

**NRES Committee East of England -  
Cambridge South**

**Annual Report**

**01 April 2011 – 31 March 2012**

*Part 1 – Committee Membership and Training*

<b>Name of REC:</b>	NRES Committee East of England - Cambridge South
<b>Type of REC:</b>	Type III
<b>Type of Flag:</b>	IRB Registered Research Involving Children
<b>Chair:</b>	Dr Leslie Gelling
<b>Vice-Chair:</b>	Dr Frank Wells
<b>Co-ordinator:</b>	Miss Susan Davies
<b>PRSC Co-ordinator:</b>	Miss Susan Davies
<b>Assistant Co-ordinator:</b>	Miss. April Saunders (from October 2011)
<b>Committee Address:</b>	Victoria House Capital Park Fulbourn Cambridge CB21 5XB
<b>Telephone:</b>	01223 597653
<b>Fax:</b>	01223 597645
<b>Email:</b>	susan.davies@eoe.nhs.uk

*Chair's overview of the past year:*

It has been a busy year for this new Committee but having the majority of members transfer from the closing Cambridgeshire 4 REC made it possible for Cambridge South REC to quickly get into its stride with ethical review. Cambridge South REC has quickly become a committee demonstrating thoroughness in review and a commitment to providing a high quality service for researchers and for NRES.

One of the most significant changes this year has been the introduction of proportionate review. This Committee has put in place a process for PRS membership selection and application review that works well, with the workload shared amongst members of the committee. Sub-committees also work extremely well with the considerable support of Dr Frank Wells and, when necessary and/or required, other members of the committee.

The committee has had several co-ordinators during the year, which risks having an impact on the successful functioning of a committee, but all those who have stepped into this role have offered strong support to the Chair and the committee.

I have no concerns about how this committee functions and it is a privilege to chair Cambridge South REC.

*NRES Committee East of England - Cambridge South Membership:*

Name	Occupation	Expert or Lay	Dates	
			Appointed	Resigned
Mrs Martha Byrne	Clinical QA Manager	Lay	01/04/2011	
Dr Katherine Catford	Specialist Registrar in Paediatrics	Expert	01/04/2011	
Dr Andrew Clark	Consultant in Paediatric Allergy	Expert	01/04/2011	
Dr Ian Dumbelton	Retired General Medical Practitioner	Expert	01/04/2011	
Dr Leslie Gelling	(Chair) Reader in Research Ethics	Expert	01/04/2011	
Mr Colin Green	Drugs & Therapeutics Pharmaceutical Advisor	Expert	01/04/2011	
Mrs Alison Hall	Project Manager	Lay	01/04/2011	
Mr Malcolm Lee	Retired Teacher	Lay Plus	01/04/2011	
Miss Angela Palmer	Retired Patent Litigator	Lay Plus	01/04/2011	
Miss Carol Smee	Regulatory Advisor	Expert	01/04/2011	
Mr Phil Tempest	Compliance Manager	Lay	01/04/2011	
Dr Frank Wells	(Vice-Chair) Retired Pharmaceutical Physician	Expert	01/04/2011	
Dr Kate Williams	Senior Research Associate	Lay	01/04/2011	
Miss Louise Wilmer	Pharmacist Team Manager - Cancer Services	Expert	01/04/2011	
Dr Rashid Zaman	Consultant Psychiatrist and Director of Bedfordshire Centre for Mental Health Research	Expert	01/04/2011	

**Deputy Members**

Name	Occupation	Expert or Lay	Meeting date attended
Mrs Nikki Phillimore	Antibiotic/infection management pharmacist	Expert	28/04/2011 25/05/2011 25/08/2011 17/06/2011 24/11/2011 26/01/2012 23/02/2012

**Co-opted Members**

Name	Occupation	Expert or Lay	Meeting date attended
------	------------	---------------	-----------------------

--	--	--	--

**Member Bank**

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

*NRES Committee East of England - Cambridge South: Members' Declarations of Interest:*

