

**NRES Committee London - West
London**

Annual Report

01 April 2011 – 31 March 2012

Part 1 – Committee Membership and Training

Name of REC:	NRES Committee London - West London
Type of REC:	Type 1 and 3
Type of Flag:	Low Risk Gene Therapy Applications (via GTAC)
Chair:	Dr Catherine Urch
Vice-Chair:	Professor Gary Frost
Alternate Vice-Chair:	n/a
Co-ordinator:	Andrea Graham previously Clive Collett
PRSC Co-ordinator:	n/a
Assistant Co-ordinator:	n/a
Committee Address:	The Old Chapel Royal Standard Court Nottingham NG1 6FS
Telephone:	0115 883 9311
Email:	nrescommittee.london-westlondon@nhs.net

Chair's overview of the past year:

This year has been one of great change. Clive Collett our long serving and highly efficient co-ordinator left for greater things at NREAP. This was part of a much wider restructuring of administrative support for REC and change of location and personnel. After some upheaval we welcome Andrea Graham as our new co-ordinator. The committee has also had to say farewell to some much respected and long serving colleagues: Professor Apperley and Alison Collins, but has welcomed new members, new babies and a PhD! The changes in the NHS continue to be felt especially in the difficulty for many clinical staff to secure time to attend the meetings, this will need to be considered and newer ways of job –sharing might need to be considered. My thanks goes to all those who have come to help us over the year to ensure quorate committees and to the dawn conference calls to complete discussions. Throughout the committee has continued to be a source of lively debate, humour and exciting clinical research. My thanks not only goes to all the members, administrators but also to the researchers who continue to develop medicine inch by inch.

NRES Committee London - West London Membership:

Name	Occupation	Expert or Lay	Dates	
			Appointed	Resigned
Miss Maryam Alfa-Wali	Clinical Research Fellow, Academic Surgery Unit	Expert	10/02/2011	
Prof Jane F Apperley	Department of Haematology	Expert	01/09/2001	01/09/2011
Professor Bob Brecher	Reader in Moral Philosophy	Lay Plus	23/01/2012	
Dr Tom Cairns	Consultant Nephrologist	Expert	01/06/2007	
Dr Tanya Carthy	GP	Expert	18/07/2011	
Dr Peter Chow	Consultant Neonatologist	Expert	18/07/2011	
Dr Sheila Coates	GP	Expert	19/12/2001	23/09/2011
Mrs Alison Collins	Lay member	Lay Plus	01/04/2007	
Mr Stephen Cryan	Business Consultant	Lay Plus	23/09/2009	
Dr Simon Day	Statistician	Expert	07/04/2008	
Dr Lydia Drumright	Lecturer	Expert	18/07/2011	
Professor Gary Frost	Chair of Nutrition	Expert	23/09/2009	
Ms Ann Jacklin	Pharmacist	Expert	24/01/2011	23/01/2012
Ms Victoria Latham	Lead Pharmacist Clinical Trials & Pharmacovigilance	Expert	23/07/2008	
Dr Fraser Macfarlane	Senior Lecturer in Health Care Management	Lay Plus	01/09/2009	
Dr Michael Maier	Head of London School of Psychiatry, Hon. Senior lecturer & Consultant	Expert	22/07/2010	
Dr Graham Miller	Reader in Management (Vice-Chair)	Lay	21/01/2003	19/05/2011
Dr Lidia Tyszczyk	Consultant in Neonatal Medicine	Expert	21/12/2007	30/04/2011
Dr Catherine Urch	Consultant Palliative Medicine (Chair)	Expert	21/12/2007	
Dr Caroline Vaughan	Lay member	Lay	01/12/2002	
Ms Mo Yale	Lay member	Lay Plus	01/01/2003	23/06/2011

Deputy Members

Name	Occupation	Expert or Lay	Meeting date attended

Co-opted Members

Name	Occupation	Expert or Lay	Meeting date attended

Miss Stephanie Ellis	Lay Member	Lay	17/08/2011
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Member Bank

