

NRES Committee London - Dulwich

Annual Report

01 April 2011 - 31 March 2012

Part 1 - Committee Membership and Training

Name of REC: NRES Committee London - Dulwich

Type of REC: Type 3

Type of Flag: Medical Devices

Research Involving Children

Chair: Dr Michael Philpot (from 01/02/2012)

Previous Chair - Dr David Jewitt

Vice-Chair: Mr Colin Standfield

Alternate Vice-Chair: None

Co-ordinator: Stephanie Hill (from 01/04/2012)

Alene Pointon (during 31/07/2011 - 31/03/2012)

Juliet Kirk-Buaku (up to 31/07/2011)

PRSC Co-ordinator: Stephanie Hill (from 01/04/2012)

Alene Pointon (up to 31/03/2012)

Assistant Co-ordinator: Claude Beckles

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Chair's overview of the past year:

The past year has been another of change and development. We have evolved from the anonymous South East London 3 to NRES Committee London - Dulwich. A number of key retirements and resignations have had their impact – most notably the departure of Dr David Jewitt who retired after 10 years as Chair. He made a tremendous contribution to the committee and supporting other RECs in the area. His will be a hard act for me to follow. In addition, Dr Colin Ball and Professor Nora Donaldson have also left us after excellent work during their tenure. Colin Standfield has joined us as Vice-Chair.

Over the past two years we have lost a number of experts and are relieved that NRES is now (Sept 2012) beginning to recruit replacements.

During the report year we have had at least two coordinators: Juliet Kirk-Buaku left to pursue a teaching career and her successor Alene Pointon (previously at the Ealing REC) took early retirement. We now look forward to a period of stability with our new coordinator, Stephanie Hill with the help of an assistant coordinator.

With regard to activity: there has been a reduction in studies reviewed at full committee and by proportionate review sub-committee. It is disappointing that the proportion of studies and amendments exceeding the time targets has increased. I believe that the succession of coordinators and the increase in their workload, office moves and uncertainty about the future of the service have all played a part.

NRES Committee London - Dulwich Membership:

Name	Occupation	Expert or	Dates	
		Lay	Appointed	Resigned
Dr Colin Ball	Consultant Paediatrician	Expert	11/12/2001	31/01/2012
Dr Will Bernal	Consultant Liver Intensivist	Expert	31/03/2006	
Mr Kai Loke Chan	Assistant Director of	Expert	20/02/2005	
	Pharmacy			
Ms Madeleine Colvin	Barrister	Lay Plus	17/09/2007	
Dr Nora Donaldson	Statistician	Expert	01/01/2001	15/10/2011
Mr John Fowler	Lay Member	Lay	31/05/2005	
Dr Patrick Gordon	Consultant	Expert	01/09/2007	
	Rheumatologist			
Dr David Jewitt	Consultant Cardiologist	Expert	01/01/2007	31/01/2012
Mrs Carole Jordan	Senior Nurse	Expert	01/04/2010	
Dr Thomas Kabir	MHRN Service Users in	Lay	10/02/2010	
	Research Coordinator			
Mr Enock Khoromana	Stroke Research	Lay	01/10/2010	
	Coordinator			
Dr Michael Philpot	Consultant Psychiatrist	Expert	30/12/2007	
Ms Anna Ramberg	Research Development	Lay Plus	01/10/2010	
	Manager			
Mr Krzysztof Rutkowski	Research Nurse	Lay Plus	01/08/2010	
Mr Colin Standfield	Charity Worker	Lay	01/02/2012	
Ms Catherine Walton	Consultant Midwife	Expert	30/06/2006	

Deputy Members

Name	Occupation	Expert or Lay	Meeting date attended

Co-opted Members

Name	Occupation	Expert or Lay	Meeting date attended
Mr Brady Pohle	Legal Services Advisor	Lay Plus	17/08/2011
Ms Sally Gordon Boyd	Medical Ethicist	Lay	17/08/2011

