

# NRES Committee South Central - Oxford B

**Annual Report** 

01 April 2011 – 31 March 2012

#### Part 1 - Committee Membership and Training

Name of REC NRES Committee South Central - Oxford B

Type of REC: REC recognised to review CTIMPS in patients - type iii

Type of Flag: IRB Registered

Phase 1 Studies in Patients

Chair: Prof Margaret Rees

Vice-Chair: Mr Robert King

Alternate Vice-Chair: N/A

Co-ordinator: Miss Siobhán McDonagh

**PRSC Co-ordinator:** As above

**Assistant Co-ordinator:** Vicky Canfield (0.4 wte)

Committee Address: Bristol REC Centre

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#### Chair's overview of the past year:

The Annual Report 2011-2012 accurately reflects the hard work of both the Committee Members and the Coordinator. Oxford B members routinely attend more than the required number of REC and training meetings.

In the course of the past year, Oxford B have embraced Chair's Actions and Sub Committee documents via e-mail, as well as PR and teleconferencing.

The difficulties of annual leave cover in August are accurately portrayed in the report as well as other overruns. This issue has now been addressed with the addition of support within the office as well as the appointment of an Alternative Vice Chair.

# NRES Committee South Central - Oxford B Membership:

Name	Occupation	Expert or	Da	tes
		Lay	Appointed	Resigned
Mr Peter Brown	Lay Plus Member	Lay Plus	01/09/2011	
Dr Kim Cheetham	Retired Consultant	Expert	01/09/2010	
	Paediatrician			
Mrs Susan Dutton	Medical Statistician	Expert	30/08/2007	
Ms Linda Goffey	Lay Member	Lay	01/01/2007	11/01/2012
Mr Robert King	Retired University Lecturer (Philosophy)/ Committee Vice Chair	Lay Plus	12/01/2004	
Dr Wilhelm Kuker	Consultant Neuroradiologist	Expert	01/12/2010	
Dr Pamela Laurie	Retired Consultant Anaesthetist	Expert	05/06/2006	
Mr Ian MacKenzie	Retired Consultant / Reader Emeritus in Obstetrics and Gynaecology	Expert	09/11/2010	
Dr Liesl Osman	Retired Research Advisor	Lay	10/10/2009	
Rev Emma Percy	Lay Plus Member	Lay Plus	01/09/2011	
Dr Jonathan Price	Qualitative Expert	Expert	01/07/2002	
Prof Margaret Rees	Retired Consultant / Reader Emeritus in Gynaecology / Committee Chair	Expert	12/01/2004	
Dr Iveta Simera	Head of Programme Development, EQUATOR Network, Centre for Statistics in Medicine	Lay	21/09/2011	
Mrs Kate Thompson	Retired In patient and day hospice manager	Expert	10/03/2009	
Canon Jessica Turner	Hospital Chaplain/ Committee Alternative Vice Chair	Lay Plus	01/01/2006	11/01/2012
Mr Paul Windscheif	Pharmacist	Expert	07/12/2006	
Dr Zenobia Zaiwalla	Consultant in Paediatric Neurophysiology	Expert	13/12/2010	

# NRES Committee South Central - Oxford B: Members' Declarations of Interest:

Name	Declaration of Interest	Date
Prof Margaret Rees	Nil	01/01/2012
Mr Robert King	Nil	01/01/2012
Dr Pamela Laurie	Nil	01/01/2012
Mrs Susan Dutton	Nil	01/01/2012
Mr Paul Windscheif	Nil	01/01/2012
Mrs Kate Thompson	Nil	01/01/2012
Dr Liesl Osman	Nil	01/01/2012
Dr Jonathan Price	Nil	01/01/2012
Mr Ian MacKenzie	Nil	01/01/2012
Dr Zenobia Zaiwalla	Nil	01/01/2012
Dr Wilhelm Kuker	Nil	01/01/2012
Rev Emma Percy	Nil	01/01/2012
Mr Peter Brown	Nil	01/01/2012
Dr Iveta Simera	Nil	01/01/2012

