

**South West - Central Bristol Research Ethics
Committee**

Annual Report

01 April 2016 - 31 March 2017



Part 1 – Committee Membership and Training

Name of REC:	South West - Central Bristol Research Ethics Committee
Type of REC:	Type III (CTIMP)
Type of Flag:	Research Databases Research Tissue Banks IRB registered
Chair:	Dr Pamela Cairns (upto 28/7/2016) Dr Julie Woodley (from 29/07/2016)
Vice-Chair:	Vacant (upto 31/05/2016) Mr Brian Pixton (from 01/06/2016)
Alternate Vice-Chair:	Mr Brian Pixton (upto 01/06/2016) Vacant (01/06/2016 to 01/02/2017) Dr Margaret Saunders (from 01/02/2017)
REC Manager:	Mrs Naazneen Nathoo
REC Assistant:	Miss Frances Race (to 13/01/2017) Vacant (14/01/2017 to 31/03/2017)
Committee Address:	Whitefriars Level 3, Block B Lewin's Mead Bristol BS1 2NT Email: nrescommittee.southwest-bristol@nhs.net
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Chair's overview of the past year:

Dr Julie Woodley took over as Chair from 29 July 2016 as the then Chair wished to step down slightly earlier than the previously envisaged December date that would have been the end of Dr Pamela Cairns' term of office.

Mr Brian Pixton was promoted to Vice Chair; and Dr Margaret Saunders was appointed as Alternate Vice Chair on 01 February 2017. During the reporting period, three members stepped down; one new member was appointed.

Ms Fran Race (REC Assistant) left the HRA mid-January 2017 and the REC Manager has been working almost single-handedly since then. The workload for this committee is steadily increasing and all the committee suggested the REC manager is afforded some more support in the very near future.

A training day on Genomics & Genetics was held for members on 24 February 2017. Members from neighbouring RECs were invited, resulting in a very good turnout. The committee found this presentation very informative and thought provoking.

I am pleased with the Committee's performance with regard to the opinions it has given for full reviews: just under half were favourable or favourable with conditions; the rest being given a provisional opinion. The level of debate is very friendly and inclusive and good use is made of the expertise of all committee members.

The Committee continues to be busy – we have a fairly steady flow of challenging reviews at full committee and PRSC. Sub-Committee business is also steady with a continued increase in substantial reviews that require attention.

South West - Central Bristol Research Ethics Committee Membership

Name	Profession	Expert or Lay	Dates	
			Appointed	Left
Dr Kay Barnard	Ex-research scientist	Lay	01/04/2012	31/03/2017
Dr Robert Beetham	Retired Consultant Clinical Biochemist	Lay	01/02/2014	
Ms Susan Bradford	Solicitor	Lay Plus	18/02/2016	
Dr Pamela Cairns	Consultant Neonatologist	Expert	01/12/2006	28/07/2016
Dr Elizabeth Coates	Research Governance Coordinator	Lay	01/09/2016	
Dr Ian Davies	Consultant in Cardiac Anaesthesia & Intensive Care	Expert	01/05/2011	
Mr Richard Gibson	Administrator	Lay Plus	01/02/2016	
Mr Alexander Howard	Humanist Funeral Celebrant	Lay Plus	08/08/2014	
Dr Adrian Kendrick	Consultant Clinical Scientist	Expert	20/01/2013	
Mr Paul Lewis	Patient Experience Lead (Surveys and Evaluation)	Lay Plus	01/05/2011	30/04/2016
Ms Sally Morgan-Fletcher	Clinical Scientist	Expert	01/05/2015	
Mr Brian Pixton	Retired solicitor	Lay Plus	11/03/2013	
Dr Colette Reid	Consultant in Palliative Medicine	Expert	01/08/2013	
Dr Margaret Saunders	Consultant Clinical Scientist	Expert	01/05/2015	
Mr Adam Turner	Pharmacist	Expert	01/03/2016	27/10/2016
Dr Julie Woodley	Senior Lecturer/ Chair of Faculty Ethics Committee	Expert	08/08/2014	

