

National Research Ethics  
Service

  
*Health Research Authority*

# NRES Committee South Central - Southampton A

## Annual Report

**01 April 2011 – 31 March 2012**

## Part 1 – Committee Membership and Training

<b>Name of REC:</b>	NRES Committee South Central - Southampton A
<b>Type of REC:</b>	REC recognised to review CTIMPS in patients - type iii
<b>Type of Flag:</b>	Research Involving Adults Lacking Capacity Research Involving Children
<b>Chair:</b>	Dr Iain MacIntosh
<b>Vice-Chair:</b>	Dr Simon Kolstoe
<b>Alternate Vice-Chair:</b>	N/A
<b>Co-ordinator:</b>	Maxine Knight
<b>PRSC Co-ordinator:</b>	Maxine Knight
<b>Assistant Co-ordinator:</b>	None
<b>Committee Address:</b>	Level 3, Block B Whitefriars Lewins Mead Bristol BS1 2NT
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### Chair's overview of the past year:

We have a satisfactory number of members and all the officer posts are now filled. However we often do not have a pharmacist and I know that in the absence of the chair and assistant vice chair we do not have enough medically qualified members. Although the meeting is quorate it is often the case that the vice chair feels they need the benefit of the advice of medically qualified people. Our co-ordinator is working efficiently and cheerfully. The lack of unfavourable responses reflects a desire on the committee's part to work with researchers to resolve issues. Proportionate review (PR) has had a mixed response from members. Some have found PR by correspondence straightforward, others see the experience of communicating by email as not as rich a way of uncovering the views of members as a face-to-face meeting. There is clearly a necessity to get these less ethically challenging studies reviewed efficiently. It may be that a meeting preceding the full committee, running concurrently with the sub-committee, without the attendance of researchers and with a time cap on discussions would marry the positive elements of both approaches. We regularly review 6 applications and generally get the researchers out on time.

## NRES Committee South Central - Southampton A Membership:

Name	Occupation	Expert or Lay	Dates	
			Appointed	Resigned
Dr Clifford Allen	Corporate Development and Learning	Lay	14/10/2011	
Mr Richard Andoh	Pharmacist	Expert	01/12/2009	
Dr Catherine Angell	Midwife/Lecturer	Expert	01/12/2010	01/11/2011
Mrs Lisa Frances Armstrong	Senior Lecturer Social Work	Lay Plus	14/10/2011	
Dr Ronja Bahadori	Clinical Trial Coordinator	Expert	01/06/2011	15/12/2011
Rev'd Dr Rosemary Baker	Consultant in Learning Disabilities	Expert	01/12/2005	09/12/2011
Dr Stewart Bruce-Low	Laboratory Director & Senior Lecturer	Expert	01/11/2010	
Mrs Nina Marinova Delaney	Gateway Assessor	Lay	14/10/2011	
Dr Paul Diprose	Consultant Anaesthetist	Expert	01/12/2007	
Mrs Grania Howard	Operating Department Practitioner	Expert	01/10/2009	04/08/2011
Dr Simon Kolstoe	Academic Research Scientist/Vice-Chair	Expert	01/07/2009	
Dr Mary Lanyon	Retired Veterinarian	Lay Plus	01/01/2010	
Dr Iain MacIntosh	Consultant Paediatric Intensive Care	Expert	01/10/2006	
Dr Chris Markham	Senior Lecturer in Health Service & Research	Expert	01/10/2008	
Mr John Roskilly	Healthcare Support Worker	Lay	06/09/2011	
Mr Anwar Shahed	Student	Lay	14/10/2010	25/01/2012
Mr Jack Steer	Student	Lay Plus	14/10/2011	
Mrs Margaret Stephens	Senior Specialist, Speech & Language Therapist (Adult Neurology & Elderly Care)	Expert	10/07/2008	

### Deputy Members

Name	Occupation	Expert or Lay	Meeting date attended

### Co-opted Members

Name	Occupation	Expert or Lay	Meeting date attended
Dr Leonard G Brookes		Expert	12/04/2011
Dr Karl Nunkoosing	Principal Lecturer	Expert	12/04/2011