<b>Name</b>	<b>Declaration of Interest</b>	<b>Date</b>
Dr Kate Williams	Researcher at the University of Cambridge, General Practice and Primary care Research Unit.	03/01/2012
Mrs Martha Byrne	CQA Manger for a Private family owned pharmaceutical company. My role requires independent oversight of clinical trials phase I - IV and I have to be independent of the research Group.	03/01/2012
Mrs Martha Byrne	Addenbrookes Hospital NHS Foundation Trust public member since 2006 - I do not have any direct involvement in R&D activities.	03/01/2012
Miss Angela Palmer	Owner of Glaxosmithkline shares	03/01/2012
Miss Angela Palmer	Has work all working life with GlaxoSmithKline and its predecessor companies GlaxoWellcome and Glaxo, and receives a pension from GlaxoWellcome. (However has not had any contact with the Cambridge/Addenbrookes branch of GSK).	03/01/2012
Dr Leslie Gelling	Reader in Research Ethics at Anglia Ruskin university where he undertakes research, supervise post-grad research students and act as sponsor's. Representative for some applications for ethical approval.	20/01/2012
Dr Leslie Gelling	Member of royal college of Nursing (RCN) research and development governance group which has oversight of all research being undertaken in the RCN. Some of this research could involve seeking ethical approval.	20/01/2012
Dr Frank Wells	Elected member of BMA medical ethics committee. Member of Independent Scientific an ethical committee of IMS health Ltd. Nominated member of EFGCP ethics Working Party. None of these involves research.	20/01/2012
Dr Andrew Clark	Actively involved in research, both government and industry funded. Occasional payment to attend conference of reimburse time from industry (Novartis).	20/01/2012
Miss Carol Smee	Regulatory adviser at the Wellcome Trust Sanger Institute - A research establishment. A research establishment funded by a charity (The Wellcome Trust).	20/01/2012
Mrs Alison Hall	Senior policy advisor employed by the PHG foundation (foundation for genomics and population health) charitable company registered in England and Wales.	20/01/2012
Miss Louise Wilmer	Lead Pharmacist for Cancer services (including clinical trials) - Peterborough City Hospital - Reviewing trials within the hospital cancer services. Line manager member of staff who sits on R&D	25/01/2012

	committee and very occasionally may cover R&D committee meeting (so far once in 3 years).	
Dr Rashid Zaman	Dr Zaman is the director of Bedfordshire centre for mental health research in association with university of Cambridge BCMHR - CU. This is not a private company but a group under umbrella of Cambridge university and Trust (NHS Mental Health).	26/01/2012
Dr Rashid Zaman	Member of mental health GP and (past Chair) south Asian health foundation, a charity for patients.	26/01/2012
Dr Rashid Zaman	Member of SEPT (NHS mental health trust) research governance group.	26/01/2012
Mr Phil Tempest	Philip Tempest is an employee of Amgen Ltd. And also has shareholdings in Amgen Ltd and GSK Ltd.	27/01/2012
Dr Katherine Catford	None	22/06/2012
Mrs Nikki Phillimore (Deputy member)	None	31/03/2012
Mr Colin Green	None	10/04/2012
Dr Ian Dumbelton	None	10/04/2012
Mr Malcolm Lee	None	10/04/2012

*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	28/04/2011	12
May	26/05/2011	12
June	17/06/2011	12
June	23/06/2011	11
July	28/07/2011	9
August	25/08/2011	12
September	22/09/2011	9
October	27/10/2011	9
November	24/11/2011	10
January	26/01/2012	13
February	23/02/2012	12
March	22/03/2012	13

12 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>
August	11/08/2011	4
September	08/09/2011	4
October	06/10/2011	4
November	10/11/2011	4
December	08/12/2011	4
February	09/02/2012	4
March	08/03/2012	4