South West - Central Bristol Research Ethics Committee: Deputy Members

Name	Profession	Status	Meeting date attended

South West - Central Bristol Research Ethics Committee: Co-opted Members

Name	Profession	Status	Meeting date attended

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

Name	Declaration of Interest	Date
Dr Kay Barnard	Trustee for Burden Neurological Institute, Bristol	01/02/2017
Dr Robert Beetham	Shareholding in Smith & Nephew plc.	31/03/2017
Ms Susan Bradford	None	01/02/2017
Dr Elizabeth Coates	None	14/09/2016
Dr Ian Davies	None	01/02/2017
Mr Richard Gibson	None	01/02/2017
Mr Alexander Howard	None	01/02/2017
Dr Adrian Kendrick	X2 Non-disclosure agreements, one with Industry and one with London Law Firm PhD student co-funded by Airbus Innovate Industries. External Grant Application Reviewer for British Lung Foundation; NIHR; Wellcome. University of West of England: Year 3 project supervisor in Clinical Physiology; PhD Student (Airbus Innovate)	31/03/2017
Ms Sally Morgan-Fletcher	None	01/02/2017
Mr Brian Pixton	None	01/02/2017
Dr Colette Reid	None	01/02/2017
Dr Margaret Saunders	R&D Lead for Division of Diagnostics & Therapies (D&T), UH Bristol NHS FT	01/02/2017
Dr Julie Woodley	Chair of their faculty ethics committee and at present acting chair of the university committee	03/02/2017

Meetings for Full Ethical Review 01 April 2016 - 31 March 2017:

Month	Date	Number of Members Present at Meeting
April	29/04/2016	11
May	27/05/2016	10
July	29/07/2016	8
August	26/08/2016	10
September	30/09/2016	10
October	28/10/2016	10
November	25/11/2016	11
January	27/01/2017	11
March	31/03/2017	9

9 full committee meetings were held during the reporting period.

Proportionate Review Sub-Committee Meetings held during 01 April 2016 - 31 March 2017:

Month	Date	Number of Members Present at Meeting
April	18/04/2016	3
May	23/05/2016	3
July	25/07/2016	3
August	22/08/2016	3
October	24/10/2016	3
November	21/11/2016	3
February	20/02/2017	3
March	23/03/2017	3

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

Sub-Committee Meetings held during 01 April 2016 - 31 March 2017:

Month	Date	Number of Members Present at Meeting
April	11/04/2016	2
April	12/04/2016	2
April	25/04/2016	2
May	09/05/2016	2
May	24/05/2016	2
May	24/05/2016	2
June	20/06/2016	3
June	21/06/2016	2
July	04/07/2016	2
July	18/07/2016	2
July	27/07/2016	2
July	29/07/2016	2
August	15/08/2016	2
August	26/08/2016	2

September	09/09/2016	2
September	19/09/2016	2
October	08/10/2016	2
October	23/10/2016	2
October	31/10/2016	2
November	06/11/2016	2
November	22/11/2016	2
December	02/12/2016	2
December	18/12/2016	2
December	21/12/2016	2
January	04/01/2017	2
January	13/01/2017	2
January	16/01/2017	2
February	24/02/2017	2
March	10/03/2017	2
March	24/03/2017	2

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

Details of inquorate meeting held:01 April 2016 - 31 March 2017

None

Attendance of Members at full committee meetings:01 April 2016 - 31 March 2017

Name	Number of Meetings Attended
Dr Kay Barnard	7
Dr Robert Beetham	9
Ms Susan Bradford	7
Dr Pamela Cairns	1
Dr Elizabeth Coates	3
Dr Ian Davies	5
Mr Richard Gibson	6
Mr Alexander Howard	8
Dr Adrian Kendrick	5
Mr Paul Lewis	1
Ms Sally Morgan-Fletcher	7
Mr Brian Pixton	8
Dr Colette Reid	6
Dr Margaret Saunders	7
Mr Adam Turner	2
Dr Julie Woodley	8