Member Bank

Name	Occupation	Expert or Lay	Meeting date attended

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

Name	Declaration of Interest	Date
Dr Michael Philpot	Membership of the following: Alzheimer's Society British Psychological Society British Neuropsychiatry Association	30/03/2012
Mr Colin Standfield	Occasional patient and public representative on the STOPAH study: pentoxifyline in alcoholic hepatitis. Trustee of Drugscope. Lay Member of NICE Appeals Panel	30/03/2012
Mr Kai Loke Chan	None	30/03/2012
Dr Will Bernal	Active Clinical Researcher.Peer reviewer for medical journals.	30/03/2012
John Fowler	Married to an NHS Consultant (Dr B Cooper) whose contract is held by GSTT.	30/03/2012
Dr Thomas Kabir	King's College London employee (NIHR Mental Health Research Network). Occasional work for the Royal College of Psychiatrists. Co-operate member of The Institute of Physics. Involved in many mental health research studies through employment role.	30/03/2012
Mrs Carole Jordan	None.	30/03/2012
Mr Krzysztof Rutkowski	None.	30/03/2012
Ms Catherine Walton	Occasional attendance of Women's R & D Group at King's College Hospital.	30/03/2012
Ms Anna Ramberg	Research Development Manager, City University London. This involves the overview of our local RECs, including Secretary to Senate REC.	30/03/2012

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

Month	Date	Number of Members Present at Meeting	
April	20/04/2011	9	
May	18/05/2011	11	
June	15/06/2011	10	
July	20/07/2011	7	
August	17/08/2011	8	
September	21/09/2011	10	
October	19/10/2011	11	
November	16/11/2011	9	
January	18/01/2012	12	
February	22/02/2012	11	
March	21/03/2012	7	

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
April	06/04/2011	3
May	04/05/2011	3
May	20/05/2011	2
June	01/06/2011	3
July	06/07/2011	3
August	10/08/2011	3
September	14/09/2011	3
October	05/10/2011	3
November	07/11/2011	3
December	07/12/2011	3
February	01/02/2012	3
March	07/03/2012	3

¹² 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
John Fowler	10
Mr Kai Loke Chan	10
Mrs Carole Jordan	9
Ms Anna Ramberg	9
Mr Krzysztof Rutkowski	9
Dr Thomas Kabir	8
Dr Colin Ball	8
Dr Michael Philpot	8
Dr David Jewitt	7
Dr Will Bernal	6
Ms Catherine Walton	6
Ms Madeleine Colvin	4
Mr Enock Khoromana	4
Dr Patrick Gordon	3
Mr Colin Standfield	2
Mr Brady Pohle	1
Ms Sally Gordon Boyd	1

Number of inquorate meetings held: None

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

Name	Number of Meetings Attended
Dr Michael Philpot	12
Mr John Fowler	11
Dr Nora Donaldson	6
Mr Enock Khoromana	4
John Fowler	1
Dr Will Bernal	1

Training 01 April 2011 – 31 March 2012:

Name of Member	Date	Event(s) attended
Dr Michael Philpot	26/01/2012 – 26/01/2012	NRES Medical Devices Training (Code PO3003)
Ms Catherine Walton	28/02/2012 - 28/02/2012	NRES Qualitative Research and Ethical Review
Mr Enock Khoromana	22/06/2011 - 22/06/2011	Induction
Ms Anna Ramberg	26/07/2011 - 26/07/2011	Medical Devices training
Ms Anna Ramberg	28/02/2012 - 28/02/2012	Qualitative Research and Ethical Review
Ms Catherine Walton	14/03/2012 - 14/03/2012	NRES Members National Training Day - London, NRES
Ms Catherine Walton	19/01/2012 - 19/01/2012	Shared Ethical Debate
Dr Will Bernal	29/02/2012 - 29/02/2012	Personal data in research: a workshop for members of Research Ethics Committees, NRES
Mr Colin Standfield	07/09/2011 - 07/09/2011	Chairing Skills, NRES
Mr Krzysztof Rutkowski	15/09/2011 - 15/09/2011	Human Tissue Act Training (Code PO5001), 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	5	7.35
Phase 1	0	0.00
Gene Therapy	0	0.00
Research Tissue Bank	0	0.00
Research Database	0	0.00
Others	63	92.65
Total Applications Reviewed	68	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	17
Number of paediatric applications reviewed	13
Number of device applications reviewed	16
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	10	14.71
Favourable Opinion with Additional Conditions	19	27.94
Unfavourable Opinion	1	1.47
Provisional Opinion	38	55.88
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	68	100
Number of studies sent back to full committee meeting for final opinion	1	