7 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>
Miss Angela Palmer	12
Dr Leslie Gelling	11
Mr Malcolm Lee	11
Dr Ian Dumbelton	10
Dr Kate Williams	10
Dr Katherine Catford	9
Dr Frank Wells	9
Miss Carol Smee	9
Mrs Alison Hall	8
Mr Colin Green	8
Mrs Martha Byrne	7
Mr Phil Tempest	7
Dr Rashid Zaman	6
Dr Andrew Clark	5
Miss Louise Wilmer	5

**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 Leslie Gelling	7
Mr Phil Tempest	4
Miss Carol Smee	3
Dr Katherine Catford	2
Dr Andrew Clark	2
Dr Frank Wells	2
Mrs Martha Byrne	2
Mrs Nikki Phillimore	1
Mrs Alison Hall	1
Dr Ian Dumbelton	1
Dr Kate Williams	1
Miss Louise Wilmer	1
Miss Angela Palmer	1



Training 01 April 2011 – 31 March 2012:

<b>Name of Member</b>	<b>Date</b>	<b>Event(s) attended</b>
Miss Carol Smee	06/04/2011 - 08/04/2011	Research Ethics in a Higher Education Context Training'
Miss Carol Smee	13/04/2011 - 13/04/2011	Equality & Diversity, NRES
Miss Angela Palmer	22/06/2011 - 22/06/2011	Induction, NRES
Dr Kate Williams	06/05/2011 - 06/05/2011	Equality & Diversity, Online Training
Miss Louise Wilmer	01/11/2011 - 01/11/2011	Clinical Trials of Investigational Medicinal Products , NRES
Mrs Nikki Phillimore	01/11/2011 - 01/11/2011	Clinical Trials of Investigational Medicinal Products , NRES
Dr Leslie Gelling	02/11/2011 - 02/11/2011	'The Nuts and Bolts of running a REC' , NRES
Mr Phil Tempest	30/06/2011 - 30/06/2011	Equality & Diversity, NRES
Dr Frank Wells	28/05/2011 - 28/05/2011	Equality & Diversity, NRES
Dr Ian Dumbelton	18/08/2011 - 18/08/2011	Equality & Diversity, NHS
Miss Angela Palmer	14/09/2011 - 14/09/2011	Update Session with Janet Wisely, NRES
Dr Frank Wells	14/09/2011 - 14/09/2011	Update Session with Janet Wisely, NRES
Dr Leslie Gelling	14/09/2011 - 14/09/2011	Update Session with Janet Wisely, NRES
Mr Colin Green	11/07/2011 - 11/07/2011	MCA DVD for NRES Committee Members, NRES
Miss Carol Smee	29/02/2012 - 29/02/2012	Personal Data in Research, NRES
Dr Frank Wells	17/01/2012 - 17/01/2012	Adults Lacking Capacity, NRES
Dr Kate Williams	29/02/2012 - 29/02/2012	NRES Personal Data in Research, NRES
Dr Ian Dumbelton	19/01/2012 - 19/01/2012	Shared Ethical Debate, NRES
Miss Angela Palmer	19/10/2011 - 19/10/2011	Equality & Diversity, NRES
Mrs Alison Hall	30/09/2011 - 30/09/2011	Equality & Diversity, NRES
Dr Katherine Catford	14/03/2012 - 14/03/2012	NRES Members National Training Day , NRES
Dr Frank Wells	28/07/2011 - 28/07/2011	Shared Ethical Debate - CTIMP in Children
Mrs Martha Byrne	28/07/2011 - 28/07/2011	Shared Ethical Debate - CTIMP in Children, NRES
Dr Ian Dumbelton	28/07/2011 - 28/07/2011	Shared Ethical Debate - CTIMP in Children, NRES
Mr Colin Green	28/07/2011 - 28/07/2011	Shared Ethical Debate - CTIMP in Children, NRES
Mrs Alison Hall	28/07/2011 - 28/07/2011	Shared Ethical Debate - CTIMP in Children, NRES
Miss Angela Palmer	28/07/2011 - 28/07/2011	Shared Ethical Debate - CTIMP in Children, NRES
Miss Carol Smee	28/07/2011 - 28/07/2011	Shared Ethical Debate - CTIMP in Children, NRES