Name	Occupation	Expert or Lay	Meeting date attended

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

Name	Declaration of Interest	Date
Professor Bob Brecher	None.	13/04/2011
Ms Ann Jacklin	Co-chair the "Centre of the Medication & service quality" Lead for Imperial NIHR funded "Centre for Patient Safety and Service Quality"	29/06/2011
Ms Stephanie Ellis	None.	16/03/2012
Mr Suresh Akula	None.	27/01/2012
Professor Gary Frost	Professor of nutrition and dietetics	16/11/2011
Dr Catherine Urch	None.	30/12/2011
Mrs Alison Collins	None.	14/12/2011
Dr Tom Cairns	None.	20/04/2011
Dr Simon Day	Employee of Roche products.	21/01/2011
Dr Fraser Macfarlane	Senior Research Fellow at Queen Mary University of London, Centre for primary care and public health (until March 2012).	14/12/2011
Mr Stephen Cryan	Spouse is a clinical oncologist and runs a Phase 1 unit at Hammersmith Hospital/Imperial College.	14/12/2011
Dr Michael Maier	None.	20/04/2011
Miss Maryam Alfa-Wali	None.	16/12/2011
Dr Peter Chow	Consultant neonatologist at Imperial College Healthcare NHS Trust. Honorary Lecturer at Imperial College, London.	13/12/2011
Dr Lydia Drumright	Active in academic research as lecturer at Imperial College London.	14/12/2011
Ms Victoria Latham	Pharmacist with responsibility for clinical trials at Imperial College Healthcare NHS Trust (undated, but approximated February 2011).	02/04/2011
Dr Caroline Vaughan	None.	19/03/2008
Dr Tanya Carthy	None.	14/12/2011

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

Month	Date	Number of Members Present at Meeting
April	20/04/2011	11
May	18/05/2011	9
June	22/06/2011	10
July	20/07/2011	9
August	17/08/2011	8
September	21/09/2011	7
November	16/11/2011	10
December	14/12/2011	7
January	18/01/2012	9
February	15/02/2012	7
March	21/03/2012	11

11 full committee meetings were held during the reporting period.

Proportionate Review Sub Committee Meetings held during 01 April 2011 - 31 March 2012:

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

Name	Number of Meetings Attended
Dr Caroline Vaughan	10
Dr Catherine Urch	10
Professor Gary Frost	8
Mr Stephen Cryan	7
Dr Fraser Macfarlane	6
Dr Tanya Carthy	6
Dr Tom Cairns	6
Miss Maryam Alfa-Wali	6
Dr Michael Maier	5
Dr Sheila Coates	5
Dr Simon Day	5
Ms Ann Jacklin	5
Dr Lydia Drumright	4
Mrs Alison Collins	3
Ms Mo Yale	3
Ms Victoria Latham	2
Prof Jane F Apperley	2
Professor Bob Brecher	2
Miss Stephanie Ellis	1
Dr Peter Chow	1
Dr Graham Miller	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
Miss Maryam Alfa-Wali	22/06/2011 - 22/06/2011	Induction, NRES
Dr Fraser Macfarlane	10/05/2011 - 10/05/2011	Equality & Diversity, NHS Core Learning Unit
Miss Maryam Alfa-Wali	05/06/2011 - 05/06/2011	Equality & Diversity, NHS Core Learning Unit
Dr Peter Chow	10/01/2012 - 10/01/2012	Induction, NRES
Dr Lydia Drumright	10/01/2012 - 10/01/2012	Induction, NRES
Dr Tanya Carthy	10/01/2012 - 10/01/2012	Induction, NRES
Professor Gary Frost	10/01/2012 - 10/01/2012	Induction, NRES
Dr Catherine Urch	29/06/2011 - 29/06/2011	Equality & Diversity, NHS
Dr Caroline Vaughan	14/07/2011 - 14/07/2011	Equality & Diversity, NHS
Dr Simon Day	18/07/2011 - 18/07/2011	Equality & Diversity, NHS
Dr Catherine Urch	06/12/2011 - 06/12/2011	NRES Chairs National Training , NRES
Dr Lydia Drumright	15/09/2011 - 15/09/2011	BioEthics Committee Simulation: http://ethicssim.brunel.ac.uk/index.htm , Brunel University
Dr Catherine Urch	22/09/2011 - 22/09/2011	MCA video for NRES Committee members v1 February 2011
Dr Caroline Vaughan	22/09/2011 - 22/09/2011	MCA video for NRES Committee members v1 February 2011
Dr Tom Cairns	22/09/2011 - 22/09/2011	MCA video for NRES Committee members v1 February 2011
Dr Michael Maier	22/09/2011 - 22/09/2011	MCA video for NRES Committee members v1 February 2011
Miss Maryam Alfa-Wali	22/09/2011 - 22/09/2011	MCA video for NRES Committee members v1 February 2011
Dr Tanya Carthy	22/09/2011 - 22/09/2011	MCA video for NRES Committee members v1 February 2011
Mrs Alison Collins	10/10/2011 - 10/10/2011	MCA video for NRES Committee members v1 February 2011, NRES
Mrs Alison Collins	28/02/2012 - 28/02/2012	NRES Qualitative Research and Ethical Review; OP6001 , NRES
Mr Stephen Cryan	07/11/2011 - 07/11/2011	MCA video for NRES Committee members v1 February 2011, NRES
Dr Peter Chow	07/11/2011 - 07/11/2011	MCA video for NRES Committee members v1 February 2011, NRES
Dr Lydia Drumright	07/11/2011 - 07/11/2011	MCA video for NRES Committee members v1 February 2011, NRES
Ms Ann Jacklin	07/11/2011 - 07/11/2011	MCA video for NRES Committee members v1 February 2011, NRES

Dr Catherine Urch	08/11/2011 - 08/11/2011	NRES Training Day for New REC Chairs (OP3001), NRES
Dr Simon Day	12/12/2011 - 12/12/2011	MCA video for NRES Committee members v1 February 2011, NRES
Dr Fraser Macfarlane	12/12/2011 - 12/12/2011	MCA video for NRES Committee members v1 February 2011, NRES
Dr Tanya Carthy	29/02/2012 - 29/02/2012	Personal data in research: a workshop for members of Research Ethics Committees, NRES
Professor Gary Frost	14/12/2011 - 14/12/2011	Prof Andrew George - Training Session: "Who's afraid of the big bad gene?"
Dr Caroline Vaughan	14/12/2011 - 14/12/2011	Prof Andrew George - Training Session: "Who's afraid of the big bad gene?"
Dr Michael Maier	14/12/2011 - 14/12/2011	Prof Andrew George - Training Session: "Who's afraid of the big bad gene?"
Dr Tanya Carthy	14/12/2011 - 14/12/2011	Prof Andrew George - Training Session: "Who's afraid of the big bad gene?"
Dr Simon Day	14/12/2011 - 14/12/2011	Prof Andrew George - Training Session: "Who's afraid of the big bad gene?"
Mr Stephen Cryan	14/12/2011 - 14/12/2011	Prof Andrew George - Training Session: "Who's afraid of the big bad gene?"
Ms Victoria Latham	13/02/2012 - 13/02/2012	ICR GCP Forum training day, ICR
Dr Catherine Urch	15/02/2012 - 15/02/2012	Shared Ethical Debate (SED 9) – Qualitative study - 'Collaborative Learning on the Web', nres
Dr Caroline Vaughan	15/02/2012 - 15/02/2012	Shared Ethical Debate (SED 9) – Qualitative study - 'Collaborative Learning on the Web', n
Mrs Alison Collins	15/02/2012 - 15/02/2012	Shared Ethical Debate (SED 9) – Qualitative study - 'Collaborative Learning on the Web', NRES
Dr Tom Cairns	15/02/2012 - 15/02/2012	Shared Ethical Debate (SED 9) – Qualitative study - 'Collaborative Learning on the Web', NRES
Dr Simon Day	15/02/2012 - 15/02/2012	Shared Ethical Debate (SED 9) – Qualitative study -