**Member Bank**

<b>Name</b>	<b>Occupation</b>	<b>Expert or Lay</b>	<b>Meeting date attended</b>

**NRES Committee South Central - Southampton A: Members' Declarations of Interest:**

<b>Name</b>	<b>Declaration of Interest</b>	<b>Date</b>
Mrs Lisa Frances Armstrong	Works as a Senior Lecturer at Portsmouth University. Is involved in her own research in the area of Social Care.	31/03/2012
Mrs Nina Marinova Delaney	Gateway Assessor.Owner of The Real Estate Agency.Chairperson of a non-governmental organisation in the past, in Bulgaria.	31/03/2012

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

<b>Month</b>	<b>Date</b>	<b>Number of Members Present at Meeting</b>
April	12/04/2011	8
May	10/05/2011	9
June	14/06/2011	8
July	12/07/2011	9
August	09/08/2011	7
October	11/10/2011	7
November	08/11/2011	10
December	13/12/2011	9
January	10/01/2012	12
February	14/02/2012	9
March	13/03/2012	9

11 full committee meetings were held during the reporting period.

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

<b>Month</b>	<b>Date</b>	<b>Number of Members Present at Meeting</b>
January	27/01/2012	3

1 proportionate review sub-committee meetings were held during the reporting period.

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

<b>Name</b>	<b>Number of Meetings Attended</b>
Dr Mary Lanyon	10
Dr Iain MacIntosh	9
Dr Simon Kolstoe	9
Mr Richard Andoh	8
Dr Paul Diprose	7
Dr Stewart Bruce-Low	6
Mr John Roskilly	6
Mrs Lucy Sayer	5
Mrs Margaret Stephens	5
Rev'd Dr Rosemary Baker	5
Dr Ronja Bahadori	4
Dr Clifford Allen	3
Dr Catherine Angell	3
Dr Chris Markham	3
Mr Jack Steer	3
Mrs Lisa Frances Armstrong	3
Mrs Nina Marinova Delaney	3
Dr Karl Nunkoosing	2
Dr Leonard G Brookes	1
Mrs Grania Howard	1
Chris Skidmore	1

**Number of inquorate meetings held: 0**

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

<b>Name</b>	<b>Number of Meetings Attended</b>
Dr Iain MacIntosh	1
Mr John Roskilly	1
Mrs Margaret Stephens	1

## Training 01 April 2011 – 31 March 2012:

Name of Member	Date	Event(s) attended
Dr Simon Kolstoe	07/12/2011 - 07/12/2011	NRES Statistics Training for NRES REC Members, NRES
Dr Paul Diprose	20/04/2011 - 20/04/2011	Online E&D Learning
Dr Simon Kolstoe	20/04/2011 - 20/04/2011	Online E&D Learning
Dr Ronja Bahadori	01/07/2011 - 01/07/2011	South Central - Oxford A Training day, NRES
Dr Ronja Bahadori	04/10/2011 - 04/10/2011	Induction, NRES
Dr Mary Lanyon	05/07/2011 - 05/07/2011	Equality & Diversity
Dr Ronja Bahadori	27/07/2011 - 27/07/2011	The ethical review of medicines based research: A workshop for researchers and committee members (co, NRES
Dr Simon Kolstoe	01/11/2011 - 01/11/2011	Reviewing Clinical Trials of Investigational Medicinal Products
Dr Mary Lanyon	28/02/2012 - 28/02/2012	NRES Qualitative Research and Ethical Review
Mrs Margaret Stephens	28/02/2012 - 28/02/2012	NRES Qualitative Research and Ethical Review, NRES
Dr Chris Markham	09/08/2011 - 09/08/2011	Mental Capacity Act DVD Training
Dr Simon Kolstoe	09/08/2011 - 09/08/2011	Mental Capacity Act DVD Training
Rev'd Dr Rosemary Baker	09/08/2011 - 09/08/2011	Mental Capacity Act DVD Training
Dr Mary Lanyon	09/08/2011 - 09/08/2011	Mental Capacity Act DVD Training
Mrs Lucy Sayer	09/08/2011 - 09/08/2011	Mental Capacity Act DVD Training , NRES
Dr Stewart Bruce-Low	09/08/2011 - 09/08/2011	Mental Capacity Act DVD Training
Mrs Grania Howard	09/08/2011 - 09/08/2011	Mental Capacity Act DVD Training
Dr Ronja Bahadori	28/10/2011 - 28/10/2011	NRES Update Session, NRES
Dr Ronja Bahadori	20/10/2011 - 20/10/2011	Equality & Diversity, NRES - Online
Dr Ronja Bahadori	04/11/2011 - 04/11/2011	Shared Ethical Debate, NRES
Mrs Nina Marinova Delaney	08/02/2012 - 08/02/2012	Induction, NRES
Dr Iain MacIntosh	19/01/2012 - 19/01/2012	NRES Shared Ethical Debate, NRES
Mr Richard Andoh	19/01/2012 - 19/01/2012	NRES Shared Ethical Debate training, NRES
Mr Richard Andoh	06/03/2012 - 06/03/2012	Research using Human Tissue, 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:**