Attendance of Members at proportionate review sub-committee meetings: 01 April 2016 - 31 March 2017

Name	Number of Meetings Attended
Dr Kay Barnard	1
Dr Robert Beetham	3
Ms Susan Bradford	2
Dr Pamela Cairns	1
Mr Alexander Howard	3
Dr Adrian Kendrick	2
Mr Brian Pixton	3
Dr Colette Reid	2
Dr Margaret Saunders	4
Dr Julie Woodley	3

Attendance of Members at sub-committee meetings: 01 April 2016 - 31 March 2017

Name	Number of Meetings Attended
Dr Kay Barnard	1
Dr Robert Beetham	11
Ms Susan Bradford	3
Dr Pamela Cairns	2

Mr Alexander Howard	2
Dr Adrian Kendrick	2
Ms Sally Morgan-Fletcher	3
Mr Brian Pixton	19
Dr Colette Reid	3
Dr Margaret Saunders	2
Dr Julie Woodley	12

Training 01 April 2016 - 31 March 2017

Name of Member	Date	Event(s) attended
Dr Kay Barnard	16/02/2017	National Members Training Day
Dr Kay Barnard	24/02/2017	Genetics & Genomics
Dr Robert Beetham	14/10/2016	Genetic and Genomic Research
Ms Susan Bradford	14/09/2016	Handling Health-Related Findings in Research (Joint MRC/HRA)
Ms Susan Bradford	30/11/2016	Members induction
Ms Susan Bradford	24/02/2017	Genetics & Genomics
Dr Elizabeth Coates	11/05/2016	Assessing the Consequences (benefits & harms) of research
Dr Elizabeth Coates	24/02/2017	Genetics & Genomics
Dr Ian Davies	24/02/2017	Genetics and Genomics
Mr Richard Gibson	26/10/2016	Qualitative Research and Ethical Review
Mr Richard Gibson	06/12/2016	Committee Member Induction
Mr Alexander Howard	29/09/2016	Handling health-related findings in research
Dr Adrian Kendrick	24/02/2017	Genetics & Genomics
Ms Sally Morgan-Fletcher	26/10/2016	Qualitative Research and Ethical Review
Ms Sally Morgan-Fletcher	24/02/2017	Genetics & Genomics
Mr Brian Pixton	19/05/2016	NREAP / REC Chairs' Network Meeting
Mr Brian Pixton	24/02/2017	Genomics and Genetics
Dr Colette Reid	24/02/2017	Genetics & Genomics
Dr Margaret Saunders	24/02/2017	Genetics and Genomics
Dr Julie Woodley	14/09/2016	Handling Health-Related Findings in Research (Joint MRC/HRA)
Dr Julie Woodley	09/11/2016	Training for new chairs
Dr Julie Woodley	01/12/2016	National Training Day for Committee Chairs
Dr Julie Woodley	27/03/2017	Chairs Review Programme Workshop

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	13	25.49
Phase 1	0	0.00
Gene Therapy	0	0.00
Research Tissue Bank (including renewals)	2	3.92
Research Database (including renewals)	1	1.96
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	0
Number of applications withdrawn prior to the meeting	0
Number of student applications reviewed	14
Number of paediatric applications reviewed	10
Number of device applications reviewed	2
Number of prisoner applications reviewed	1
Number of applications involving adults unable consent reviewed	0
Number of applications reviewed that are funded by the US DHHS	2
Number of qualitative applications reviewed	6

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	7	13.73
Favourable Opinion with Additional Conditions	16	31.37
Unfavourable Opinion	0	0.00
Provisional Opinion	28	54.90
Provisional Opinion Pending Consultation with Referee	0	0.00
Total	51	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	22	43.14
Further Information Favourable Opinion with Additional Conditions	3	5.88
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	7	13.73
Favourable Opinion with Additional Conditions	16	31.37
Unfavourable Opinion	0	0.00
Provisional Opinion	2	3.92
Provisional Opinion Pending Consultation with Referee	0	0.00
Further Information response not complete	0	0.00
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	22
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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	2
Number of studies withdrawn prior to the meeting	0
Number of student applications reviewed	9
Number of paediatric applications reviewed	3
Number of device applications reviewed	1
Number of qualitative applications reviewed	3