Mr Phil Tempest	28/07/2011 - 28/07/2011	Shared Ethical Debate - CTIMP in Children, NRES
Dr Kate Williams	28/07/2011 - 28/07/2011	Shared Ethical Debate - CTIMP in Children, NRES
Mrs Martha Byrne	29/03/2012 - 29/03/2012	Induction, 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	23.81
Phase 1	0	0.00
Gene Therapy	0	0.00
Research Tissue Bank	0	0.00
Research Database	0	0.00
Others	48	76.19
<b>Total Applications Reviewed</b>	<b>63</b>	<b>100</b>

Table 2: Other REC activity during the reporting period:

Number of applications made invalid by co-ordinator	7
Number of studies withdrawn prior to the meeting	9
Number of student applications reviewed	25
Number of paediatric applications reviewed	10
Number of device applications reviewed	1
Number of prisoner applications reviewed	0
Number of applications involving adults unable consent reviewed	1
Number of applications reviewed funded by the US DHHS	2

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	3	4.69
Favourable Opinion with Additional Conditions	3	4.69
Unfavourable Opinion	7	10.94
Provisional Opinion	50	78.13
Invalid	0	0.00
No Opinion Pending Consultation with Referee	1	1.56
Provisional Opinion Pending Consultation with Referee	0	0.00
Not Requiring Review by NHS REC	0	0.00
<b>Total</b>	<b>64</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:

Status of applications at date of generation of report	Number	%
Further Information Favourable Opinion with Standard Conditions	38	60.32
Further Information Favourable Opinion with Additional Conditions	9	14.29
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	3	4.76
Favourable Opinion with Additional Conditions	3	4.76
Unfavourable Opinion	7	11.11
Provisional Opinion	2	3.17
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	1.59
<b>Total</b>	<b>63</b>	<b>100</b>

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

<b>Total Applications Reviewed</b>	<b>16</b>
------------------------------------	-----------

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	3	18.75
Favourable Opinion with Additional Conditions	0	0.00
No Opinion transfer to full committee for review	2	12.50
Provisional Opinion	11	68.75
Unfavourable Opinion	0	0.00
<b>Total</b>	<b>16</b>	<b>100</b>

Table 7: Other Management Information for the reporting period:

<b>Average number of applications reviewed per full meeting</b>	5.25
<b>Number of applications for full ethical review over 60 days</b>	2
<b>Number of applications over 60 days as a % of total</b>	3.17%
<b>Number of days taken to final decision - average</b>	42
<b>Number of days taken to final decision - mode</b>	28
<b>Number of SSAs (non-Phase 1) reviewed</b>	6
<b>Number of applications for SSA review over 25 days</b>	0
<b>Number of applications for SSA review over 25 days as % of all non-Phase 1 (SSAs)</b>	0.0%
<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>	146
<b>Number of substantial amendments over 35 days</b>	1
<b>Number of substantial amendments over 35 days as a % of total substantial amendments</b>	0.7%
<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>	11
<b>Number of modified amendments over 14 days</b>	0
<b>Number of modified amendments over 14 days as a % of total modified amendments</b>	0.0%
<b>Number of proportionate review applications for ethical review over 14 days*</b>	6
<b>Number of proportionate review applications over 14 days as a % of total</b>	42.86%

