

RES Committee South West - Central Bristol

Annual Report

01 April 2014 - 31 March 2015



Part 1 – Committee Membership and Training

Name of REC:	RES Committee South West - Central Bristol
Type of REC:	Type III (CTIMP)
Type of Flag:	Research Databases Research Tissue Banks Paediatric IRB registered
Chair:	Dr Pamela Cairns
Vice-Chair:	Dr Margrid Schindler
Alternate Vice-Chair:	Mr Brian Pixton
REC Manager:	Mrs Naazneen Nathoo
REC Assistant:	Miss Lidia Gonzalez (up to May 2014) Miss Tanya Muravyeva (May 2014 to February 2015) Miss Fran Race (from February 2015)
Committee Address:	Whitefriars Level 3, Block B Lewin's Mead Bristol BS1 2NT
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Chair's overview of the past year:

The Central Bristol REC remains busy, dealing with full and PR applications, as well as substantial amendments.

Demonstration of the tablet to test the onscreen review of the REC documents took place during the September 2014 full committee meeting. The committee used the tablet as part of the HRA pilot project for the next two meetings.

Members were advised that it would soon be possible to view documents via HARP. A demonstration of same would be scheduled as soon as the portal was ready.

Due to increasingly heavy workload, our pharmacist member (and alternate vice chair) stepped down at the beginning of December 2014. A replacement pharmacist member will be sought. Another member stepped down in March 2014. Mr Pixton was appointed Alternate Vice Chair.

An interesting training day for the membership was held on 27 February 2015, which was also attended by members from the Frenchay REC.

In line with the guidance when applicants cannot attend the full committee meeting in person, they are contacted via telephone (where contact details had been supplied to the Committee.) Use of the speaker phone has enabled this to work well.

There have been three REC Assistants: Lidia Gonzalez, Tanya Muravyeva and Fran Race, who help the REC Manager. All four have been kept busy keeping track of the ever increasing paper work and gently chivvy members along to respond in a timely way to substantial amendments and proportionate reviews. I am very grateful for all of their hard work.

I would like to thank the Vice Chair and the Alternate Vice Chair in particular for their support over the past few months.

RES Committee South West - Central Bristol Membership

Name	Profession	Expert or Lay	Dates	
			Appointed	Left
Dr Kay Barnard	Ex-research scientist	Lay	01/04/2012	
Dr Robert Beetham	Retired Consultant Clinical Biochemist	Lay	01/02/2014	
Mr Trevor Beswick	Director - SW Medicines, Information & Training	Expert	20/02/2009	31/03/2015
Dr Pamela Cairns	Consultant Neonatologist	Expert	01/12/2006	
Mrs Angela Clarke	Ex-social worker	Lay Plus	10/06/2004	10/06/2014
Dr Simon Croxson	Consultant Physician	Expert	11/02/2008	
Dr Ian Davies	Consultant in Cardiac Anaesthesia & Intensive Care	Expert	01/05/2011	
Dr Michael Halliwell	Medical Physicist (retired)	Lay	01/01/2006	27/02/2015
Mr Alexander Howard	Humanist Funeral Celebrant	Lay Plus	08/08/2014	
Mr Geoffrey Jones	Retired solicitor	Lay Plus	01/04/2012	28/04/2014
Dr Adrian Kendrick	Consultant Clinical Scientist	Expert	20/01/2013	
Mr Paul Lewis	Patient Involvement Coordinator	Lay Plus	01/05/2011	
Mr Brian Pixton	Retired solicitor	Lay Plus	11/03/2013	
Dr Colette Reid	Consultant in Palliative Medicine	Expert	01/08/2013	
Dr Margrid Schindler	Consultant Senior Lecturer	Expert	06/03/2007	
Dr Julie Woodley	Senior Lecturer/ Chair of Faculty Ethics Committee	Expert	08/08/2014	

RES Committee South West - Central Bristol: Deputy Members

Name	Profession	Status	Meeting date attended
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RES Committee South West - Central Bristol: Co-opted Members

Name	Profession	Status	Meeting date attended

RES Committee South West - Central Bristol: Members' Declarations of Interest:

Name	Declaration of Interest	Date
Dr Kay Barnard	Grassroots Food Ltd. J & K Barnard Farms Ltd. Involved in overseas development particularly food and agriculture in Africa.	31/03/2015
Dr Robert Beetham	Shareholding in Smith and Nephew plc	24/02/2015
Mr Trevor Beswick	None	31/03/2015
Dr Pamela Cairns	Co-investigator in a few neonatal studies. Invited reviewer of grants and papers	27/05/2014
Dr Simon Croxson	Currently on or previously been on the professional advisory boards of several companies:- NovoNordisk; Novartis; Servier; Merck; Takeda; GSK/SKB Paid lectures for many drug companies presently and in the past: Internis, Bayer, MSD• Servier, Merck, Aventis, NovoNordisk Eli Lilly, Novartis, Pfizer, Sanofi, Takeda, Schering, Sankyo, SKB/GSK, BMS, Boehringer Ingelheim	27/03/2015
Dr Ian Davies	None	27/03/2015
Mr Alexander Howard	None	28/08/2014
Dr Adrian Kendrick	Retts UK Provide external advice to parents of children with Retts syndrome. Speaker at regional and national meetings of Retts UK Co-author (in preparation) of review article for Retts UK Funded research by Retts UK CDKL5Charity linked to patients with Retts syndrome variant Funded research by CDKL5CureRett Charity linked to patients with Retts syndrome Funded research by Cure Rett Association for Respiratory Technology & Physiology Member of Research Committee	31/03/2015
Mr Paul Lewis	PL holds all of his shares through intermediary fund management companies, who choose the shares independently on his behalf.	27/03/2015
Mr Brian Pixton	Wife is an administrator in the R&D Office at Weston-super-mare Hospital.	27/03/2015
Dr Colette Reid	None	27/03/2015
Dr Margrid Schindler	None	31/03/2015
Dr Julie Woodley	Snr Lecturer and Chair of faculty ethics committee in Faculty of Health and Social Sciences	06/03/2015

Meetings for Full Ethical Review 01 April 2014 - 31 March 2015:

Month	Date	Number of Members Present at Meeting
April	25/04/2014	11
May	30/05/2014	9
June	27/06/2014	9
July	25/07/2014	8
August	29/08/2014	9
September	26/09/2014	10
October	31/10/2014	10
November	28/11/2014	13
January	30/01/2015	10
March	27/03/2015	8

10 full committee meetings were held during the reporting period.

Proportionate Review Sub-Committee Meetings held during 01 April 2014 - 31 March 2015:

Month	Date	Number of Members Present at Meeting
April	14/04/2014	3
May	19/05/2014	3
June	16/06/2014	3
August	18/08/2014	3
September	15/09/2014	3
October	20/10/2014	3
November	17/11/2014	3
January	12/01/2015	3
March	09/03/2015	3

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

Sub-Committee Meetings held during 01 April 2014 - 31 March 2015:

Month	Date	Number of Members Present at Meeting
April	07/04/2014	2
April	21/04/2014	2
May	05/05/2014	2
May	19/05/2014	2
June	04/06/2014	2
June	18/06/2014	2
July	04/07/2014	3
July	11/07/2014	2
August	01/08/2014	2
August	06/08/2014	2
August	25/08/2014	3
September	22/09/2014	2

October	06/10/2014	4
October	20/10/2014	3
November	03/11/2014	2
November	17/11/2014	2
December	01/12/2014	2
December	15/12/2014	2
January	09/01/2015	2
January	21/01/2015	2
January	26/01/2015	2
February	05/02/2015	2
February	09/02/2015	2
February	23/02/2015	2
March	09/03/2015	2
March	23/03/2015	2

26 sub-committee meetings were held during the reporting period.

Details of inquorate meeting held:01 April 2014 - 31 March 2015

0

Attendance of Members at full committee meetings: 01 April 2014 - 31 March 2015

Name	Number of Meetings Attended
Dr Kay Barnard	6
Dr Robert Beetham	9
Mr Trevor Beswick	8
Dr Pamela Cairns	5
Mrs Angela Clarke	2
Dr Simon Croxson	9
Dr Ian Davies	6
Dr Michael Halliwell	5
Mr Alexander Howard	4
Mr Geoffrey Jones	1
Dr Adrian Kendrick	7
Mr Paul Lewis	8
Mr Brian Pixton	9
Dr Colette Reid	6
Dr Margrid Schindler	7
Dr Julie Woodley	5

Attendance of Members at proportionate review sub-committee meetings: 01 April 2014 - 31 March 2015

Name	Number of Meetings Attended
Dr Kay Barnard	1
Dr Robert Beetham	4
Mr Trevor Beswick	2
Dr Pamela Cairns	4
Mrs Angela Clarke	1
Dr Michael Halliwell	1
Dr Adrian Kendrick	4
Mr Paul Lewis	3
Mr Brian Pixton	6
Dr Colette Reid	1