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	36	52.94
Conditions		
Further Information Favourable Opinion with Additional	2	2.94
Conditions		
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	10	14.71
Favourable Opinion with Additional Conditions	19	27.94
Unfavourable Opinion	1	1.47
Provisional Opinion	0	0
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	0	0.00
Total	68	100

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

Total Applications Reviewed	36

Table 6: Decisions given at proportionate review sub-committee meetings held within the reporting period:

Decisions taken at proportionate review sub-	Number	%
committee meetings		
Favourable Opinion with Standard Conditions	19	52.78
Favourable Opinion with Additional Conditions	12	33.33
No Opinion transfer to full committee for review	2	5.56
Provisional Opinion	3	8.33
Unfavourable Opinion	0	0.00
Total	36	100

Table 7: Other Management Information for the reporting period:

	1
Average number of applications reviewed per full meeting	6.18
Number of applications for full ethical review over 60 days	13
Number of applications over 60 days as a % of total	19.12%
Number of days taken to final decision - average	44
Number of days taken to final decision - mode	28
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	79
Number of substantial amendments over 35 days	31
Number of substantial amendments over 35 days as a % of	39.2%
total substantial amendments	
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	0.0%
modified amendments	
Number of proportionate review applications for athird	00
Number of proportionate review applications for ethical review over 14 days*	26
Number of proportionate review applications over 14 days	76.47%
as a % of total	

^{*}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/0256	EURO CANAL Trial	44
11/LO/0397	Parental attitudes to minimally invasive autopsy	31
11/LO/0555	Cardiovascular morbidity in children and young people with lupus v2	30
11/LO/0601	(duplicate) rTMS therapy for promoting continence in Spinal Cord Injur	28
11/LO/0674	Clinical evaluation SOLO micropump insulin delivery system with IBGM	53
11/LO/0784	COSIRA - REDCLN-006 Rev.A	61
11/LO/0798	Safewards	70
11/LO/0932	Long-term Antibiotic Therapy in Stable COPD	37
11/LO/1026	Single Incision -vs- Laparoscopic Surgery for morbidly obese patients	34
11/LO/1043	RETILASE TRIAL	64
11/LO/1092	Leukocytes and inflammatory mediators in critical illness	53
11/LO/1243	Childhood blindness: genetic diagnosis for clinical management	57
11/LO/1250	SPPB and Gait Speed during acute exacerbations of COPD	36
11/LO/1256	Ranibizumab vs dexamethasone in branch retinal vein occlusion	40
11/LO/1260	Sleep efficiency assessed by PSG in advanced Parkinson's disease	50
11/LO/1408	ABSORB II RCT: 10-393	31
11/LO/1424	REMEDEE OCT , VP-0509, V1.0, 9 March 2011	72
11/LO/1453	AL Amyloidosis Bone Marrow Study	42
11/LO/1504	Optical Imaging of Barrett's Esophagus Using Nvision pVLE 11_01	57
11/LO/1505	Immune T cell study from the cord blood, bone marrow and blood	40
11/LO/1574	Pipelle Endometrial Sampling in Non-viable Early Gestations (PESNEG)	71
11/LO/1607	ProSpare II	70
11/LO/1661	Electroanatomical Mapping using Rhythmia System & Catheter TP-092 Rev5	86
11/LO/1687	Obstructive sleep apnoea in type 2 diabetes version 1.3	40
11/LO/1776	Urinary Proteomics for HIGH Risk pregnancies (UP HIGH R)	71
11/LO/2017	The Evaluation of the Firesetting Intervention Programme	79
11/LO/2037	Psychological Burden in Major Trauma	46
12/LO/0043	The AMBER Care Bundle in the hospital: A pilot study	60
12/LO/0044	The IARE Study	52