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	5	22.73
Favourable Opinion with Additional Conditions	2	9.09
No Opinion transfer to full committee for review	0	0.00
Provisional Opinion	15	68.18
Unfavourable Opinion	0	0.00
Total	22	100

Table 8: Other Management Information based on the number of completed applications for the reporting period:

Average number of applications reviewed per full meeting	5.67
Number of completed applications for full ethical review	50
Number of completed applications for full ethical review over 60 days	0
Number of completed applications over 60 days as a % of total	0.00%
Number of completed applications for full ethical review over 40 days	5
Number of completed applications over 40 days as a % of total	9.80%
Number of days taken to final decision – average (mean)	30
Number of completed proportionate review applications for ethical review	21
Number of completed proportionate review applications for ethical review over 14 days [please note, the timeline for the review of PR was extended from 14 to 21 calendar days in December 2016]	7
Number of completed proportionate review applications for ethical review over 21 days	1
Number of completed proportionate review applications over 14 days as a % of total	33.33%
Number of SSAs (non-Phase 1) reviewed	11
Number of completed applications for SSA review over 25 days	4
Number of completed applications for SSA review over 25 days as % of all non- Phase 1 SSAs	36.36%
Number of SSAs (Phase 1) reviewed	0
Number of completed applications for SSA review over 14 days	0
Number of completed applications for SSA review over 14 days as % of all Phase 1 SSAs	0.00%
Number of substantial amendments reviewed	106
Number of completed substantial amendments over 35 days	4
Number of completed substantial amendments over 35 days as a % of total substantial amendments	3.77%
Number of completed substantial amendments over 28 days	23
Number of completed substantial amendments over 28 days as a % of total substantial amendments	21.70%
Number of modified amendments reviewed	4
Number of completed modified amendments over 14 days	0
Number of completed modified amendments over 14 days as a % of total modified amendments	0.00%
Number of non substantial amendments received	77

Number of substantial amendments received for information	1
Number of substantial amendments received for new sites/PIs	22
Number of annual progress reports received	30
Number of safety reports received	12
Number of Serious Adverse Events received	0
Number of final reports received	6

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
16/SW/0090	Ustekinumab in Subjects with Radiographic Axial Spondyloarthritis	45
16/SW/0120	EKOS and r-tPA thrombolysis in Pulmonary Embolism (OPTALYSE STUDY)	40
16/SW/0126	Prevalence of PTSD in psychosis and at-risk mental states	39
16/SW/0154	STAR trial	36
16/SW/0186	Peacock - A Paediatric Cortisol Study	32
16/SW/0201	CENTERA	35
16/SW/0232	R-RID - Rifaximin to Reduce Infection in Decompensated Cirrhosis	37
16/SW/0252	Non-invasive diagnosis of laryngeal closure	30
16/SW/0255	Low-intensity intervention for people with personality disorder	37
16/SW/0260	Training in the Fasted State, Glucose Metabolism and Energy Balance	37
16/SW/0267	Optic Nerves in Children born Early (ONCE) Study	33
16/SW/0273	Bristol Imperial MDMA in Alcoholism Study (BIMA)	31
16/SW/0297	Implementation of Mental Practice after Stroke: a novel method	36
16/SW/0301	F1RST - evaluation of early initiation of secukinumab	30
16/SW/0311	Online grammatical reasoning training for older adults (START)	25
16/SW/0316	TN10 Anti-CD3 Prevention v UK1	47
16/SW/0327	PPK Clinical Outcomes Study, v1	26
16/SW/0328	DECODE (V1)	29
16/SW/0329	TOLERANCE AND ACCEPTABILITY EVALUATION OF AYMES 'SOFIA'	17
16/SW/0331	Natural adaptive immunity to high risk human papillomavirus (HR HPV)	34
17/SW/0011	Bruton's Tyrosine Kinase Inhibitor, Treatment for Follicular Lymphoma	30
17/SW/0072	PTSD Symptoms and Support for Young People Following Acute Trauma 1	27