Attendance of Members at sub-committee meetings: 01 April 2014 - 31 March 2015

Name	Number of Meetings Attended
Dr Robert Beetham	9
Mr Trevor Beswick	10
Dr Pamela Cairns	9
Dr Mike Halliwell	1

Dr Adrian Kendrick	1
Mr Paul Lewis	3
Mr Brian Pixton	17
Dr Colette Reid	4
Dr Margrid Schindler	3

Training 01 April 2014 - 31 March 2015

Name of Member	Date	Event(s) attended
Dr Kay Barnard	05/09/2014	Oxford B training day
Dr Kay Barnard	27/02/2015	Local Training Day
Dr Robert Beetham	12/01/2015	CTIMP training
Dr Robert Beetham	19/02/2015	Complex Cases
Dr Pamela Cairns	27/02/2015	Local Training Day
Dr Simon Croxson	24/07/2014	SDL
Dr Simon Croxson	19/12/2014	UH Bristol consultant away day including session on Research
Dr Simon Croxson	05/02/2015	Equality & diversity
Dr Ian Davies	27/02/2015	Local Training Day
Dr Michael Halliwell	27/02/2015	Local Training Day
Mr Alexander Howard	19/11/2014	Equality & Diversity Training
Mr Alexander Howard	25/11/2014	Induction
Mr Alexander Howard	27/02/2015	Local Training Day
Dr Adrian Kendrick	27/02/2015	Local Training Day
Mr Paul Lewis	27/02/2015	Local Training Day
Mr Brian Pixton	05/09/2014	Oxford B training day
Mr Brian Pixton	20/11/2014	South West NREAP/REC Chairs Network Meeting
Mr Brian Pixton	27/02/2015	Local Training Day
Dr Colette Reid	12/06/2014	Induction
Dr Colette Reid	21/11/2014	Equality & Diversity
Dr Margrid Schindler	08/01/2015	IRAS module
Dr Margrid Schindler	29/01/2015	Clinical trials statistics lecture
Dr Margrid Schindler	30/01/2015	NRES Informed consent in CTIMPs
Dr Margrid Schindler	27/02/2015	Local Training Day
Dr Julie Woodley	27/02/2015	Local Training Day
Dr Julie Woodley	09/03/2015	Induction

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	11	21.57
Phase 1	0	0.00
Gene Therapy	0	0.00
Research Tissue Bank (including renewals)	2	3.92
Research Database (including renewals)	3	5.88
Others	35	68.63
Total Applications Reviewed	51	100

Table 2: Breakdown of full applications and other activity during reporting period

Number of applications made invalid by the REC Manager	1
Number of applications withdrawn prior to the meeting	0
Number of student applications reviewed	8
Number of paediatric applications reviewed	18
Number of device applications reviewed	1
Number of prisoner applications reviewed	0
Number of applications involving adults unable consent reviewed	0
Number of applications reviewed that are funded by the US DHHS	3
Number of qualitative applications reviewed	2

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	3	5.88
Favourable Opinion with Additional Conditions	12	23.53
Unfavourable Opinion	2	3.92
Provisional Opinion	34	66.67
Provisional Opinion Pending Consultation with Referee	0	0.00
Total	51	100
Number of studies sent back to full committee meeting for final opinion	2	

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	28	54.90
Further Information Favourable Opinion with Additional Conditions	2	3.92
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	3	5.88
Favourable Opinion with Additional Conditions	12	23.53
Unfavourable Opinion	2	3.92
Provisional Opinion	2	3.92
Provisional Opinion Pending Consultation with Referee	0	0.00
Further Information response not complete	1	1.96
No decision entered on system	0	0.00
Number of studies withdrawn after the meeting	1	1.96
Total	51	100

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

Total Applications Reviewed	21
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Table 6: Breakdown of PRS applications and other activity during reporting period:

Number of applications made invalid by the REC Manager	12
Number of studies withdrawn prior to the meeting	2
Number of student applications reviewed	11
Number of paediatric applications reviewed	1
Number of device applications reviewed	0
Number of qualitative applications reviewed	6

Table 7: 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	6	28.57
Favourable Opinion with Additional Conditions	2	9.52
No Opinion transfer to full committee for review	2	9.52
Provisional Opinion	9	42.86
Unfavourable Opinion	2	9.52
Total	21	100

Table 8: Other Management Information for the reporting period:

Average number of applications reviewed per full meeting	5.10
Number of applications for full ethical review	50
Number of applications for full ethical review over 60 days	1
Number of applications over 60 days as a % of total	1.96%
Number of applications for full ethical review over 40 days	19
Number of applications over 40 days as a % of total	37.25%
Number of days taken to final decision – average (mean)	38
Number of proportionate review applications for ethical review	19
Number of proportionate review applications for ethical review over 14 days	4
Number of proportionate review applications over 14 days as a % of total	21.05%
Number of SSAs (non-Phase 1) reviewed	1
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	0.00%
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	0.00%
Number of substantial amendments reviewed	98
Number of substantial amendments over 35 days	4
Number of substantial amendments over 35 days as a % of total substantial amendments	4.08%
Number of substantial amendments over 28 days	13
Number of substantial amendments over 28 days as a % of total substantial amendments	13.27%
Number of modified amendments reviewed	2
Number of modified amendments over 14 days	0
Number of modified amendments over 14 days as a % of total modified amendments	0.00%
Number of minor amendments received	39
Number of substantial amendments received for information	0
Number of substantial amendments received for new sites/PIs	10
Number of annual progress reports received	83
Number of safety reports received	10
Number of Serious Adverse Events received	0
Number of final reports received	17

Table 9.1: Breakdown of current status of all full applications reviewed within the reporting period

Further Information Favourable Opinion with Standard Conditions		
REC Reference	Title	Number of Days on Clock
14/SW/0059	Risk factors & outcomes for incontinence in children & adolescents(1)	28
14/SW/0085	Comparison of the paper and electronic versions of the DLQI and PASI	42
14/SW/0091	A Phase 3 Veliparib plus Chemotherapy Study in Adv/Met squamous NSCLC	37
14/SW/0112	The Bristol Archive Project	38
14/SW/0114	The effect of plasma proteins on tissue healing	23
14/SW/0118	BP in coarctation:genomic,autonomic and ventricular-vascular influence	29
14/SW/1003	Barriers to Recovery from Substance Misuse in Dorset	46
14/SW/1008	Prospective Memory in Children with an Acquired Brain Injury	41
14/SW/1023	The Twilight Study	51
14/SW/1027	Do aquaporins protect against renal damage in PUJ obstruction? (V1)	40
14/SW/1029	218MS305-Fampridine in Subjects with Multiple Sclerosis (ENHANCE)	52
14/SW/1031	The feasibility of YP Face IT for young people with a burn injury	33
14/SW/1050	The Pulses Study	37
14/SW/1058	IMPACT-PC	42
14/SW/1078	DRIFT School age follow-up	28
14/SW/1085	Placebo controlled Radium-223, plus exemestane and everolimus in mBC	48
14/SW/1108	Equivalence in analgesic efficacy & bowel function taking OXN tablets.	39
14/SW/1127	A Mediterranean diet score validation in people at cardiovascular risk	41
14/SW/1131	Paediatric or Adult Critical Care for Teenagers	28
14/SW/1141	1289.5 BI409306 compared to placebo in Alzheimer's Disease	49
14/SW/1144	ARENA study	65
14/SW/1164	MEDI4736 in Recurrent or Metastatic PD-L1 Positive SCCHN	39
15/SW/0001	Language and Memory in Neurodevelopmental Conditions	40
15/SW/0004	Examining mechanisms underlying the anti-cancer effect of exercise-v1	53
15/SW/0006	Exercise in the Fasted State, Glucose Metabolism and Energy Balance	37
15/SW/0083	Bioimpedance monitoring in diabetic ketoacidosis V3	45
15/SW/0085	Footprints in Primary Care	45
15/SW/0086	Daratumumab + rd vs rd in subjects with previously untreated MM	58

Further Information Favourable Opinion with Additional Conditions		
REC Reference	Title	Number of Days on Clock

14/SW/0140	Preventing opiate substitution therapy deaths: an observation study	51
14/SW/1006	Septrin in severe head injury	45

Further Information Unfavourable Opinion

REC Reference	Title	Number of Days on Clock
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Favourable Opinion with Standard Conditions

REC Reference	Title	Number of Days on Clock
14/SW/0075	REDUCE Trial	27
14/SW/1089	EXTEND and the Peninsula Research Bank - 5 year extension 1	28
14/SW/1143	Surveillance of Type 2 Diabetes in children	48

Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
09/H0102/32+5	The Bristol Self-Harm Monitoring System	25
14/SW/0073	TrialNet LIFT Study	27
14/SW/0113	ALSPAC Siblings and Grandparents Saliva Collection and Questionnaire	25
14/SW/1024	THRIVE: Trust in Human-Robot Interaction (Pilot Experiment)	43
14/SW/1060	Evaluation of calculus formation after 12 weeks toothpaste/gel use.	27
14/SW/1061	TrialNet TN18 Abatacept Prevention	41
14/SW/1084	Newborn Hearing Screening and the risk of SIDS	33
14/SW/1088	National Registry for Rare Kidney Diseases (RaDaR)	33
14/SW/1148	University of Birmingham Dentistry Research Tissue Bank	25
14/SW/1160	Life after Weight Loss Surgery	27
15/SW/0079	SJIA disease burden caregiver research	31
15/SW/0084	PUMA-Paediatric early warning systems: Utility and Mortality Avoidance	31

Unfavourable Opinion

REC Reference	Title	Number of Days on Clock
14/SW/0103	DATABASE OF POTENTIAL PARTICIPANTS FOR DEVELOPMENTAL RESEARCH AT CRHDL	25
14/SW/1033	Equivalence in analgesic efficacy & bowel function taking OXN tablets.	30

Provisional Opinion		
REC Reference	Title	Number of Days on Clock
15/SW/0002	Coronary venous arterialisation in patients with refractory angina	n/a
15/SW/0010	Rates of depression & anxiety in diagnostic laparoscopy	n/a

Provisional Opinion Pending Consultation with Referee		
REC Reference	Title	Number of Days on Clock

Further information response not complete		
REC Reference	Title	Number of Days on Clock
14/SW/1054	Child Health Outcomes Following Surgical Sperm Retrieval	n/a

Withdrawn after the meeting		
REC Reference	Title	Number of Days on Clock
14/SW/0071	Consultations and self-care for minor ailments: Perceptions on resilie	27

Table 9.2: Breakdown of current status of all PRS applications reviewed within the reporting period

Further Information Favourable Opinion with Standard Conditions		
REC Reference	Title	Number of Days on Clock
14/SW/0100	Innate immunity & predisposition to infection & allergy in children	24
14/SW/1065	Describing and valuing health with single-sided deafness	14
14/SW/1071	Patient reported outcomes in prostate cancer radiotherapy version 1.1	11
14/SW/1093	Sickle Cell Disease and the Family	14
15/SW/0020	EASE	9
15/SW/0070	Understanding health promotion for people with Down syndrome: version 1	18
15/SW/0071	Corneal ulcer pressure study	27
15/SW/0072	Exploring the lived experience of stoma surgery	12

15/SW/0073	Masculine Identity After Traumatic Brain Injury	14
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Further Information Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
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Further Information Unfavourable Opinion

REC Reference	Title	Number of Days on Clock
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Favourable Opinion with Standard Conditions

REC Reference	Title	Number of Days on Clock
14/SW/0128	The role of information sources before a diagnosis of lung cancer	12
14/SW/0130	Validation of a new method for measuring 5HIAA in blood - version 1	7
14/SW/1094	Childhood uveitis	8
14/SW/1153	Diabetic wound healing and its relationship to vascular circulation.	10
14/SW/1163	LOTUS: long term follow up study of triple negative breast cancer	8
15/SW/0015	Evaluation of past and present implementation of Telemonitoring NI	9

Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
14/SW/1009	Patients' experience in the ELUCIDATE trial	11
14/SW/1162	Faecal and urinary Volatile Organic Compounds (VOCs)in bowel cancer	9

Unfavourable Opinion

REC Reference	Title	Number of Days on Clock
14/SW/1098	Strategic planning process for use of Point Of Care Testing (POCT)	9
15/SW/0016	PFO device closure in cerebrovascular events version 1	9

Provisional Opinion

REC Reference	Title	Number of Days on Clock
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Further information response not complete

REC Reference	Title	Number of Days on Clock
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Withdrawn after the meeting

REC Reference	Title	Number of Days on Clock
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Table 10.1: Breakdown of current status of all substantial amendments reviewed within the reporting period