12/LO/0056	IRIS, 11-001	42
12/LO/0249	Improving Sperm Cryopreservation	54
12/LO/0253	Think Breech Study	65
12/LO/0255	Metabolic Changes in Liver Disorders of Pregnancy	59
12/LO/0269	IPET version 1.0 27.01.2012	58
12/LO/0270	THRIVE-III	36
12/LO/0371	The Evaluation of OCT(Optical Coherence Tomography)	104
12/LO/0415	Preoperative diet: effect on wound healing after bariatric surgery	88
12/LO/0461	Exploring Perceptions about Insignificant/Significant Prostate Cancer	49

Further Information Favourable Opinion with Additional Conditions		
REC Reference	Application Short Title	Number of Days on Clock
11/LO/0369	PARACHUTE	48
12/LO/0463	Ethnicity and Attitudes to Intensive Care	46
12/LO/0361	#0802: The GRANVIA®-C cervical disc prosthesis	106

Further Informati	on 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/0400	Mechanisms of impaired innate immunity to bacterial infection in COPD	48
11/LO/0602	Abbey Wood Infant Feeding Project	14
11/LO/0609	Do at risk populations need routine screening for Hepatitis B and C?	16
11/LO/0654	CT scans - Suchey Brooks	9
11/LO/0775	Lactose Intolerance in Children with Cow's Milk Allergy	49
11/LO/0788	Prevalence of domestic abuse amongst elderly service users of aCMHT	17
11/LO/0789	Radiation Injury Risk and Patient Consent	9
11/LO/0825	(duplicate) Differential storage of hydroxyethyl starch (HES) in the h	37
11/LO/1251	Recovery Nurses' Pain Assessment and Management Survey	22
11/LO/1255	Understanding Consent for Consent (C4C)	34
11/LO/1430	NNC-NEC Study Version 1	21
11/LO/1513	A pilot follow up study of twins in utero (version 1)	26

44/10/4545	No contract Transfer and October 10 to 10	40
11/LO/1515	Neonatal Transitional Care (Version 1)	19
11/LO/1518	Evaluation of the National Problem Gambling Clinic	21
11/LO/1524	Development of RAPP-PI outcome measures	16
11/LO/1592	Laparoscopic single incision vs multiple incision gastric band surgery	21
11/LO/1665	What are patient's feelings concerning the setting of recovery goals?	21
11/LO/1666	Psychological services for parents in CAMHS- Parents' perspective	20
11/LO/1697	Improving engagement in early interventions in psychosis	21
11/LO/1767	Communication in Multimorbidity and Discharge (CoMMandD study)	12
11/LO/1811	The role of VEGF-A in ocular melanoma	17
11/LO/1813	Self-management after stroke study	6
11/LO/1816	A study of patient preferences for allergy testing. Version 1, 1/10/11	10
11/LO/1818	Sensor based assessment of the upper limb following stroke: version 1	13
11/LO/2046	Analysis of cortisol and cortisone by LC-MSMS	19
12/LO/0083	DAFNE-Hypoglycaemia Awareness Restoration Trial (HART) version 2	42
12/LO/0235	ETOP LUNGSCAPE master protocol and LUNGSCAPE-001-ALK v1.0	34
12/LO/0239	Vitamin B12 status in pregnancy	34
12/LO/0470	UK standardisation for BICAMS	39

Favourable Opinion with Additional Conditions		
REC Reference	Application Short Title	Number of Days on Clock
11/LO/0389	Application of spectroscopic skin imaging to transdermal drug delivery	55
11/LO/0406	Chemotherapy Enhanced Support Programme	49
11/LO/0593	Exploratory study of a binocular therapy for anisometropic amblyopia	47
11/LO/0604	Bowel Screening: A specialist screening practitioner's perspective 1.0	21
11/LO/0613	Power in the workplace	26
11/LO/0681	Telemedicine for retinopathy of prematurity	27
11/LO/0743	PARACHUTE III	28
11/LO/0800	A study of A&E triage decisions.	9
11/LO/1013	Application of digital technology in colour matching facial prostheses	23
11/LO/1028	(PRS) An organisational study of Alongside Midwifery Units	24
11/LO/1058	Evaluation of NAAT and POCT for detection of Trichomonas vaginalis	21
11/LO/1080	The economic impact of oropharyngeal infection in childhood	21
11/LO/1145	Inhaled fine charged particle deposition in the human lung	30