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

Month	Date	Number of Members Present at Meeting
April	12/04/2011	9
May	10/05/2011	11
June	14/06/2011	14
July	12/07/2011	12
September	13/09/2011	13
October	11/10/2011	10
November	08/11/2011	16
December	13/12/2011	12
January	10/01/2012	11
February	14/02/2012	12
March	13/03/2012	8

<sup>11</sup> 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
October	31/10/2011	3
December	05/12/2011	3
January	20/01/2012	3
March	26/03/2012	3

<sup>4</sup> 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
Dr Kim Cheetham	11
Mr Paul Windscheif	11
Mrs Kate Thompson	9
Prof Margaret Rees	9
Mr Robert King	9
Mr Ian MacKenzie	9
Dr Wilhelm Kuker	8
Dr Zenobia Zaiwalla	8
Mrs Susan Dutton	8
Ms Linda Goffey	7
Dr Jonathan Price	7
Dr Liesl Osman	7
Canon Jessica Turner	7
Dr Pamela Laurie	7
Dr Iveta Simera	4
Rev Emma Percy	4
Mr Peter Brown	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
Prof Margaret Rees	4
Mr Robert King	2
Mr Ian MacKenzie	2
Mrs Kate Thompson	1
Ms Linda Goffey	1
Dr Kim Cheetham	1
Dr Liesl Osman	1

# Training 01 April 2011 – 31 March 2012:

Name of Member	Date	Event(s) attended
Dr Zenobia Zaiwalla	22/06/2011 - 22/06/2011	Induction, NRES
Dr Kim Cheetham	26/07/2011 - 26/07/2011	NRES Medical Devices Training
Prof Margaret Rees	27/07/2011 - 27/07/2011	The ethical review of medicines
		based research: A workshop for
		researchers and committee
		members (co, NRES
Canon Jessica Turner	21/07/2011 - 21/07/2011	Equality & Diversity, NRES
Mrs Susan Dutton	04/07/2011 - 04/07/2011	Equality & Diversity, NRES
Mr Robert King	27/09/2011 - 27/09/2011	NRES Update, NRES
Dr Pamela Laurie	28/10/2011 - 28/10/2011	NRES Update Session with
		Janet Wisely
Prof Margaret Rees	28/10/2011 - 28/10/2011	NRES Update Session, Janet
		Wisely
Dr Iveta Simera	10/01/2012 - 10/01/2012	Induction, NRES
Dr Iveta Simera	11/10/2011 - 11/10/2011	MCA and MCA in emergency
		situations, Siobhan McDonagh
Dr Iveta Simera	11/10/2011 - 11/10/2011	Decision making , Siobhan
		McDonagh
Prof Margaret Rees	10/01/2012 - 10/01/2012	NRES MCA Video, NRES
Mr Robert King	10/01/2012 - 10/01/2012	NRES MCA DVD, NRES
Ms Linda Goffey	11/10/2011 - 11/10/2011	MCA DVD, NRES
Ms Linda Goffey	11/10/2011 - 11/10/2011	MCA IN EMERGENCY
		SITUATIONS, Siobhan
Dr Pamela Laurie	11/10/2011 - 11/10/2011	MCA DVD AND MCA in
		Emergency Situation, Siobhan
Mr Paul Windscheif	11/10/2011 - 11/10/2011	MCA and MCA in Emergency
		Situations, NRES - REC
		Training Meeting
Mrs Kate Thompson	11/10/2011 - 11/10/2011	MCA and MCA in Emergency
		Situations, NRES - REC
5 1 11 5	11/10/0011	Training Meeting
Dr Jonathan Price	11/10/2011 - 11/10/2011	MCA and MCA in Emergency
D 16' OL 11	44/40/0044 44/40/0044	Situations, Siobhan
Dr Kim Cheetham	11/10/2011 - 11/10/2011	MCA and MCA in Emergency
Do King Ob and board	44/40/0044 44/40/0044	Situations, Siobhan
Dr Kim Cheetham	11/10/2011 - 11/10/2011	Help with Decision making,
Du Wille also Kulson	44/40/0044 44/40/0044	NRES MCA DVD and MCA in
Dr Wilhelm Kuker	11/10/2011 - 11/10/2011	
Mr.lon Mookonzia	11/10/2011 11/10/2011	Emergency Situations, Siobhan
Mr Ian MacKenzie	11/10/2011 - 11/10/2011	Induction, NRES
Mr Ian MacKenzie	01/11/2011 - 01/11/2011	Equality & Diversity, NRES
Dr Iveta Simera	14/03/2012 - 14/03/2012	Members National Training Day
		2012, 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	16	26.67
Phase 1	0	0.00
Gene Therapy	0	0.00
Research Tissue Bank	0	0.00
Research Database	0	0.00
Others	44	73.33
Total Applications Reviewed	60	100