		'Collaborative Learning on the Web' , NRES
Dr Fraser Macfarlane	15/02/2012 - 15/02/2012	Shared Ethical Debate (SED 9) – Qualitative study - 'Collaborative Learning on the Web' , NRES
Mr Stephen Cryan	15/02/2012 - 15/02/2012	Shared Ethical Debate (SED 9) – Qualitative study - 'Collaborative Learning on the Web' , NRES
Dr Michael Maier	15/02/2012 - 15/02/2012	Shared Ethical Debate (SED 9) – Qualitative study - 'Collaborative Learning on the Web' , NRES
Miss Maryam Alfa-Wali	15/02/2012 - 15/02/2012	Shared Ethical Debate (SED 9) – Qualitative study - 'Collaborative Learning on the Web' , NRES
Dr Lydia Drumright	15/02/2012 - 15/02/2012	Shared Ethical Debate (SED 9) – Qualitative study - 'Collaborative Learning on the Web' , NRES
Dr Tanya Carthy	15/02/2012 - 15/02/2012	Shared Ethical Debate (SED 9) – Qualitative study - 'Collaborative Learning on the Web' , NRES
Ms Victoria Latham	15/02/2012 - 15/02/2012	Shared Ethical Debate (SED 9) – Qualitative study - 'Collaborative Learning on the Web' , NRES
Professor Gary Frost	21/03/2012 - 21/03/2012	Chairing Skills 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	21	32.31
Phase 1	0	0.00
Gene Therapy	0	0.00
Research Tissue Bank	0	0.00
Research Database	0	0.00
Others	44	67.69
Total Applications Reviewed	65	100

Table 2: Other REC activity during the reporting period:

Number of applications made invalid by co-ordinator	2
Number of studies withdrawn prior to the meeting	7
Number of student applications reviewed	23
Number of paediatric applications reviewed	6
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	5	7.69
Favourable Opinion with Additional Conditions	7	10.77
Unfavourable Opinion	5	7.69
Provisional Opinion	48	73.85
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	65	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	42	64.62
Further Information Favourable Opinion with Additional Conditions	2	3.08
Further Information Unfavourable Opinion	1	1.54
Favourable Opinion with Standard Conditions	5	7.69
Favourable Opinion with Additional Conditions	7	10.77
Unfavourable Opinion	5	7.69
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	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	3	4.62
Total	65	100

Table 5: Other Management Information for the reporting period:

Average number of applications reviewed per full meeting	5.91
Number of applications for full ethical review over 60 days	3
Number of applications over 60 days as a % of total	4.62%
Number of days taken to final decision - average	367
Number of days taken to final decision - mode	3724
Number of SSAs (non-Phase 1) reviewed	16
Number of applications for SSA review over 25 days	1
Number of applications for SSA review over 25 days as % of all non-Phase 1 (SSAs)	6.3%
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	90
Number of substantial amendments over 35 days	12
Number of substantial amendments over 35 days as a % of total substantial amendments	13.3%
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	6
Number of modified amendments over 14 days	1
Number of modified amendments over 14 days as a % of total modified amendments	16.7%