\*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/EE/0151	Neuromuscular-electrical stimulation in pulmonary rehab of severe COPD	43
11/EE/0160	systemic psychotherapy and the family courts	32
11/EE/0185	An observational study to characterise LAL deficiency/ CESD phenotype.	34
11/EE/0186	An exploratory study of staff experience of Case Formulation	58
11/EE/0198	Investigation of compulsivity and motivation in disorders of addiction	28
11/EE/0203	Epigenomic profiling in patients with heart failure (version 1)	56
11/EE/0218	ESTEEM Effective Support for Self help/mutual aid groups: Stage Two	60
11/EE/0229	Pasireotide LAR in patients with Cushing's disease	36
11/EE/0244	Tear film osmolarity in epiphora	54
11/EE/0291	Efficacy and Safety of Lenalidomide/Dexamethasone +/- Elotuzumab in MM	35
11/EE/0293	Open label extension study of GSK2402968 in DMD (version 1)	40
11/EE/0298	Efficacy of a multi-session CBM-I task in social phobia.	28
11/EE/0304	What are the psychological needs of children with IBD. V1.	28
11/EE/0307	Experiences of Ending Therapy: Adolescents who are looked after.	38
11/EE/0311	MO25455	54
11/EE/0313	Ethical implications of whole genome studies. Version 1	19
11/EE/0324	Staff Perceptions of a Psychosocial Forum in a Medical Setting	12
11/EE/0352	FAT METABOLISM IN SEVERE INSULIN RESISTANCE	57
11/EE/0371	Views and attitudes of patients discharged from day hospice.	13
11/EE/0376	Obesity risk tool in the healthy child program: it is a good idea?	19
11/EE/0386	Priming Hand-washing with Olfactory and Visual Cues	9
11/EE/0417	Facilitation of Self-Management in a Haemodialysis Unit: An Evaluation	46
11/EE/0419	Investigating the subtypes of postnatal mood disorders (Version 1.0)	44
11/EE/0425	RALMIR	14
11/EE/0435	Diagnosis of type 1 diabetes in children interview study	41
11/EE/0437	MEG/EEG studies of visual object processing	33
11/EE/0450	GO-AHEAD	43
11/EE/0452	A trial to assess the anti-inflammatory effects of roflumilast in COPD	42
11/EE/0465	Effect of gt and coffee polyphenols on cardiometabolic function (v3.4)	42
11/EE/0473	Name change by patients in a rural forensic service	34
11/EE/0477	Exploring Aspirations: Choice and parenthood in young people - a case	20

11/EE/0478	Does Telephone follow up promote healthy lifestyle in TIA patients?	22
11/EE/0481	A3051075 Smoking Cessation Through Reduction Study	59
11/EE/0483	BO25430 - Trastuzumab Emtansine (T-DM1) Extension Study	46
11/EE/0499	Study of MRSA carriage and infection in the UK	41
11/EE/0530	Educating adolescents at risk of anaphylaxis	25
11/EE/0540	Diet, exercise and the insulin resistance syndrome: a pilot study	60
12/EE/0044	Exome and protein analysis in HPV associated cancer / pre-cancer	58
12/EE/0045	Middle aged women's experience of living with chronic heart failure	35
12/EE/0046	Biopsy of prostate cancer metastases	56
12/EE/0047	A pilot study assessing bladder filling reproducibility 1.0	40
12/EE/0081	Non-fatal repetition of self-harm: A retrospective study in TeesValley	15
12/EE/0085	Analysis of exercise responses in chronic thromboembolic disease.	42
12/EE/0091	The role of oxytocin in appetite regulation	47
12/EE/0124	Nasal Staphylococcus aureus and thyroid eye disease - A Pilot Study v1	44
12/EE/0125	Smartphone Reminder Cues for Patients with Memory Difficulty	63
12/EE/0132	MOR006 Efficacy & Safety of BMN110 in Patients with Morquio A Syndrome	62
12/EE/0135	Losmapimod in COPD patients stratified by fibrinogen (EVOLUTION)	55

#### Further Information Favourable Opinion with Additional Conditions

REC Reference	Application Short Title	Number of Days on Clock
11/EE/0197	IMPACT DME Version 1	46
11/EE/0215	Are vodcasts a viable teaching method v2.0	48
11/EE/0230	Using postmortem to improve diagnosis and treatment after brain injury	45
11/EE/0250	Monitoring Plasma Tumour DNA in Colorectal Cancer (ver 1)	28
11/EE/0251	Evaluation of the peer employment project at CPFT	40
11/EE/0342	(duplicate) A phenomenological exploration of midwives and obstetric	28
11/EE/0368	MUST FS	39
11/EE/0434	Working memory training for children who have survived a brain injury	60
11/EE/0479	The impact of diagnosis on coping with low back pain	13
12/EE/0036	Study to Evaluate the Efficacy & Safety of LY2439821 Vs Placebo in Ps	54