<b>Applications for full ethical review – Study Type</b>	<b>Number</b>	<b>%</b>
Clinical Trial of Investigational Medicinal Product	15	22.73
Phase 1	0	0.00
Gene Therapy	0	0.00
Research Tissue Bank	0	0.00
Research Database	0	0.00
Others	51	77.27
<b>Total Applications Reviewed</b>	<b>66</b>	<b>100</b>

**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	2
Number of student applications reviewed	27
Number of paediatric applications reviewed	17
Number of device applications reviewed	0
Number of prisoner applications reviewed	0
Number of applications involving adults unable consent reviewed	5
Number of applications reviewed funded by the US DHHS	0

**Table 3: Decisions given at meetings held within the reporting period:**

<b>Decisions taken at meetings following review of applications</b>	<b>Number</b>	<b>%</b>
Favourable Opinion with Standard Conditions	8	12.12
Favourable Opinion with Additional Conditions	9	13.64
Unfavourable Opinion	0	0.00
Provisional Opinion	49	74.24
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
<b>Total</b>	<b>66</b>	<b>100</b>
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:**

<b>Status of applications at date of generation of report</b>	<b>Number</b>	<b>%</b>
Further Information Favourable Opinion with Standard Conditions	47	71.21
Further Information Favourable Opinion with Additional Conditions	2	3.03
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	8	12.12
Favourable Opinion with Additional Conditions	9	13.64
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	0	0.00
<b>Total</b>	<b>66</b>	<b>100</b>

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

<b>Total Applications Reviewed</b>	<b>3</b>
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**Table 6: Decisions given at proportionate review sub-committee meetings held within the reporting period:**

<b>Decisions taken at proportionate review sub-committee meetings</b>	<b>Number</b>	<b>%</b>
Favourable Opinion with Standard Conditions	0	0.00
Favourable Opinion with Additional Conditions	3	100.00
No Opinion transfer to full committee for review	0	0.00
Provisional Opinion	0	0.00
Unfavourable Opinion	0	0.00
<b>Total</b>	<b>3</b>	<b>100</b>