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/0384	Clinical interventions on sex and gender	31
11/LO/0385	Gender identity and the sexed body	45
11/LO/0448	QAX576:Safety, Tolerability, Efficacy, PD & PK in progressive IPF	37
11/LO/0543	Assessing the mechanisms of recovery of aphasic speech production.V1	39
11/LO/0599	To assess the use of a cosmetic product for cracked heels in diabetics	56
11/LO/0606	Patient Comfort and Safety While Undergoing Peripheral Arteriography	39
11/LO/0632	CRD007 for treatment of Abdominal Aorta Aneurysm. Version 1.0	21
11/LO/0673	Correlation of calcium to creatinine ratio in spot and 24 hour urine	50
11/LO/0839	MINT- Melatonin Neuroprotection Trial Study -Ver 1	31
11/LO/0860	The effect of prunes on gastrointestinal health (version 1)	36
11/LO/0883	New sequencing technologies for investigation of Mendelian disease	51
11/LO/0891	Translational study Of Pre-operative Pazopanib in Sarcomas (TOPPS)	23
11/LO/0996	A Phase I/II three-part study in prostate cancer	34
11/LO/1021	Physical activity augmentation with pedometers during PR	47
11/LO/1057	Uterine Transplantation: From the animal model to the human setting	27
11/LO/1069	Allergy Testing in Adult Eosinophilic Oesophagitis	40
11/LO/1082	Effects of APTD on the symptomatology of anorexia nervosa - version 1	39
11/LO/1184	MP4CO in adult sickle cell patients	43
11/LO/1247	Valuing Health in AMD (Version 1.2)	47
11/LO/1249	Parental preference for preventive interventions in GA children	54
11/LO/1401	SSAT 043 Atazanavir/ritonavir and zinc pharmacokinetic study	37
11/LO/1491	Ventricular remodelling and association with type of bariatric surgery	23
11/LO/1500	NITRITE-AMI	37
11/LO/1519	MDMA fMRI: version 1	50
11/LO/1520	Corticospinal tract organisation, muscle growth & motor control in BCP	47
11/LO/1782	The effect of chronic glucagon infusion in human volunteers	42
11/LO/1799	Donepezil trial for motor recovery in acute stroke	36
11/LO/1842	Significance of the recovery point during prism fusion range testing.	39
11/LO/1863	Anti-TNF and Tuberculosis	30

11/LO/2030	IMM-101 treatment, combined with CyberKnife, in Colorectal Cancer	38
12/LO/0004	Drug Lung Deposition In COPD	27
12/LO/0033	Effect of electrical stimulation on left neglect in acute stroke v1	72
12/LO/0087	Trial for improving outcome from stroke in renal disease. Version 1.0	57
12/LO/0093	Sexual health service review	35
12/LO/0095	A1444-046 Observational fup from BMS-650032/790052 Hepatitis C trials	62
12/LO/0190	Four-Part: Effect of GSK2118436 in pts with BRAF Solid Mutant Tumours	28
12/LO/0191	Rollover Study: GSK2118436 Continued Treatment for BRAF+ Tumours	28
12/LO/0396	Body composition in obesity and PCOS	72
12/LO/0413	Research study to identify anti-inflammatory compounds - V1	51
12/LO/0414	The Role of Serotonergic and Dopaminergic Mechanisms in LID's.	37
12/LO/0443	Vemurafenib in patients with BRAF V600 mutation-positive cancers	46
12/LO/0446	Imatinib with BKM120 in patients with Gastrointestinal Stromal Tumour	40

Further Information Favourable Opinion with Additional Conditions

REC Reference	Application Short Title	Number of Days on Clock
11/LO/0868	Diabetes remission and bariatric surgery	44
11/LO/1023	Efficacy and safety of Ozurdex vs Lucentis in patients with BRVO	32

Further Information Unfavourable Opinion

REC Reference	Application Short Title	Number of Days on Clock
11/LO/0846	What is the emotional impact of dedicated DRSS clinics (version 1.0)	36

Favourable Opinion with Standard Conditions

REC Reference	Application Short Title	Number of Days on Clock
11/LO/0863	OPTiMiSE MRI	36
11/LO/0866	Patients' preferences of general practice services: A pilot study	35
11/LO/1055	Tissue Engineering Human Heart Valves	22
11/LO/1065	Survivorship care plans following gynaecological cancer treatment	31
11/LO/1521	Quantum dots and biomarkers in colorectal cancer tissues. Version 1	23