# Table 2: Other REC activity during the reporting period:

Number of applications made invalid by co-ordinator	5
Number of studies withdrawn prior to the meeting	6
Number of student applications reviewed	24
Number of paediatric applications reviewed	4
Number of device applications reviewed	5
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	Number	%
applications		1
Favourable Opinion with Standard Conditions	11	1.67
Favourable Opinion with Additional Conditions	3	5.00
Unfavourable Opinion	4	6.67
Provisional Opinion	50	83.33
Invalid	0	0.00
No Opinion Pending Consultation with Referee	2	3.33
Provisional Opinion Pending Consultation with Referee	0	0.00
Not Requiring Review by NHS REC	0	0.00
Total	60	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	43	71.67
Conditions		
Further Information Favourable Opinion with Additional	6	10.00
Conditions		
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	1	1.67
Favourable Opinion with Additional Conditions	3	5.00
Unfavourable Opinion	5	8.33
Provisional Opinion	1	1.67
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	1.67
Total	60	100

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

Total Applications Reviewed	11

# 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	3	27.27
Favourable Opinion with Additional Conditions	2	18.18
No Opinion transfer to full committee for review	4	36.36
Provisional Opinion	2	18.18
Unfavourable Opinion	0	0.00
Total	11	100

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

Average number of applications reviewed per full meeting	5.45
Number of applications for full ethical review over 60 days	4
Number of applications over 60 days as a % of total	6.66%
Number of days taken to final decision - average	40
Number of days taken to final decision - mode	39
Number of SSAs (non-Phase 1) reviewed	5
Number of applications for SSA review over 25 days	1
Number of applications for SSA review over 25 days as % of	20.0%
all non-Phase 1 (SSAs)	
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	0%
all Phase 1 (SSAs)	
Number of substantial amendments reviewed	139
Number of substantial amendments over 35 days	31
Number of substantial amendments over 35 days as a % of	22.3%
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	0%
total Section 30 applications	
Number of modified amendments reviewed	6
Number of modified amendments over 14 days	6
Number of modified amendments over 14 days as a % of	100.0%
total modified amendments	
·	
Number of proportionate review applications for ethical	1
review over 14 days*	
Number of proportionate review applications over 14 days	14.29%
as a % of total	