**Table 7: Other Management Information for the reporting period:**

<b>Average number of applications reviewed per full meeting</b>	6.00
<b>Number of applications for full ethical review over 60 days</b>	7
<b>Number of applications over 60 days as a % of total</b>	10.61%
<b>Number of days taken to final decision - average</b>	43
<b>Number of days taken to final decision - mode</b>	60
<b>Number of SSAs (non-Phase 1) reviewed</b>	5
<b>Number of applications for SSA review over 25 days</b>	3
<b>Number of applications for SSA review over 25 days as % of all non-Phase 1 (SSAs)</b>	60.0%
<b>Number of SSAs (Phase 1) reviewed</b>	0
<b>Number of applications for SSA review over 14 days</b>	0
<b>Number of applications for SSA review over 14 days as % of all Phase 1 (SSAs)</b>	0%
<b>Number of substantial amendments reviewed</b>	148
<b>Number of substantial amendments over 35 days</b>	19
<b>Number of substantial amendments over 35 days as a % of total substantial amendments</b>	12.8%
<b>Number of Section 30 applications reviewed</b>	0
<b>Number of Section 30 applications over 60 days</b>	0
<b>Number of Section 30 applications over 60 days as a % of total Section 30 applications</b>	0%
<b>Number of modified amendments reviewed</b>	16
<b>Number of modified amendments over 14 days</b>	1
<b>Number of modified amendments over 14 days as a % of total modified amendments</b>	6.3%
<b>Number of proportionate review applications for ethical review over 14 days*</b>	3
<b>Number of proportionate review applications over 14 days as a % of total</b>	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:**

<b>Further Information Favourable Opinion with Standard Conditions</b>		
<b>REC Reference</b>	<b>Application Short Title</b>	<b>Number of Days on Clock</b>
11/SC/0104	Genetic causes of Headache	68
11/SC/0106	Pharmacogenetic correlations in age related macular degeneration	51
11/SC/0107	ARM Pain Trial	44
11/SC/0111	Screening and diagnosis of familial kidney diseases	59
11/SC/0134	A qualitative study of adolescents experience of admission to PICU (2)	48
11/SC/0146	REFRAMED version 1.1	44
11/SC/0157	Muscle MRI in Congenital Myasthenia	32
11/SC/0158	The relationship between sleep and postpartum mood	32
11/SC/0162	ASPEN	38
11/SC/0169	Trial of Ipilimumab Versus Placebo in Subjects with Lung Cancer	52
11/SC/0204	Neurological conditions and oncology: immunology and interactions	35
11/SC/0214	The effect of bypass on microparticles	54
11/SC/0222	A comparison of clinical interview technique in vestibular assessment	71
11/SC/0226	Psychopathology in adults with intellectual disabilities and epilepsy	47
11/SC/0231	Development of a HRQOL questionnaire for cancer patients with cachexia	60
11/SC/0242	Naturalistic observation of mothers & infants with cleft lip version1	31
11/SC/0261	Investigation of WCFS1 on the gut microbiota of ASD children (V2)	58
11/SC/0263	Music perception testing in cochlear implant users	56
11/SC/0264	Genetic investigation of Congenital Heart Disease (new samples) - v1	60
11/SC/0265	Genetic investigation of congenital heart disease(stored samples)- v1	60
11/SC/0267	PD-Exercise version 1	62
11/SC/0274	Understanding Society-UK Household Longitudinal: Data Linkage Wave 4	57
11/SC/0294	Out of Hours End of Life Case Studies	60
11/SC/0313	Efficacy study of a quadrivalent flu vaccine in children (FLU D-QIV)	51
11/SC/0438	REPLACE - FCH vs. placebo in cardiovascular surgery	38
11/SC/0446	9HB01EXT - Long-Term Safety and Efficacy of (rFIXFc) Haemophilia B	47
11/SC/0459	Feasibility study to assess body composition in children aged 4 years	49
11/SC/0461	Autonomic Dysfunction and Colorectal Cancer	60
11/SC/0468	Dose-Ranging study with ABT-126 in subjects with mild to moderate AD.	42
11/SC/0470	Computerised acoustic analysis of lung sounds in viral bronchiolitis 1	43

