

**NRES Committee South Central -
Berkshire**

Annual Report

01 April 2011 – 31 March 2012

Part 1 – Committee Membership and Training

Name of REC:	NRES Committee South Central - Berkshire
Type of REC:	RECs recognised to review CTIMPS in healthy volunteers - type i RECs recognised to review CTIMPS in patients - type iii
Type of Flag:	IRB Registered Phase 1 Studies in Healthy Volunteers Phase 1 Studies in Patients Research Involving Adults Lacking Capacity Research Involving Children
Chair:	Mr David Carpenter
Vice-Chair:	Mr Arden Bhattacharya
Alternate Vice-Char:	Ms Susan Tonks
Co-ordinator:	Ms Rae Granville
PRSC Co-ordinator:	Ms Rae Granville
Assistant Co-ordinator:	None
Committee Address:	Bristol REC Centre Whitefriars Level 3, Block B Lewins Mead Bristol BS1 2NT
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Chair's overview of the past year:

The membership of the committee changed significantly during the year in question. At the beginning of the year membership was declining both in number and expertise; a relatively 'low level' recruitment campaign was remarkably successful and quoracy problems have been averted. It has never been necessary to cancel any meeting as a result of inquoracy nor has it been necessary to co-opt additional members. All new members have settled into the Committee extremely well and several are now comfortable in undertaking extra sub-committee and PRC work in addition to the main business. Seven new members were appointed during the year, one member resigned as a result of external pressures and four members resigned having completed their contracted terms of office. Whilst the Committee has been able to sustain its core business it is unfortunate that the resignations have included a statistician, a consultant physician and a very experienced biomedical scientist; these losses have been largely compensated by the efforts of other members. Given the number and nature of the Committee 'flags' I am firmly of the belief that this expertise should be replaced, however attempts to do so have been declined as a result of the continuing closures and mergers programme. I fully understand the need for cautious recruitment at this stage but I hope that this matter can be resolved over the forthcoming year.

Approximately half way through the year the Committee experienced significant administrative changes as a result of closure of the Reading office and relocation to the Bristol Centre. My opinion with regard to the geographical changes was, and remains, largely positive given my support for remote working and conducting as much business online as possible. The Committee already had robust arrangements for online review of reports, responses to provisional opinions and conducting sub-committee business so the relocation made little difference. The biggest loss to the Committee was that of the assistant coordinator, Lavenda Lee and the temporary coordinator, Megan Walmsley, who, despite her 'temp' status was remarkably able and efficient. I am very pleased to report that Megan was seamlessly replaced by Rae. It is probably fair to state that it took some time for the Bristol Centre and its numerous newly appointed staff to function efficiently and effectively and I did experience several administrative frustrations. My impression was that Rae (and others) was over-worked and that systems were taking some time to settle; it was however clear that Rae made every effort to accommodate all of my requests (no doubt, some of which were irritatingly idiosyncratic) and by the end of the reporting year things were running much more smoothly. At the time of writing this report (August 2012) I am clear that administrative support is largely very effective; Rae has continued to accommodate new and increasingly effective procedures which, no doubt, has been helped by some rationalisation of her workload. Notwithstanding changes of membership and administration, the Committee was successfully audited in October 2011 and complimented on some aspects of its operation.

The clear trend has been a declining number of applications for review by full committee, which I believe should be welcomed. In common with other committees, Berkshire REC has benefitted from the introduction of PR; by the end of this reporting period we were piloting an online reviewing PR reviewing system using Google software. In my opinion, the time saved as a result of fewer applications was put to good use. We have been able to spend more time on updating and informal education; for example I gave a presentation on the revised version of GAfREC more than 2 months before it came into force. The Committee has also been able to focus upon and discuss in much more detail, matters of ethics thus marking a shift from being overly preoccupied with policy and procedure. Discussions on ethics have included debates about tensions between individual autonomy and the common good, respecting the autonomy of children, and inducement and coercion. Much of this discussion was initiated in response to review of specific studies; some has been inspired by advice from the NREAP. In similar vein it has been possible to devote more time to shared ethical debate exercises and I think that Berkshire has been a strong contributor to this national strategy. I am also of the opinion that fewer reviews by full committee has been helpful in informally educating new members – there has been time to pause and provide explanation.