Favourable opinion				
Amendment REC Reference	Title	Version	Date	Number of Days on Clock
04/Q2002/84/AM05	Mechanisms of Steroid Resistance v1.0	4	22/05/2014	7
04/Q2002/84/AM06	Mechanisms of Steroid Resistance v1.0	5	20/10/2014	21
04/Q2006/102/AM09	Natural History Study of the development of Type 1 Diabetes - May 2004	12, 28 JAN 2014	28/01/2014	22
04/Q2006/102/AM10	Natural History Study of the development of Type 1 Diabetes - May 2004	13, 16/4/14	16/04/2014	11
06/Q2001/197/AM04	Vascular progenitor cells in human vessels	4 April 2014	04/04/2014	10
06/Q2002/101/AM02	Cultured Glomerular Cells	Substantial Amendment 2 dated	13/10/2014	20
06/Q2006/54/AM02	Vascular Permeability In Pre-eclampsia	1st amendment, version 5	27/01/2015	16
07/H0106/172/AM09	The OXIC-2 Trial	11	12/08/2014	25
07/H0106/172/AM09	The OXIC-2 Trial	11	26/09/2014	25
08/H0102/11/AM06	Investigation of pleural disease:improving the patient pathway.1.	7	05/06/2014	14
08/H0102/12/AM07	Structural and Functional imaging in epilepsy	4	05/07/2014	42
087/99/AM05	Developing and evaluating a questionnaire to assess incontinence: the	24 17thMarch 2014	27/03/2014	16
087/99/AM06	Developing and evaluating a questionnaire to assess incontinence: the	25	01/10/2014	3
087/99/AM07	Developing and evaluating a questionnaire to assess incontinence: the	26	20/10/2014	18
09/H0102/64/AM13	DUTY: The Diagnosis of UTI in Young Children Study. v 1.0	13	06/06/2014	22
09/H0106/19+5/AM01	(duplicate) SPLDv3	1	12/03/2015	8
09/H0106/34/AM05	The interaction between pulmonary vasculature and airway functionv5.0	4 02/05/2014	02/05/2014	11
09/H0106/65/AM05	Large Diameter Advantaâ„¢ V12 Covered Stent Trial	1	19/02/2015	11

09/H0106/80/AM03	National Study of Steroid Resistant Nephrotic Syndrome in Childhood	1, 28 March 2014	28/03/2014	9
09/H0106/80/AM04	National Study of Steroid Resistant Nephrotic Syndrome in Childhood	2	16/12/2014	17
09/H0106/83/AM08	TrialNet Oral Insulin Study	2014/01/30	30/01/2014	9
10/H0106/10/AM06	Genetic susceptibility of preterm infants to brain injury	6	02/12/2014	29
10/H0106/57/AM03	CL Institute of Ophthalmology and Moorfields Eye Hospital - Eye Tissue	3	17/11/2014	17
10/H0106/80/AM03	Enteral feeding following hospital	4	24/06/2014	33
11/SW/0018/AM10	Royal Devon & Exeter Tissue Bank	4	13/02/2015	28
11/SW/0053/AM03	Facilitating Activity and Self-management in Arthritis	Amendment 2;03/02/14	03/02/2014	28
11/SW/0053/AM04	Facilitating Activity and Self-management in Arthritis	Amendment 3 ³ / ₄ 22.05.14	22/05/2014	12
11/SW/0078/AM03	Intravenous and subcutaneous microdialysis of free cortisol	3	26/01/2015	7
11/SW/0110/AM05	ALSPAC Focus on Mothers 2 & 3. Version 1	5	05/06/2014	4
11/SW/0160/AM04	UK Multiple Sclerosis Register	4 18/3/2014	18/03/2014	28
11/SW/0160/AM05	UK Multiple Sclerosis Register	5	10/06/2014	28
11/SW/0160/AM06	UK Multiple Sclerosis Register	6	14/11/2014	10
12/SW/0015/AM01	VEGF165b and Infertility	1 12/03/2014	01/12/2003	9
12/SW/0039/AM02	An investigation into enterocyte substrate utilization	2	13/10/2014	9
12/SW/0047/AM06	Intermittent Bilateral GDNF for Parkinson's Disease	v6	02/06/2014	14
12/SW/0047/AM07	Intermittent Bilateral GDNF for Parkinson's Disease	7	05/08/2014	35
12/SW/0047/AM08	Intermittent Bilateral GDNF for Parkinson's Disease	8	24/09/2014	5
12/SW/0055/AM05	COCO90s Version 1.0	AM05	03/03/2015	28
12/SW/0084/AM01	Study of Intravitreal LFG316 in patients with multifocal choroiditis	Amendment Protocol vers. 2, 28	19/03/2014	14
12/SW/0084/AM02	Study of Intravitreal LFG316 in patients with multifocal choroiditis	AM02 Substantial Amendment 02	08/07/2014	34
12/SW/0084/AM03	Study of Intravitreal LFG316 in patients with multifocal choroiditis	AM03	09/03/2015	15
12/SW/0264/AM02	Pulmonary Arterial Hypertension: Working on Anxiety and Stress	Substantial Amendment 1, 08/03	08/03/2014	14
12/SW/0264/AM03	Pulmonary Arterial Hypertension: Working on Anxiety and Stress	v2	28/05/2014	7