11/LO/1244	Genetics Of RA In Individuals Of African Ancestry	33
11/LO/1245	Validation of the Evaluation of Intervention Scale version 1.7	33
11/LO/1246	Effect of a probiotic supplement on gastrointestinal well-being	27
11/LO/1252	Exploring self-management in chronic low-back disorder Version 01	22
11/LO/1253	A survey study on surgical complications and patient wellbeing	18
11/LO/1254	Attitudes to exercise in CF patients over the age of 40 years	26
11/LO/1510	NHRM - Nocturnal Hypoglycaemia Risk Mitigation	16
11/LO/1514	Direct Flow Medical Percutaneous Aortic Valve 18F System IP 010	16
11/LO/1527	ADVOCATE	19
11/LO/1596	A RCT of PCI versus no PCI prior to TAVI	21
11/LO/1606	Cognitive Remediation Therapy for Anorexia Nervosa	28
11/LO/1654	Characterisation of the human scoliotic spinal growth plate (version2)	20
11/LO/1792	Families experience of mental health services with a relative with BPD	28
11/LO/1834	Comparison of 3 picture vision tests with ETDRS	27
12/LO/0062	Ranolazine for Incomplete Vessel Revascularization post-PCI	28
12/LO/0236	A process evaluation of EPT to treat cancer survivors with PTSD	31
12/LO/0241	Dietary change in response to type 2 diabetes. V1	31
12/LO/0264	Phenomenology of rumination in depressed youth	41

Unfavourable Opinion		
REC Reference	Application Short Title	Number of Days on Clock
11/LO/1843	Measurement of Salivary Cortisol & Cortisone by LC-MS/MS	28

Provisional Opini	on	
REC Reference	Application Short Title	Number of Days on Clock

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

Further informati	on 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	
Invalid Applicatio	n		
REC Reference	Application Short Title	Number of Days on Clock	
No Opinion Pend	ling 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/0784	COSIRA - REDCLN-006 Rev.A	61
11/LO/0798	Safewards	70
11/LO/1043	RETILASE TRIAL	64
11/LO/1424	REMEDEE OCT , VP-0509, V1.0, 9 March 2011	72
11/LO/1574	Pipelle Endometrial Sampling in Non-viable Early Gestations (PESNEG)	71
11/LO/1607	ProSpare II	70
11/LO/1661	Electroanatomical Mapping using Rhythmia System & Catheter TP-092 Rev5	86
11/LO/1776	Urinary Proteomics for HIGH Risk pregnancies (UP HIGH R)	71
11/LO/2017	The Evaluation of the Firesetting Intervention Programme	79
12/LO/0253	Think Breech Study	65
12/LO/0361	#0802: The GRANVIA®-C cervical disc prosthesis	106
12/LO/0371	The Evaluation of OCT(Optical Coherence Tomography)	104
12/LO/0415	Preoperative diet: effect on wound healing after bariatric surgery	88

Proportionate review applications for ethical review over 14 days timeline		
REC Reference	Application Short Title	Number of Days on Clock
11/LO/0604	Bowel Screening: A specialist screening practitioner's perspective 1.0	21
11/LO/0609	Do at risk populations need routine screening for Hepatitis B and C?	16
11/LO/0788	Prevalence of domestic abuse amongst elderly service users of aCMHT	17
11/LO/1028	(PRS) An organisational study of Alongside Midwifery Units	24
11/LO/1058	Evaluation of NAAT and POCT for detection of Trichomonas vaginalis	21
11/LO/1080	The economic impact of oropharyngeal infection in childhood	21
11/LO/1251	Recovery Nurses' Pain Assessment and Management Survey	22
11/LO/1252	Exploring self-management in chronic low-back disorder Version 01	22
11/LO/1253	A survey study on surgical complications and patient wellbeing	18
11/LO/1254	Attitudes to exercise in CF patients over the age of 40 years	26
11/LO/1515	Neonatal Transitional Care (Version 1)	19