Outside of the main business I had a particularly busy year. There were several occasions involving lengthy conference calls as a result of appeals, breaches of protocol and challenges to unfavourable and provisional opinions. I believe that there is an increasing tendency to challenge the Committee's opinions by appealing to the Chair; needless to say, these strategies are unsuccessful but nevertheless extremely time consuming. On a more positive note there were many informal enquiries and requests for advice and support; in the main enquirers were extremely grateful and were positive about the service as a whole. I believe that Berkshire enjoys a good reputation within the research community – though obviously it is difficult to substantiate such a claim. It is hard to estimate my workload over the year but I believe that Berkshire is one of the busiest committees partly as a result of inherited business from previous closures and mergers. Whilst busy, I am delighted to report that I have found the year challenging and enjoyable. I am more than aware that I equally challenged others within the organisation but I remain a loyal supporter of it.

NRES Committee South Central - Berkshire Membership:

Name	Occupation	Expert or Lay	Dates	
			Appointed	Resigned
Dr Kuna Aiyasamy	Senior Dental Officer	Expert	04/06/2008	
Mr Arden Bhattacharya	Barrister	Lay Plus	01/07/2002	
Mr David Carpenter	Social Scientist	Expert	01/11/2010	
Dr Mike Emanuel	Pharmaceutical Consultant	Lay	23/11/2009	
Mr Richard Havelock	Retired Clinical Director	Expert	01/08/2011	
Mrs Liz Hunter	Midwifery Guidelines Co-ordinator	Expert	16/01/2012	
Mrs Vivienne Laurie	Barrister	Lay Plus	01/11/2002	
Dr Vandana Luthra	R&D Research Co-ordinator	Expert	01/09/2011	
Dr Karen Luxton	Associate Specialist in Cardiology	Expert	01/10/2001	30/09/2011
Mr Richard Merewood	Director	Lay Plus	01/10/2011	
Mrs Rita Morrison	CAMHS Manager	Expert	01/01/2004	05/08/2011
Dr Joanne Philpot	Consultant Paediatrician	Expert	01/10/2011	
Dr M.J. Proven	Coordinator for Quality Assurance in Research	Lay	01/09/2011	
Ms Ann Quinn	Head of the School of Health and Social Care	Lay	01/03/2012	
Mr Donald Scott-Collett	Lead Pharmacist for Elderly Care, Neuro-rehabilitation, Dermatology and Clinical Governance	Expert	05/11/2010	
Dr Chris Skidmore	Retired University Teacher	Lay	30/01/2007	30/01/2012
Mr Roy Staley	Retired Public Servant	Lay Plus	13/07/2006	31/08/2011
Ms Susan Tonks	Senior Research Support Associate	Expert	01/05/2007	
Mrs Nicola Williams	Medical Statistician	Expert	01/03/2010	17/05/2011

Deputy Members

Name	Occupation	Expert or Lay	Meeting date attended

Co-opted Members

Name	Occupation	Expert or Lay	Meeting date attended

Member Bank

Name	Occupation	Expert or Lay	Meeting date attended

		Lay	

NRES Committee South Central - Berkshire: Members' Declarations of Interest:

Name	Declaration of Interest	Date
Mr David Carpenter	University of Portsmouth - Ethics Adviser	13/12/2011
Mr Arden Bhattacharya	None	13/12/2011
Ms Susan Tonks	Senior Research Support Associate: University of Oxford	13/12/2011
Mrs Vivienne Laurie	Shareholdings in Astra Zeneca	13/12/2011
Dr Kuna Aiyasamy	None	17/01/2012
Dr Mike Emanuel	Consultant to Actogenix NV (Belgium)Consultant to Celegene (USA)Shareholder in Johnson & Johnson	13/12/2011
Mr Donald Scott-Collett	Member of staff at Royal Berkshire NHS Foundation Trust Pharmacy Department.	13/12/2011
Mr Richard Havelock	None	13/12/2011
Dr Vandana Luthra	None	13/12/2011
Dr Joanne Philpot	None	17/01/2012
Mrs Liz Hunter	None	16/01/2012

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

Month	Date	Number of Members Present at Meeting
April	19/04/2011	8
May	17/05/2011	9
June	21/06/2011	10
August	16/08/2011	10
September	20/09/2011	11
October	18/10/2011	10
November	15/11/2011	12
December	13/12/2011	10
January	17/01/2012	11
February	21/02/2012	12
March	20/03/2012	9

11 full committee meetings were held during the reporting period.

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

Month	Date	Number of Members Present at Meeting
January	30/01/2012	3
March	08/03/2012	3
March	12/03/2012	3
March	28/03/2012	3

4 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 Mike Emanuel	11
Mr David Carpenter	11
Mr Donald Scott-Collett	11
Mrs Vivienne Laurie	10
Ms Susan Tonks	10
Mr Arden Bhattacharya	10
Dr Kuna Aiyasamy	8
Dr Chris Skidmore	6
Dr M.J. Proven	6
Mr Richard Havelock	6
Mr Richard Merewood	5
Dr Vandana Luthra	5
Dr Joanne Philpot	4
Mr Roy Staley	3
Mrs Liz Hunter	3
Dr Karen Luxton	2
Ms Ann Quinn	1

Number of inquorate meetings held:

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

Name	Number of Meetings Attended
Mr David Carpenter	3
Mr Richard Merewood	2
Ms Ann Quinn	2
Ms Susan Tonks	2
Dr M.J. Proven	2
Dr Chris Skidmore	1

Training 01 April 2011 – 31 March 2012:

Name of Member	Date	Event(s) attended
Mr Donald Scott-Collett	07/12/2011 - 07/12/2011	NRES Statistics Training for NRES REC Members, NRES
Mr David Carpenter	19/05/2011 - 19/05/2011	NRES Research with Adolescents, NRES
Mr Donald Scott-Collett	28/02/2012 - 28/02/2012	NRES Qualitative Research and Ethical Review, NRES
Mr Arden Bhattacharya	15/09/2011 - 15/09/2011	NRES Human Tissue Act training, NRES
Mr David Carpenter	19/05/2011 - 19/05/2011	Nuffield Council on Bioethics 2011 - public lecture, Nuffield Council on Bioethics
Dr Kuna Aiyasamy	30/06/2011 - 30/06/2011	Equality and Diversity Learning, NRES
Ms Susan Tonks	01/07/2011 - 01/07/2011	Equality & Diversity Learning, NRES
Dr Kuna Aiyasamy	07/12/2011 - 07/12/2011	NRES Statistics Training for NRES REC Members, NRES
Dr Kuna Aiyasamy	28/09/2011 - 28/09/2011	NRES Phase 1 training, NRES
Dr Mike Emanuel	04/07/2011 - 04/07/2011	Equality and Diversity Learning, NRES
Mr David Carpenter	02/08/2011 - 02/08/2011	Self Directed Learning inc. E&D training, University of Portsmouth
Dr Chris Skidmore	10/08/2011 - 10/08/2011	Equality and Diversity Learning, NRES
Mr Donald Scott-Collett	11/08/2011 - 11/08/2011	Equality and Diversity Learning, NRES
Dr Chris Skidmore	28/09/2011 - 28/09/2011	NRES Phase 1 training, NRES
Dr M.J. Proven	27/09/2011 - 27/09/2011	NRES Update Session, NRES
Mr David Carpenter	28/10/2011 - 28/10/2011	NRES Update Session: Oxford, NRES
Dr M.J. Proven	16/11/2011 - 16/11/2011	Induction, NRES
Ms Susan Tonks	31/01/2012 - 31/01/2012	NRES Phase 1 Training: PO4001, NRES
Mr David Carpenter	10/10/2011 - 10/10/2011	AREC Conference, AREC
Dr M.J. Proven	22/11/2011 - 22/11/2011	Adults Lacking Capacity workshop for RECs: PO1001, NRES
Dr Vandana Luthra	08/02/2012 - 08/02/2012	Induction, NRES
Dr Joanne Philpot	20/03/2012 - 20/03/2012	Induction, NRES
Mr Richard Merewood	20/03/2012 - 20/03/2012	Induction, NRES
Mr David Carpenter	17/05/2011 - 17/05/2011	GAfREC Training, NRES
Mr Arden Bhattacharya	17/05/2011 - 17/05/2011	GAfREC Training, REC Training
Dr Kuna Aiyasamy	17/05/2011 - 17/05/2011	GAfREC Training, REC Training
Dr Mike Emanuel	17/05/2011 - 17/05/2011	GAfREC Training, REC Training
Mrs Vivienne Laurie	17/05/2011 - 17/05/2011	GAfREC Training, REC Training
Dr Karen Luxton	17/05/2011 - 17/05/2011	GAfREC Training, REC Training
Dr Chris Skidmore	17/05/2011 - 17/05/2011	GAfREC Training, REC Training
Ms Susan Tonks	17/05/2011 - 17/05/2011	GAfREC Training, REC Training
Mr Donald Scott-Collett	17/05/2011 - 17/05/2011	GAfREC Training, REC Training