11/SC/0481	Study E7080-703. Randomized Phase II study of E7080 in NSCLC	34
11/SC/0509	Understanding immunity in lymph nodes. V 1	61
11/SC/0523	GS 0115 Open label cobicistat regimen in HIV	39
11/SC/0524	GS 0121 Open label cobicistat regimen in HIV	39
11/SC/0530	The effect of incremental doses of iron in humans. Final Version 2.1	47
11/SC/0545	Neural markers of emotion regulation in adhd	39
12/SC/0003	Coagulative effects of androgen deprivation therapy in Prostate Cancer	60
12/SC/0005	Antiplatelet therapy response variability	48
12/SC/0047	Locus of control beliefs and IAPT psychological treatment	64
12/SC/0049	Symptom prevalence and help-seeking of patients at risk of lung cancer	65
12/SC/0098	Safety and Efficacy Study for Adolescents and Adults with Asthma	42
12/SC/0103	Diabetes Wellbeing Course Project for West Berks PCT Area - v1.	45
12/SC/0104	Non-invasive and continuous blood pressure monitoring	28
12/SC/0114	The resting and the waiting brain activities in ADHD	28
12/SC/0120	ABT-126 with Mild to Moderate Alzheimers subjects on AChEIs	43
12/SC/0129	A phase III study of pasireotide in patients with acromegaly Version 1	31
12/SC/0143	Acknowledging and responding to early signs of dementia	39

#### Further Information Favourable Opinion with Additional Conditions

REC Reference	Application Short Title	Number of Days on Clock
12/SC/0044	Functional Genetics of Immunity and Inflammation	66
12/SC/0110	Serum bupivacaine levels associated with the use of wound catheters.	51

#### 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/SC/0095	Screening and detection of mutations in ELA2 gene.	22
11/SC/0114	Development of assay to detect minimal residual disease	34
11/SC/0151	PAIn SoluTions In the Emergency Setting (PASTIES)	24
11/SC/0154	Association between quality of primary care, IMD and CHD outcomes	24
11/SC/0228	Transition Experiences of Young Adults with ADHD (Vers.1).	35
11/SC/0230	Cardiovascular Tissue Studies	39

11/SC/0368	EORTC LC13 Revision	27
11/SC/0420	LBC samples called BNCHG: Is ProExC useful in confirming HG disease?	27

### Favourable Opinion with Additional Conditions

REC Reference	Application Short Title	Number of Days on Clock
11/SC/0091	Failure analysis of modular total hip replacements	22
11/SC/0153	CF Eating behaviour and attitudes. Body Image and Coping Styles	24
11/SC/0273	Study of a new drug for untreated multiple myeloma patients - V00	29
11/SC/0304	Asenapine Specialist Cohort Event-Monitoring study (OSCAR)	25
11/SC/0306	Development of a modular intervention for -ve symptoms in Psychosis v2	25
11/SC/0418	Practitioners' experiences of treating LBP: NHS Vs Private	27
11/SC/0419	Bereavement care delivery in acute NHS hospitals v2	27
11/SC/0479	Carfilzomib for Advanced Refractory Multiple Myeloma European Study	28
12/SC/0007	Study of Ceftaroline Fosamil vs Vancomycin Plus Aztreonam for CSSI	22
12/SC/0064	Acute effect of dietary nitrate supplementation on post-MI patients	21
12/SC/0065	Monitoring and training in hand hygiene using camera surveillance	20
12/SC/0069	Ellipse Assura NTA	21

### 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
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<b>Invalid Application</b>		
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<b>REC Reference</b>	<b>Application Short Title</b>	<b>Number of Days on Clock</b>
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<b>No Opinion Pending Consultation with Referee</b>		
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<b>REC Reference</b>	<b>Application Short Title</b>	<b>Number of Days on Clock</b>
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<b>Not Requiring Review by NHS REC</b>		
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<b>REC Reference</b>	<b>Application Short Title</b>	<b>Number of Days on Clock</b>
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**Table 9: Items exceeding timelines:**

<b>Full applications for ethical review over 60 day timeline</b>		
<b>REC Reference</b>	<b>Application Short Title</b>	<b>Number of Days on Clock</b>
11/SC/0104	Genetic causes of Headache	68
11/SC/0222	A comparison of clinical interview technique in vestibular assessment	71
11/SC/0267	PD-Exercise version 1	62
11/SC/0509	Understanding immunity in lymph nodes. V 1	61
12/SC/0044	Functional Genetics of Immunity and Inflammation	66
12/SC/0047	Locus of control beliefs and IAPT psychological treatment	64
12/SC/0049	Symptom prevalence and help-seeking of patients at risk of lung cancer	65