11/LO/1524	Development of RAPP-PI outcome measures	16
11/LO/1527	ADVOCATE	19
11/LO/1654	Characterisation of the human scoliotic spinal growth plate (version2)	20
11/LO/1665	What are patient's feelings concerning the setting of recovery goals?	21
11/LO/1666	Psychological services for parents in CAMHS- Parents' perspective	20
11/LO/1811	The role of VEGF-A in ocular melanoma	17
11/LO/2037	Psychological Burden in Major Trauma	46
11/LO/2046	Analysis of cortisol and cortisone by LC-MSMS	19
12/LO/0235	ETOP LUNGSCAPE master protocol and LUNGSCAPE-001-ALK v1.0	34
12/LO/0236	A process evaluation of EPT to treat cancer survivors with PTSD	31
12/LO/0239	Vitamin B12 status in pregnancy	34
12/LO/0241	Dietary change in response to type 2 diabetes. V1	31
12/LO/0461	Exploring Perceptions about Insignificant/Significant Prostate Cancer	49
12/LO/0463	Ethnicity and Attitudes to Intensive Care	46
12/LO/0470	UK standardisation for BICAMS	39

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
09/H0808/100/AM08	EMG in paediatric asthma	Amendment 7, 11 Oct 2010	72
10/H0808/62/AM01	Comparison of GnRH analogue and tourniquet on blood loss in myomectomy	1968, version 3, 18 April 2011	42
07/Q0703/36/AM03	Health and well being survey of members of the UK Armed Forces V1	Version 1.1, May 2011	36
10/H0808/111/AM01	Prevalence of medication use in early pregnancy	Number 1, 11 Apr 2011	43

10/H0808/14/AM04	COSAK	Substantial amendment no. 2	44
08/H0808/105/AM01	Evaluation of the genetic influences on chronic trigeminal pain		37
10/H0808/76/AM07	DEC-MDS version 1.0	10/H0808/76/AM07	54
10/H0808/129/AM04	MUK one	Substantial Amendment 4, 23 Sept 2011	54
10/H0808/45/AM02	ACCEPTANCE - Pudendal Neuromodulation in Overactive Bladder, v2.0	Substantial Amendment 2, 26 September 2011	46
11/LO/1256/AM01	Ranibizumab vs dexamethasone in branch retinal vein occlusion		39
09/H0808/46/AM04	Role of nNOS in the local regulation of human vascular function Amendment 4.0 08.08.2011		49
10/H0808/62/AM02	Comparison of GnRH analogue and tourniquet on blood loss in myomectomy	Reduction of blood tests four to two, samples froz	62
09/H0808/46/AM05	Role of nNOS in the local regulation of human vascular function	Amendment 5.0 07/10/11	62
10/H0808/109/AM02	EXCEL Clinical Trial 1.0 18th June 2010	Sub Amend 1 10-389 v4.0 22 July 2011	58
10/H0808/135/AM03	Psychological risk factors for fatigue in Rheumatoid Arthritis	Amendment 6, 11/10/11	55
11/LO/0005/AM02	Non-invasive assessment of liver damage in sickle cell disease	Amendment 2 3 November 2011	49
07/H0808/174/AM06	CRIMSON: Impact of Joint crisis plans	Amendment 6, November 2011	45
11/LO/1255/AM01	Understanding Consent for Consent (C4C)	Amendment 1, 15/11/2011	45
11/LO/1255/AM02	Understanding Consent for Consent (C4C)	Amendment 2, 15/11/2011	45
10/H0808/76/AM08	DEC-MDS version 1.0	10/H0808/76/AM08	45
11/LO/1767/AM01	Communication in Multimorbidity and Discharge (CoMMandD study)	Change to Recruitment	73
11/LO/0932/AM02	Long-term Antibiotic Therapy in Stable COPD	Protocol Amendment	48

11/LO/1424/AM01	REMEDEE OCT , VP-0509, V1.0, 9 March 2011	Substantial Amendment 1	53
10/H0808/7/AM09	Cortisol and memory in Alcoholics. Version 1	Substantial Amendment 4	40
09/H0808/97/AM06	Diabetes 6 (D-6) Substantial Amendment 6		40
09/H0808/97/AM07	Diabetes 6 (D-6)	Substantial Amendment 7	50
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Modified Amendments over 14 day timeline				
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			Clock	

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			Clock	