Mr David Carpenter	13/12/2011 - 13/12/2011	MCA Video, NRES
Mr Arden Bhattacharya	13/12/2011 - 13/12/2011	MCA Video, NRES
Ms Susan Tonks	13/12/2011 - 13/12/2011	MCA Video, NRES
Dr Mike Emanuel	13/12/2011 - 13/12/2011	MCA Video, NRES
Mrs Vivienne Laurie	13/12/2011 - 13/12/2011	MCA Video, NRES
Mr Donald Scott-Collett	13/12/2011 - 13/12/2011	MCA Video, NRES
Mr Richard Havelock	13/12/2011 - 13/12/2011	MCA Video, NRES
Dr M.J. Proven	13/12/2011 - 13/12/2011	MCA Video, NRES
Dr Vandana Luthra	13/12/2011 - 13/12/2011	MCA Video, NRES
Mr Richard Merewood	13/12/2011 - 13/12/2011	MCA Video, NRES
Mrs Liz Hunter	17/01/2012 - 17/01/2012	NRES Induction DVD, NRES
Ms Ann Quinn	21/02/2012 - 21/02/2012	NRES Induction DVD, NRES
Mr David Carpenter	15/11/2011 - 15/11/2011	Shared Ethical Debate, NRES
Mr Arden Bhattacharya	15/11/2011 - 15/11/2011	Shared Ethical Debate, NRES
Ms Susan Tonks	15/11/2011 - 15/11/2011	Shared Ethical Debate, NRES
Dr Kuna Aiyasamy	15/11/2011 - 15/11/2011	Shared Ethical Debate, NRES
Dr Mike Emanuel	15/11/2011 - 15/11/2011	Shared Ethical Debate, NRES
Mrs Vivienne Laurie	15/11/2011 - 15/11/2011	Shared Ethical Debate, NRES
Mr Donald Scott-Collett	15/11/2011 - 15/11/2011	Shared Ethical Debate, NRES
Mr Richard Havelock	15/11/2011 - 15/11/2011	Shared Ethical Debate, NRES
Dr M.J. Proven	15/11/2011 - 15/11/2011	Shared Ethical Debate, NRES
Dr Vandana Luthra	15/11/2011 - 15/11/2011	Shared Ethical Debate, NRES
Mr Richard Merewood	15/11/2011 - 15/11/2011	Shared Ethical Debate, NRES
Dr Joanne Philpot	15/11/2011 - 15/11/2011	Shared Ethical Debate, NRES
Mr Richard Havelock	08/02/2012 - 08/02/2012	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:

Applications for full ethical review – Study Type	Number	%
Clinical Trial of Investigational Medicinal Product	16	25.00
Phase 1	2	3.13
Gene Therapy	0	0.00
Research Tissue Bank	0	0.00
Research Database	0	0.00
Others	46	71.88
Total Applications Reviewed	64	100

Table 2: Other REC activity during the reporting period:

Number of applications made invalid by co-ordinator	3
Number of studies withdrawn prior to the meeting	10
Number of student applications reviewed	27
Number of paediatric applications reviewed	6
Number of device applications reviewed	1
Number of prisoner applications reviewed	0
Number of applications involving adults unable consent reviewed	6
Number of applications reviewed funded by the US DHHS	1

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	1	1.56
Favourable Opinion with Additional Conditions	9	14.06
Unfavourable Opinion	16	25.00
Provisional Opinion	38	59.38
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	64	100
Number of studies sent back to full committee meeting for final opinion	0	

Table 4: Summary of current status of applications reviewed during the reporting period:

Status of applications at date of generation of report	Number	%
Further Information Favourable Opinion with Standard Conditions	32	50.00
Further Information Favourable Opinion with Additional Conditions	2	3.13
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	1	1.56
Favourable Opinion with Additional Conditions	9	14.06
Unfavourable Opinion	16	25.00
Provisional Opinion	1	1.56
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	1	1.56
Not Requiring Review by NHS REC	0	0.00
No decision entered on RED	1	1.56
Number of studies withdrawn after the meeting	1	1.56
Total	64	100

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

Total Applications Reviewed	9
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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	1	11.11
Favourable Opinion with Additional Conditions	1	11.11
No Opinion transfer to full committee for review	1	11.11
Provisional Opinion	3	33.33
Unfavourable Opinion	3	33.33
Total	9	100

Table 7: Other Management Information for the reporting period:

Average number of applications reviewed per full meeting	5.82
Number of applications for full ethical review over 60 days	1
Number of applications over 60 days as a % of total	1.56%
Number of days taken to final decision - average	34
Number of days taken to final decision - mode	34
Number of SSAs (non-Phase 1) reviewed	14
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	147
Number of substantial amendments over 35 days	8
Number of substantial amendments over 35 days as a % of total substantial amendments	5.4%
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	25
Number of modified amendments over 14 days	4
Number of modified amendments over 14 days as a % of total modified amendments	16.0%
Number of proportionate review applications for ethical review over 14 days*	0
Number of proportionate review applications over 14 days as a % of total	0.00%

*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:

Further Information Favourable Opinion with Standard Conditions		
REC Reference	Application Short Title	Number of Days on Clock
11/SC/0096	Children with language, reading and communication problems	26
11/SC/0128	ABC-04	28
11/SC/0130	Neuroimaging in HTLV-1 infection	35
11/SC/0131	The Macadamia Oil and Palm Oil Trial	38
11/SC/0172	ICON - Intensive Care Outcome Network phase 3	26
11/SC/0180	Exploring informed choice within prenatal testing: version 1	38
11/SC/0182	Mental imagery and mood in psychological disorders	30
11/SC/0183	Microparticles and Cytokines - A Marker of Cardiovascular Risk	32
11/SC/0184	Immune Cell Function in Immunodeficiency and Autoimmunity	32
11/SC/0185	Pulmonary surfactant kinetics in healthy adult volunteers	39
11/SC/0208	Multimodal brain imaging of epileptic activity, v1	29
11/SC/0225	Cognitive Impairment in End Stage Renal Disease (ESRD)	25
11/SC/0239	Exploring the Acceptability of Mindfulness for Older Adults	31
11/SC/0240	Investigating Clinical Decision Making in Mental Health Professionals	32
11/SC/0251	Preladenant in Subjects with Moderate to Severe PD (Extn Study:P06153)	29
11/SC/0312	Emotional processing in Fibromyalgia	26
11/SC/0322	Imaging the human habenula	34
11/SC/0373	International Cancer Benchmarking Partnership Module 3	61
11/SC/0374	The English Longitudinal Study of Ageing (Wave 6)	51
11/SC/0383	Antidepressant effects on emotion and motivation in healthy volunteers	37
11/SC/0384	Omega-3 fatty acids and inflammation	51
11/SC/0423	Efficacy and dosing of probiotic E.coli in gastric colonisation(V1.0)	51
11/SC/0428	"Predictors of exercise in people with Schizophrenia"	38
11/SC/0430	The Relationship of Childhood Bullying and Paranoid Thinking.Version 2	46
11/SC/0448	Enabling people with the oral allergy syndrome to eat fresh fruit	43
11/SC/0480	Cementless V Cemented UKR: 1-5 year post-operative outcome study.	52
11/SC/0486	Optimisation of amisulpride prescribing in older people	52
11/SC/0488	Xenon lung imaging in COPD: a COPD Cohort sub-study Version 1.0	59
11/SC/0519	Early brain injury after subarachnoid haemorrhage	55
12/SC/0013	Pilot Trial: Personalising Opioid Therapy for Cancer Pain Relief	25

12/SC/0031	Evaluation of BMS-790052 with Peg-Interferon Alpha-2a + Ribavirin (v1)	36
12/SC/0032	ATOM in 22qDS v4	31
12/SC/0075	Sleep disturbance in rheumatoid arthritis.	10
12/SC/0076	What do patients with type 2 diabetes think about their medicines?	11
12/SC/0156	Genetic tests with Next Generation Sequencing	11

Further Information Favourable Opinion with Additional Conditions

REC Reference	Application Short Title	Number of Days on Clock
11/SC/0132	Care Home staff experiences of the Gold Standards Framework (GSF)	40
11/SC/0454	Treatment of HBeAg positive chronic hepatitis B (CHB) in children.	34

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/0549	Synovial fluid markers in knee osteoarthritis - temporal data	34
12/SC/0151	Human papillomavirus-associated nasopharyngeal cancer.	8

Favourable Opinion with Additional Conditions

REC Reference	Application Short Title	Number of Days on Clock
11/SC/0250	Functional Imaging of Liver Metastases (FILM) Study	29
11/SC/0320	Non-attendance of 19 to 25 year olds at diabetic retinopathy screening	34
11/SC/0378	Comparing Obstetrician-led & Midwife-led AN care following previous CS	39
11/SC/0445	In-House Chlorhexidine Salivary Retention Study	31
11/SC/0487	Regional lung imaging using hyperpolarized xenon gas MR	24
11/SC/0537	Investigating functional brain connectivity using TMS/EEG	34
12/SC/0139	SafeHer: Safety study with subcutaneous trastuzumab in breast cancer	24
12/SC/0146	SAFER: Supports for Ankle Fractures in Early Rehabilitation	21
12/SC/0149	LUX-Lung 8, Afatinib versus Erlotinib in Squamous NSCLC	24
12/SC/0200	Biomechanical testing of unicortical and bicortical plate fixation	8