Favourable Opinion with Additional Conditions

REC Reference	Application Short Title	Number of Days on Clock
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11/LO/0361	The effect of Vitamin D status on outcomes in sepsis	21
11/LO/1200	The ASP Study (Protocol v1.0 dated 4th July 2011)	21
11/LO/1240	Exploring clients' experiences of Dynamic Interpersonal Therapy (DIT)	29
11/LO/1440	Clot stability- Half-life study Version 1	34
11/LO/1772	IMM-101-008 Long Term Follow Up Study of Phase I IMM-101-001	28
11/LO/1785	Auditory attention in Alzheimer's Disease	28
11/LO/1861	Catheter Contact Force and Electrogram Characteristics	30

Unfavourable Opinion

REC Reference	Application Short Title	Number of Days on Clock
11/LO/0391	A Phase III three-part study in prostate cancer	21
11/LO/1235	Predicting Multiple Sclerosis	29
11/LO/1426	Cranial bleeds in newborns at risk of inherited bleeding disorders	22
12/LO/0179	Diagnosis of ovarian disease in women with gastrointestinal symptoms	16
12/LO/0221	The role of amyloid in delirium secondary to infection	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
11/LO/0603	Prediction of graft vs host disease in stem cell transplant recipients	37
11/LO/1241	Neurophysiological detection of neuropathy in thalidomide patients	23
12/LO/0090	Phase II trial of PR1 and WT1 peptides in Chronic Myeloid Leukaemia	27

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

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

Table 7: Items exceeding timelines:

Full applications for ethical review over 60 day timeline		
REC Reference	Application Short Title	Number of Days on Clock
12/LO/0033	Effect of electrical stimulation on left neglect in acute stroke v1	72
12/LO/0095	AI444-046 Observational f up from BMS-650032/790052 Hepatitis C trials	62
12/LO/0396	Body composition in obesity and PCOS	72

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
11/LO/1992	Neuroinflammation in alcohol dependence	27

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
10/H0707/95/AM01	Adapting Medical Imaging Systems for Body Monitoring	Global amendment 3, final version, 11 May 2011	42
09/H0707/95/AM04	GRIPHON 2 / Protocol AC-065A302	Global Amendment 3	42
07/H0707/112/AM15	EFC6260 (HMR1726) Final Version: 9-May-2007	GP letter for extension period	44
06/Q0406/33/AM04	BIOBANK TO FACILITATE FUTURE THERAPY OF NEUROMUSCULAR DISORDERS	Amendment 4, 21st July 2011	36
11/LO/0606/AM02	Patient Comfort and Safety While Undergoing Peripheral Arteriography	Preg 01 dated 15 September 2011	43

04/Q0406/147/AM14	Cognitive and neural mechanisms of skilled behaviour	Substantial Amendment 12	36
05/Q0406/49/AM06	Features and Aetiology of Near Death Experiences In Cardiac Arrest	Amendment No 7 - dated 4th November	36
10/H0707/54/AM12	A Phase 2 Study of Albiglutide in Patients with Heart Failure	Substantial Amendment 6	43
05/Q0406/142/AM06	The physiological role of kisspeptin-54 in amenorrhoea	Substantial amendment #6 dated 7/12/2011	45
09/H0707/86/AM04	Generation of clinical grade T cells for adoptive cell therapy	Amendment 2 (to create protocol No. 4; 11th January	39
04/Q0406/151/AM01	Physiological role of kisspeptin-54 on reproductive hormone secretion	Substantial amendment #1, 20/1/12	56
11/LO/1500/AM01	NITRITE-AMI	Amendment 1, version 1, 18th January 2012	39

Modified Amendments over 14 day timeline

Amendment Reference	Application Short Title	Amendment Title	Number of Days on Clock
11/LO/0606/AM02/1	Patient Comfort and Safety While Undergoing Peripheral Arteriography	Preg 02 dated 9 November 2011	37

Section 30 application over 60 day timeline

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