12/SW/0280/AM02	The Bristol Fetal Brain Imaging Study (BFBI study)	2	01/05/2014	12
12/SW/0289/AM01	Understanding the autoimmune mechanism in membranous nephropathy	AM01 Substantial Amendment 01	15/09/2014	29
12/SW/0361/AM07	COMBI-AD. COMBIlation study in treatment of ADjuvant melanoma	BRF115532 Substantial Amendmen	03/04/2014	11
12/SW/0361/AM09	COMBI-AD. COMBIlation study in treatment of ADjuvant melanoma	BRF115532 Substantial Amendme	24/04/2014	25
12/SW/0361/AM10	COMBI-AD. COMBIlation study in treatment of ADjuvant melanoma	10	08/08/2014	17
12/SW/0368/AM03	Non-interventional Study of Pasireotide sc Study in Cushing's Disease	v01	20/09/2013	34
12/SW/0378/AM07	BRAVO 2/3	3	30/08/2014	23
13/SW/0064/AM03	The Cleft Collective Cohort Studies - v1	3	27/08/2014	15
13/SW/0064/AM04	The Cleft Collective Cohort Studies - v1	4	01/01/2015	11
13/SW/0065/AM02	Cardiac Gemstone Spectral Imaging	11	15/01/2015	21
13/SW/0075/AM01	DVT natural history, recurrence and PTS	1	23/05/2014	28
13/SW/0170/AM01	Behavioural and neurophysiological effects of schizophrenia risk genes	1, 13/02/2014	13/02/2014	14
13/SW/0171/AM06	Phase 1/2 Oxabact OC5 study, Protocol OC5-DB-01, version 3, Am 1	Changes to REC form	16/01/2014	5
13/SW/0171/AM07	Phase 1/2 Oxabact OC5 study, Protocol OC5-DB-01, version 3, Am 1	9	10/06/2014	21
13/SW/0181/AM03	Extension Study of Intermittent Bilateral GDNF for Parkinsons Disease	2	30/06/2014	20
13/SW/0187/AM03	Sedentary time and metabolic health in people with type 2 diabetes	2	06/06/2014	34
13/SW/0187/AM04	Sedentary time and metabolic health in people with type 2 diabetes	3	25/11/2014	27
13/SW/0199/AM03	EVRA (Early Venous Reflux Ablation) Ulcer trial Version 1.0	AM03	05/03/2015	21
13/SW/0247/AM02	Buparlisib or placebo, plus paclitaxel, in head and neck carcinoma	02	25/11/2014	12
13/SW/0269/AM01	Carers' efforts to help loved ones cope psychologically with psychosis	2	25/06/2014	18
13/SW/0270/AM01	Sequana 2013-AAR-008	1 9th May 2014	27/05/2014	28

13/SW/0297/AM01	COMET	1	28/05/2014	14
13/SW/0297/AM03	COMET	2	04/11/2014	7
13/SW/0300/AM01	CoolXenon3	2.0	15/04/2014	36
13/SW/0311/AM01	Change in dentine occlusion after use of an occluding toothpaste	1.0	05/08/2014	39
13/SW/0312/AM01	T1D, Immunology, Genetics, Endogenous Insulin Production (TIGI) vs 1	1, 17/04/14	17/04/2014	14
13/SW/0312/AM02	T1D, Immunology, Genetics, Endogenous Insulin Production (TIGI) vs 1	2	25/06/2014	9
13/SW/0312/AM03	T1D, Immunology, Genetics, Endogenous Insulin Production (TIGI) vs 1	3	22/10/2014	23
13/SW/0331/AM02	Sleep disturbance and inflammatory bowel disease. Version 1.	1	26/09/2014	19
14/SW/0021/AM01	Prevention and Risk Identification of SUDEP Mortality-PRISM v1.0	1	24/03/2014	6
14/SW/0021/AM02	Prevention and Risk Identification of SUDEP Mortality-PRISM v1.0	2	25/11/2014	19
14/SW/0033/AM01	V1: Development of a PRO Measure in Haematological Practice	1	24/10/2014	34
14/SW/0050/AM01	Identification of factors associated with speech disorder-cleft palate	1	07/07/2014	21
14/SW/0054/AM02	Peripheral chemosensitivity in hypertensive and normotensive humans	1	07/12/2014	7
14/SW/0075/AM01	REDUCE Trial	1	30/09/2014	11
14/SW/0085/AM02	Comparison of the paper and electronic versions of the DLQI and PASI	1	22/10/2014	10
14/SW/0091/AM02	A Phase 3 Veliparib plus Chemotherapy Study in Adv/Met squamous NSCLC	Substantial Amendment 2	10/07/2014	39
14/SW/0091/AM07	A Phase 3 Veliparib plus Chemotherapy Study in Adv/Met squamous NSCLC	3	11/12/2014	10
14/SW/0100/AM01	Innate immunity & predisposition to infection & allergy in children	1	13/03/2015	34
14/SW/0128/AM01	The role of information sources before a diagnosis of lung cancer	1	28/07/2014	5
14/SW/0128/AM03	The role of information sources before a diagnosis of lung cancer	2	29/11/2014	26
14/SW/1008/AM01	Prospective Memory in Children with an Acquired Brain Injury	2	22/12/2014	13