<b>Proportionate review applications for ethical review over 14 days timeline</b>		
<b>REC Reference</b>	<b>Application Short Title</b>	<b>Number of Days on Clock</b>
12/SC/0069	Ellipse Assura NTA	21
12/SC/0065	Monitoring and training in hand hygiene using camera surveillance	20
12/SC/0064	Acute effect of dietary nitrate supplementation on post-MI patients	21

<b>SSAs (non Phase 1) over 25 days timeline</b>		
<b>REC Reference</b>	<b>Application Short Title</b>	<b>Number of Days on Clock</b>
11/SC/0175	HOT II	33
11/SC/0336	Patients' Perspectives of Insomnia	32
11/SC/0364	Emotional processing in Fibromyalgia	32

<b>SSAs (Phase 1) over 14 days timeline</b>		
<b>REC Reference</b>	<b>Application Short Title</b>	<b>Number of Days on Clock</b>

<b>Substantial Amendments over 35 day timeline</b>			
<b>Amendment Reference</b>	<b>Application Short Title</b>	<b>Amendment Title</b>	<b>Number of Days on Clock</b>
08/H0502/111/AM12	A9951002 PF-04360365 in patients with Alzheimer's disease	Update to Informed Consent Docs	38

09/H0502/93/AM06	Introduction of mealtime assistance onto acute elderly medical ward	Amendment 4:18/05/2011	38
07/H0502/105/AM01	Study of mechanisms and markers of asthma exacerbations-version1	Sub amendment 2.0; March 2011	37
06/Q1702/109/AM13	The pathophysiology of Primary Ciliary Dyskinesia	Amendment 8; July 2011	37
11/SC/0242/AM01	Naturalistic observation of mothers & infants with cleft lip version1	Amendment 1; 21 July 2011	40
08/H0502/5/AM02	Long term safety and efficacy of Omnitrope	Amendment 02; August 2011	40
08/H0502/14/AM11	The PRIMIT trial	Amendment 8; 01 August 2011	39
08/H0201/33/AM03	LINC (LUCAS IN Cardiac Arrest) study	Amendment 1 ; 08July 2011 new CI	37
05/Q1702/11/AM27	probiotics and xylitol for sore throat. v7	18 ; 1st August 2011	41
07/H0502/113/AM22	MAVIDOS	452622, v1.99, 17 August 2011	41
11/H0502/10/AM01	Internet Doctor	Amendment 1; 22 August 2011	40
03/11/090/AM06	DNA Polymorphisms in Mental Illness	Amendment 6; 1 September 2011	36
05/Q1702/119/AM13	PATCHstudy-1 Prevention of Allergy Through Cow's Milk Hydrolysate	Amendment 7; 22 August 2011	41
11/SC/0146/AM03	REFRAMED version 1.1	Amendment 2; 13.01.12	41
10/H0502/95/AM05	ICE v1.0	Amendment 4.015.12.2011	38
08/H0502/14/AM13	The PRIMIT trial	Amendment 10; 30/01/12	38
06/Q1702/109/AM15	The pathophysiology of Primary Ciliary Dyskinesia	Amendment 10; Feb 2012	41
11/SC/0146/AM05	REFRAMED version 1.1	Amendment 3; 01.03.12	43
11/H0502/9/AM02	EPI-HIP-001 BOD UK	Amendment 2; ; 7 March 2012	38

#### Modified Amendments over 14 day timeline

Amendment Reference	Application Short Title	Amendment Title	Number of Days on Clock
07/H0502/98/AM11/1	OSCAR Trial (England and Wales Version) Version 1	Amendment 4- 06 May 2011	15

**Section 30 application over 60 day timeline**

<b>Amendment Reference</b>	<b>Application Short Title</b>	<b>Amendment Title</b>	<b>Number of Days on Clock</b>
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