Unfavourable Opinion

REC Reference	Application Short Title	Number of Days on Clock
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11/SC/0123	Gum-based Thickener Tolerance Study	23
11/SC/0133	Disclosure in gynaecological cancer patients	34
11/SC/0252	Community mental health clinical staff attitudes to data collection	27
11/SC/0318	ATOM in 22qDS v3	28
11/SC/0331	The Relationship of Childhood Bullying and Paranoid Thinking.Version 1	41
11/SC/0332	Do amino acid supplementation aid wound healing - version 1.0	35
11/SC/0350	The Interhospital Telemedicine Pilot Project	24
11/SC/0381	Child emotional understanding	36
11/SC/0497	Version 1 TYM Research Project	30
11/SC/0536	Prilocaine versus bupivacaine in spinal anaesthesia for obstetrics	26
11/SC/0544	'Kidney-Friendly' Ready Meals for Haemodialysis Patients	36
12/SC/0021	To assess SAR228810 in patients with Alzheimer's disease	23
12/SC/0109	Steady-state PK of oxycodone and naloxone from OXN PR tablets (112769)	23
12/SC/0140	An examination of African Caribbean male service users in acute ward	25
12/SC/0144	Triage Rule-Out Using Sensitive Troponin (TRUST) Chest Pain Study 1	31
12/SC/0150	A Pharmacodynamic Evaluation of Switching from Ticagrelor to Prasugrel	25
12/SC/0164	Psychological characteristics in epileptic and nonepileptic seizures	6
12/SC/0199	Observational Study of Patients administered Cinryze for HAE	6
12/SC/0206	Quality of Life & Outcome in Octogenarians undergoing Cardiac Surgery	5

Provisional Opinion

REC Reference	Application Short Title	Number of Days on Clock
12/SC/0045	Concept study of a feedback system for patients with neuropathy	N/A

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
11/SC/0190	Stem Cell Models of Headache	N/A

Withdrawn after the meeting

REC Reference	Application Short Title	Number of Days on Clock
11/SC/0113	Study of Patient's Perceptions of an Intergrated Service	23

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:

Full applications for ethical review over 60 day timeline		
REC Reference	Application Short Title	Number of Days on Clock
11/SC/0373	International Cancer Benchmarking Partnership Module 3	61

Proportionate review applications for ethical review over 14 days timeline		
REC Reference	Application Short Title	Number of Days on Clock

SSAs (non Phase 1) over 25 days timeline		
REC Reference	Application Short Title	Number of Days on Clock

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

Substantial Amendments over 35 day timeline			
Amendment Reference	Application Short Title	Amendment Title	Number of Days on Clock
10/H0505/99/AM03	Immune Globulin Subcutaneous (Human) (IGSC), 20%	Substantial Amendment 2 - 14/11/2011	36
11/SC/0128/AM01	ABC-04	AM01 Substantial Amendment 01	38
11/SC/0096/AM02	Children with language, reading and communication problems	AM02 Substantial Amendment 02 Dated 21st Dec 2011	38
10/H0505/108/AM07	The CAROLINA Trial. Final Protocol, Version 1, 17 Aug 2010	AM06 Substantial Amendment 5 Dated 19th Dec 2011	39
09/H0505/73/AM08	Dominantly Inherited Alzheimer Network (DIAN)	Amendment 5: 22-November-2011	41
10/H0505/41/AM04	HOVIS- Home Visits after stroke	Protocol Amendment Dated 22nd Dec 2011	38
04/12/015/AM14	Anti thyroid drug treatment of thyrotoxicosis in children and adolesce	Substantial Amendment - Temporary Halt to Recruitme	37

07/H0607/95/AM03	Culture and characterization of human cardiac stem cells	Amendment 03 Dated 09.12.2011	57
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Modified Amendments over 14 day timeline			
Amendment Reference	Application Short Title	Amendment Title	Number of Days on Clock
09/H0505/73/AM06/1	Dominantly Inherited Alzheimer Network (DIAN)	Modified Amendment 4 - 14.09.2011	18
07/H0505/176/AM11/1	Treatment of child anxiety: Predictors and Outcomes of Treatment (v1)	Modified Amendment 2 - 07.10.2011	18
11/SC/0006/AM01/1	EPOCH Pilot	Modified Amendment 1	35
10/H0505/71/AM14/1	Understanding the early pathological pathways in Parkinson's Disease	Modified Amendment 12 - 27.12.2011	21

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