<sup>\*</sup>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		
<b>REC Reference</b>	Application Short Title	Number of Days on Clock
11/SC/0093	Effect of ocular diseases on sleep and circadian rhythm. version 1.0	27
11/SC/0108	Personality, Therapeutic Alliance and Expectations in Eating Disorders	39
11/SC/0109	Subcutaneous Implantable Cardioverter-Defibrillator study	44
11/SC/0112	TMS studies of timing for attention and memory	29
11/SC/0116	Deep Brain Stimulation - the carers perspective	52
11/SC/0117	Coping strategies and quality of life in cancer patients 2	32
11/SC/0124	Pleasure in the brain: Neural effects of pramipexole on reward.	27
11/SC/0127	DISTINCT	24
11/SC/0156	Attitudes towards and effects of an RCT in a TC environment	47
11/SC/0165	Evaluation of the Thrombolux system	35
11/SC/0167	secukinumab in patients with mod to sev chronic plaque-type psoriasis	35
11/SC/0168	Comparative assessment of coronary artery disease using IVUSVH and FFR	47
11/SC/0170	NN1731-3562: Efficacy & Safety of NNC 0078-0000-0007	36
11/SC/0221	Effects of iron on exercise capacity in the elderly	43
11/SC/0223	The effects of dietary substrates on oxidative performance	47
11/SC/0224	Emotional Processing During the First Week of Antidepressant Treatment	58
11/SC/0227	Ketogenic diets for symptoms of Type 2 Diabetes Mellitus	47
11/SC/0229	Blood Flow monitoring in DBS and ONS	55
11/SC/0234	SCULPTURE study	46
11/SC/0235	Secukinumab in rheumatoid arthritis (AINF2302)	46
11/SC/0247	Physical activity in drug users - a qualitative study	48
11/SC/0260	A Michell MSc Thesis: Parental Perceptions of 22q11DS; Version 1	39
11/SC/0272	Vemurafenib in metastatic melanoma patients with brain metastasis	23
11/SC/0365	SPIN - Phase 2	56
11/SC/0369	The NICOM-OPTIMISE Study	39
11/SC/0370	The Deactivate-CRT study	39
11/SC/0376	AZD4547 v Paclitaxel in Gastric or Gastro-oesophageal Junction Cancer	59
11/SC/0390	Evaluation of Sleep and Pain in Generalized Anxiety (ESPIGA)	53
11/SC/0463	Understanding immunity after typhoid vaccination	27
11/SC/0475	What do parents learn when attending child speech therapy sessions?	25

11/SC/0478	Efficacy and safety of GSK1605786 in patients with ulcerative colitis	30	
11/SC/0515	Neural responses in face perception and recognition	45	
11/SC/0522	A study of symptoms and treatment effects in parkinsonian syndromes	61	
11/SC/0525	Phase I trial of Indium-hEGF in metastatic EGFR-positive cancers	25	
11/SC/0528	INTERLACE	36	
11/SC/0546	Food and Nutrition Amongst Opioid Substitution Recipients	45	
12/SC/0022	Promoting tolerance of children's feelings (version 1)	31	
12/SC/0026	Hydrocortisone and cognitive / emotional processing - fMRI	13	
12/SC/0028	Can Shoulder Arthroscopy Work (CSAW)	17	
12/SC/0058	Response shift in foot & ankle surgery.	10	
12/SC/0063	Genetics of gene expression in immune-related disease (version I)	47	
12/SC/0079	Single Dose IV Push Study in Patients with PONV	31	
12/SC/0085	Evaluating Emergency Services Standard Personal Protective Equipment	22	
12/SC/0111	Neural effects of THCV on reward 38		
12/SC/0121	Liraglutide in Type 2 Diabetes and Moderate Renal Impairment	38	

Further Information Favourable Opinion with Additional Conditions		
REC Reference	Application Short Title	Number of Days on Clock
11/SC/0262	Cardiac remodeling after catheter ablation of atrial fibrillation	56
11/SC/0266	The effect of mindfulness on attention	53
11/SC/0269	Splicing and disease	39
11/SC/0270	TESINT	78
11/SC/0363	A Living Well with Dementia Pilot Randomised Controlled Trial	54
11/SC/0462	Outcomes of Femoroacetabular Impingement Surgery	91

<b>Further Information</b>	on Unfavourable Opinion	
<b>REC Reference</b>	Application Short Title	Number of Days on Clock