14/SW/1023/AM01	The Twilight Study	1	14/11/2014	14
14/SW/1023/AM02	The Twilight Study	2	27/11/2014	4
14/SW/1027/AM01	Do aquaporins protect against renal damage in PUJ obstruction? (V1)	1	06/11/2014	26
14/SW/1029/AM02	218MS305-Fampridine in Subjects with Multiple Sclerosis (ENHANCE)	Prot Amendment V2 dated 12Dec2	02/02/2015	16
14/SW/1031/AM01	The feasibility of YP Face IT for young people with a burn injury	1	27/10/2014	15
14/SW/1050/AM01	The Pulses Study	1	10/12/2014	25
14/SW/1065/AM01	Describing and valuing health with single-sided deafness	1.0	21/10/2014	14
14/SW/1065/AM02	Describing and valuing health with single-sided deafness	2	10/02/2015	13
14/SW/1141/AM01	1289.5 BI409306 compared to placebo in Alzheimer's Disease	UK Protocol Amendment 1	12/02/2015	8
14/SW/1160/AM02	Life after Weight Loss Surgery	1	27/02/2015	25
14/SW/1164/AM01	MEDI4736 in Recurrent or Metastatic PD-L1 Positive SCCHN	Protocol Amendment 2 dated 24	13/02/2015	12
BA74/00-01/AM08	Prognostic Markers of outcome in Psoriatic Arthritis	10	21/08/2014	28

Unfavourable opinion

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
11/SW/0009/AM02	Maternal Filicide: An Exploration from the Perspective of Mothers. V1	2	13/06/2014	16
14/SW/1127/AM01	A Mediterranean diet score validation in people at cardiovascular risk	1	10/02/2015	15

Table 10.2: Breakdown of current status of all modified amendments reviewed within the reporting period

Favourable opinion timeline

Amendment REC	Title	Version	Date	Number of Days on
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Reference				Clock
09/H0102/64/AM12/1	DUTY: The Diagnosis of UTI in Young Children Study. v 1.0	Amendment 12, 26th February 20	26/02/2014	9
14/SW/1127/AM01/1	A Mediterranean diet score validation in people at cardiovascular risk	2	27/02/2015	1

Unfavourable opinion timeline

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
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Table 11: Items exceeding timelines**Full applications for ethical review over 60 day timeline**

REC Reference	Title	Number of Days on Clock
14/SW/1144	ARENA study	65

Proportionate review applications for ethical review over 14 day timeline

REC Reference	Title	Number of Days on Clock
14/SW/0100	Innate immunity & predisposition to infection & allergy in children	24
15/SW/0070	Understanding health promotion for people with Down syndrome: version 1	18
15/SW/0071	Corneal ulcer pressure study	27
15/SW/0073	Masculine Identity After Traumatic Brain Injury	19

SSAs (non Phase 1) over 25 day timeline

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

REC Reference	Title	Number of Days on Clock
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Substantial Amendments over 35 day timeline

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
08/H0102/12/AM07	Structural and Functional imaging in epilepsy	4	05/07/2014	42
13/SW/0300/AM01	CoolXenon3	2.0	15/04/2014	36
13/SW/0311/AM01	Change in dentine occlusion after use of an occluding toothpaste	1.0	05/08/2014	39
14/SW/0091/AM02	A Phase 3 Veliparib plus Chemotherapy Study in Adv/Met squamous NSCLC	Substantial Amendment 2	10/07/2014	39

Modified Amendments over 14 day timeline

Amendment REC	Title	Version	Date	Number of Days on
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Reference				Clock
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