose proportionality study in Japanese volunteers	56

Substantial Amendments over 35 day timeline

Amendment Reference	Application Short Title	Amendment Title	Number of Days on Clock
09/H0803/74/AM09	A Phase II study of RAD001 in advanced papillary renal cell cancer	Update to PIS and Informed Consent Form	76
09/H0803/98/AM05	Oral Ranirestat in Diabetic Sensorimotor Polyneuropathy (Eisai 291)	Addition of Patient materials - 08.4.11	49
10/H0803/140/AM01	The effects of self stigma on self esteem and empowerment	Amendment to Protocol	53
10/H0803/92/AM04	DEFEND-2:Durable-Response Therapy Evaluation For Type 1	Protocol Amendment V4.0 dated 13 May 2011	43

	Diabetes		
11/H0803/4/AM01	BAY 85-3935 dose escalation study in patients with renal anaemia	Amendment 1 - dated 13 May 2011	48
07/H0803/140/AM07	Cognitive, emotional and social causes of psychosis	Amendment 6 (2011)	73
10/H0803/32/AM01	Respiratory Muscle Training in Stroke	Amendment 1	54
10/H0803/53/AM05	Study of BMS-650032 + pegIFN + RBV for hepatitis C genotypes 1&4 (V1)	Amendment 4 - dated 3 August 2011	73
09/H0803/139/AM05	Study of the Effects of Oral AT1001 in Patients with Fabry Disease	Amendment 3 - Additional patient facing study docs	106
10/H0803/92/AM05	DEFEND-2:Durable-Response Therapy Evaluation For Type 1 Diabetes	Protocol Amendment	45
11/H0803/4/AM02	BAY 85-3935 dose escalation study in patients with renal anaemia	Substantial Amendment 2 - 26 August 2011	38
10/H0803/140/AM02	The effects of self stigma on self esteem and empowerment	Amendmen 2 - dated 20th July 2011	41
09/H0803/139/AM06	Study of the Effects of Oral AT1001 in Patients with Fabry Disease	Amendment 4 - 22 August 2011	38
10/H0803/107/AM01	HCV post OLT	Substantial Amendment 1, 23 August 2011	56
08/H0803/257/AM01	MMP's,FBN-1 and TGFBR2 deficiency in bicuspid aortic valve patients	Amendment 1 - 07/07/2011	57
10/H0803/108/AM01	Genomic Analysis and Autologous Blood Transfusion Detection	Amendment 1 - dated 13/07/2011	40
10/H0803/72/AM03	Molecular Autopsy in SADS Clinic Patients v1	Amendment 5 (24 June 2011)	54
10/H0803/74/AM04	BELIEF	Amendment 4 - update to PIS and Consent	36
10/H0803/81/AM05	TioSpir (205.452) Tiotropium Safety and performance in Respimat	Amendment 4 (2010-019802-17-SA-03)	38
09/H0803/95/AM03	DTI in stroke-related aphasia	Amendment 3 (05-07-2011)	37

10/H0803/92/AM07	DEFEND-2:Durable-Response Therapy Evaluation For Type 1 Diabetes	Sub Amendment 6, 30/08/2011	45
11/LO/0081/AM01	Companion Study of Pomalidomide in Subjects with Multiple Myeloma	Amendment 1 - 28 July 2011	42
11/LO/0082/AM01	Study of Pomalidomide in Subjects with Multiple Myeloma	Amendment 1 - 27 July 2011	42
09/H0803/9/AM03	Immune markers in early breast cancer	Amendment 3	50
10/H0803/169/AM02	Phase 1b study in early stage Huntington's Disease patients SEN0014196	10/H0808/169/AM2	49
10/H0803/167/AM03	Ramucirumab in Metastatic Gastric Adenocarcinoma	10/H0803/167/AM3	37
09/H0803/94/AM03	Clinical outcome after posterior or anterior approach in THR	09/H0803/94/AM03	36
08/H0803/257/AM02	MMP's, FBN-1 and TGFBR2 deficiency in bicuspid aortic valve patients	Increase to number of participants	40
10/H0803/151/AM01	A National Neonatal Research Database/Version 1/071010	Substantial Amendment 1	44
09/H0803/139/AM09	Study of the Effects of Oral AT1001 in Patients with Fabry Disease	Modified Amendment dated 24.02.12	46
11/LO/1739/AM04	NV27779 Quad therapy in Hep C prior null responder patients	Temporary halt of study	103

Modified Amendments over 14 day timeline

Amendment Reference	Application Short Title	Amendment Title	Number of Days on Clock
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Section 30 application over 60 day timeline

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