Favourable Opinion with Standard Conditions		
REC Reference	Application Short Title	Number of Days on Clock
12/SC/0054	Anonymous HIV Prevalence Study of Mononucleosis-tested samples. V1.0	7
12/SC/0056	Anonymous HIV Prevalence Study of HBV/HCV positive blood samples V1.0	7
12/SC/0131	Diagnostics for Chronic Malaria Infection in Blood Donors	13
12/SC/0186	Degree of pituitary down-regulation and outcome of IVF	10

Favourable Opinion with Additional Conditions		
<b>REC Reference</b>	Application Short Title	Number of Days on Clock
11/SC/0367	Understanding immunity persistence after adolescent MenC vaccination	33
11/SC/0450	STATURE study	21
11/SC/0534	Tangent versus bowl perimetry: an exploratory study (version 1.0)	3
11/SC/0542	Proof of concept of new sleep monitor using Zense	7
12/SC/0074	Electronic track & trigger and patient status alerts: ED feasibility	32

Unfavourable Opinion		
REC Reference	Application Short Title	Number of Days on Clock
11/SC/0164	Positive Psychology Interventions in an NHS Midwifery setting.	28
11/SC/0220	Semantic Access in Patients with First Episode Psychosis	33
11/SC/0271	Comprehensive Care for Older People with Cancer	28
11/SC/0431	Prevalence and impact of MUS in primary care	87
12/SC/0046	RGD-PET in cancer angiogenesis	21

Provisional Opinion		
REC Reference	Application Short Title	Number of Days on Clock
12/SC/0118	Antidepressants, emotions and personality	N/A

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

<b>Further informati</b>	on response not complete	
<b>REC Reference</b>	Application Short Title	Number of Days on Clock

Withdrawn after the meeting			
<b>REC Reference</b>	Reference Application Short Title Number of Days on Cloc		
11/SC/0166	Validation Study for the Work Readiness Questionnaire 'WORQ'	35	

<b>Invalid Applicatio</b>	n	
<b>REC Reference</b>	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/SC/0270	TESINT	78	
11/SC/0431	Prevalence and impact of MUS in primary care	87	
11/SC/0462	Outcomes of Femoroacetabular Impingement Surgery	91	
11/SC/0522	A study of symptoms and treatment effects in parkinsonian syndromes	61	

Proportionate review applications for ethical review over 14 days timeline				
<b>REC Reference</b>	C Reference Application Short Title Number of Days on Clock			
11/SC/0475	What do parents learn when attending child speech therapy sessions?	25		

SSAs (non Phase 1) over 25 days timeline		
<b>REC Reference</b>	Application Short Title	Number of Days on Clock
11/SC/0521	cardiorespiratory in DBS	33

SSAs (Phase 1) over 14 days timeline		
<b>REC Reference</b>	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
08/H0605/39/AM18	CEQUEL	Amendment Change of primary out come version 1 18	50
08/H0605/118/AM15	An extension study in patients with Relapsing-Remitting MS	CFTY720D2301E1 amendment 6, v06, 14-1-2011	37
09/H0605/111/AM03	Evaluation of current treatments for tendon disease in the shoulder	Amendment 2	52
09/H0605/113/AM16	CL3-16257-083 - SIGNIFY Study.	P/A dated 14 March 2011	40
08/H0605/109/AM06	Genetic Associations of Otitis Media	Substantial Amendment 4, 25 March 2011	47