#### Further Information Unfavourable Opinion

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



<b>Favourable Opinion with Standard Conditions</b>		
<b>REC Reference</b>	<b>Application Short Title</b>	<b>Number of Days on Clock</b>
11/EE/0152	UKCHT:UK surveillance of primary congenital hypothyroidism in children	40
11/EE/0260	Retinopathy in a cohort of young adults with type 1 diabetes	28
11/EE/0333	P12-072 Opera	8
11/EE/0360	BDNF gene neuroplasticity study	26
11/EE/0527	Timing of BCG vaccination and atopic disease in children (version 1)	5
11/EE/0528	Understanding amyloid deposition in the cardiovascular system	7

<b>Favourable Opinion with Additional Conditions</b>		
<b>REC Reference</b>	<b>Application Short Title</b>	<b>Number of Days on Clock</b>
11/EE/0166	Pathogen Census: Genetic Diversity of Chlamydia trachomatis	51
11/EE/0302	Pinch strength assessment in patients with base of thumb OA.	44
11/EE/0357	Evaluation of the role of inflammation in Chronic Airways Disease	32

<b>Unfavourable Opinion</b>		
<b>REC Reference</b>	<b>Application Short Title</b>	<b>Number of Days on Clock</b>
11/EE/0149	Macmillan Nurses' Understanding Of Spirituality. Version number 1.	40
11/EE/0154	knowledge acquisition through Vodcasts v1.0	27
11/EE/0184	Comparison of digital versus analogue mammography	33
11/EE/0191	Is Liceko ® more effective than Lyclear against head lice?	32
11/EE/0296	Phase 3 study of E7777 and CHOP in T-Cell Lymphoma	28
11/EE/0354	Immunology of failing metal-on-metal hip replacement	26
12/EE/0133	Exploring experiences of schizophrenic patients and use of cannabis	41

<b>Provisional Opinion</b>		
<b>REC Reference</b>	<b>Application Short Title</b>	<b>Number of Days on Clock</b>
12/EE/0089	The Efficacy & Safety of LY2439821, Etanercept Vs Placebo in Ps	N/A
12/EE/0129	Detectable trends over a 19 year period at a diagnostic memory clinic	N/A

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

**Further information response not complete**

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

#### Withdrawn after the meeting

REC Reference	Application Short Title	Number of Days on Clock
11/EE/0102	ChondroMimetic OMCM-2010-01, V1.1 - September 1st, 2010	26

#### Invalid Application

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

#### No Opinion Pending Consultation with Referee

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

#### Not Requiring Review by NHS REC

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

Table 9: Items exceeding timelines:

<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>
12/EE/0125	Smartphone Reminder Cues for Patients with Memory Difficulty	63
12/EE/0132	MOR006 Efficacy & Safety of BMN110 in Patients with Morquio A Syndrome	62

<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>
11/EE/0313	Ethical implications of whole genome studies. Version 1	19
11/EE/0376	Obesity risk tool in the healthy child program: it is a good idea?	19
11/EE/0478	Does Telephone follow up promote healthy lifestyle in TIA patients?	22
11/EE/0477	Exploring Aspirations: Choice and parenthood in young people - a case	20
11/EE/0530	Educating adolescents at risk of anaphylaxis	25
12/EE/0081	Non-fatal repetition of self-harm:A retrospective study in TeesValley	15

<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>

<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>
11/EE/0006/AM01	EEG complexity in epilepsy and intellectual disabilities - version 1	Substantial Amendment #1 03-10-2011	36

<b>Modified Amendments over 14 day timeline</b>			
<b>Amendment Reference</b>	<b>Application Short Title</b>	<b>Amendment Title</b>	<b>Number of Days on Clock</b>

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