10/H0605/46/AM02	A phase I study of the Human Pharmacokinetics of Elacytarabine	Protocol Amendment 13 May 2011	45
07/H0605/148/AM05	Safety and efficacy study of MACI® Implant versus Microfracture	Protocol Amendment 2.0 13 05 11	47
05/Q1605/47/AM07	Electrical stimulation of the brain in man	Substantial Amendment 09 05 2011	43
10/H0605/64/AM05	Ridaforolimus Combination vs Monotherapy in Breast Cancer (MK8669-041)	Substantial Amendment 3, 16 May 2011	41
10/H0605/65/AM06	Mesalazine for the treatment of IBS-D	Amendment 5 18 05 11	37
10/H0605/83/AM03	REVEAL Version 1.0	REVEAL Amendment 3 190511	37
09/H0605/113/AM23	CL3-16257-083 - SIGNIFY Study.	Substantial Amendment 030811	41
11/SC/0167/AM02	secukinumab in patients with mod to sev chronic plaque-type psoriasis	Substantial Amendment - Addition of Dr Referral Le	36
11/H0605/5/AM02	ExPeKT: Exploring prevention and knowledge of VTE	Substantial Amendment 1 080811	36
10/H0605/49/AM12	Comparison of FDC Linagliptin/Pioglitazone Vs Monotherapy. Version 3.0	Protocol Amendment 4: Urgent Safety Measure 110811	39
09/H0605/62/AM04	Midbrain micturition pathways	Substantial Amendment 310811- 3 August 2011	39
10/H0605/64/AM07	Ridaforolimus Combination vs Monotherapy in Breast Cancer (MK8669-041)	Substantial Amendment 300811	39
09/H0605/114/AM09	BUMPES Trial	Substantial Amendment 05 31/08/11	38
11/H0605/6/AM03	TMC278-TiDP6-C222	Substantial Amendment UK II 22/08/11	39
08/H0605/57/AM05	Oxford MEG Project	Substantial Amendment 4 dated 5 September 2011	52
09/H0605/62/AM05	Midbrain micturition pathways	Substantial Amendment 4 dated September 2011	49
11/SC/0224/AM01	Emotional Processing During the First Week of Antidepressant Treatment	Substantial Amendtment 3 dated 20 September 2011	42

10/H0605/48/AM04	Effects of Exercise on Brain Structure and Plasticity	Substantial Amendment 1.2 19/08/2011	45
08/H0605/62/AM29	A new vaccine against meningitis group B	Retrospective Substantial Amendment - Poor Immune	45
04/Q1605/20/AM16	SOFT Suppression of Ovarian Function Trial version 1.1, 17/04/03	Substantial Amendment 5 (IBCSG amendment 2) protoc	38
07/Q1605/26/AM02	Osteoarthritis of the hip: Developing an assay for early disease	Substantial Amendment - 03/08/11 Change of CI Resu	58
10/H0605/69/AM05	MACI00809: An extension protocol for MACI00206	Substantial Amendment Protocol Amendment 2: 14 Oct	52
11/SC/0001/AM01	Finding out if worries can be reduced by brief cognitive therapy	Substantial Amendment 171111	63
09/H0605/62/AM08	Midbrain micturition pathways	Substantial Amendment - Amendment 5 (November 2011	55
09/H0605/126/AM11	CAEB071A2214	Substantial Amendment 2011/1092 - Urgent Safety Me	41
10/H0605/86/AM02	Effects of Rapamycin in Renal Cancer	Substantial Amendment SA02. Version 2. 2012/01/19	49

Modified Amendments over 14 day timeline			
Amendment Reference	Application Short Title	Amendment Title	Number of Days on Clock
09/H0605/111/AM03/1	Evaluation of current treatments for tendon disease in the shoulder	Modified Amendment for Amendment 2	23
08/H0605/102/AM14/1	The population structure & carriage length of Staphylococcus aureus v1	Modified Substantial Amendment 070711	40
08/H0605/102/AM14/2	The population structure & carriage length of Staphylococcus aureus v1	Second Modificationto Substantial Amendment 070711	68
09/H0605/62/AM04/1	Midbrain micturition pathways	Modified Substantial Amenment 3 (August 2011)	30
09/H0605/114/AM09/1	BUMPES Trial	Modified Amendment - Amendment 05, 11/11/2011	36
08/H0605/85/AM05/1	A biomarker study in motor neuron disease	Re-submitted Documents for Amendment 4: 25/05/2011	19

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