Further Information Favourable Opinion with Additional Conditions		
REC Reference	Title	Number of Days on Clock
16/SW/0093	Deep Brain Stimulation for Hypertension VERSION 2	50
16/SW/0247	The effects of a 5-day meditation intervention in prison population	26
17/SW/0021	HIV treatment interruption following Stem cell transplantation	41

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
16/SW/0083	THRIVE Robot Investment Game Experiments	49
16/SW/0115	The LiBRA (Loss of implant breast reconstruction evaluation) study.	26
16/SW/0160	CHALLENGE-UK: A UK cohort of the CHALLENGE trial	26
16/SW/0219	Bloodwise Childhood Leukaemia Cellbank ethics renewal	24
16/SW/0244	Novel Glyco-tools to Study Human Milk Oligosaccharides - V3	24
17/SW/0019	ASSESS-meso	21
17/SW/0071	To investigate the protective effect of toothpaste on tooth enamel	24

Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
16/SW/0105	Evaluate - A Pancreas MRI Study	39
16/SW/0155	Kidney transplantation and myocardial mechanics in children	26
16/SW/0165	Exploring ways to support parents to look after their babies' teeth v1	27
16/SW/0166	Social Return On Investment of Orthognathic Surgery	27
16/SW/0187	Helpful therapy events: IPA of psychotherapy with clients with LD v1.0	18
16/SW/0194	The UK Multiple Sclerosis Register	18
16/SW/0202	A Clinical Trial in subjects with active Ankylosing Spondylitis	18
16/SW/0205	DopaCon	18
16/SW/0245	Quality of life and support needs in families with cleft lip/palate	14
16/SW/0250	The role of immune cells in Microbial Keratitis, Version 1.0	25
16/SW/0270	PET Scanning to Predict Response to Chemotherapy in Head and Cancer	24
16/SW/0290	An evaluation of the BHF's exercise DVD in cardiac rehabilitation	24
17/SW/0010	Novel use of TXA to reduce the need for nasal packing in epistaxis	21
17/SW/0020	The cancer therapy experience study. Version one.	21
17/SW/0077	PV versus ESR in diagnosis of prosthetic joint infection after TKR V1	35
17/SW/0080	TILT	24

Unfavourable Opinion		
REC Reference	Title	Number of Days on Clock

Provisional Opinion		
REC Reference	Title	Number of Days on Clock
17/SW/0073	Liver Unit Tissue Bank Registry	n/a
17/SW/0078	CheckMate 915	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

Withdrawn after the meeting		
REC Reference	Title	Number of Days on Clock
16/SW/0271	TN20 Immune Effects of Oral Insulin	24

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
16/SW/0158	NN9068-4264 Retrospective study_Xultophy in Adult T2 Diabetes	12
16/SW/0159	Exploring the experiences of CDSMP tutors v1	14
16/SW/0161	TUDOR V1.0	10
16/SW/0257	Understanding disease progression in PKD	13
16/SW/0258	Subjective vs objective outcomes following flexor tendon repair	18
16/SW/0332	DIAPASS: Ayendi Observational Study	5
16/SW/0333	Sensory attenuation in functional movement disorders	10

16/SW/0334	Ocular Surface Disease in Glaucoma Patients VERSION 1.0	16
17/SW/0046	Introducing Cardiovascular Wellness Software in Optometry practice1	13
17/SW/0047	Pubertal Induction V1.0	19

Further Information Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
16/SW/0251	Superior capsule reconstruction using graft jacket- a case series	15
16/SW/0253	Study of Fat Processing Systems and Autologous Fat Transfer.	11
16/SW/0303	Qualitative interviews with patients who have hTTP	14
16/SW/0304	GI symptoms in connective tissue disease & collagen vascular disorders	10

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
16/SW/0112	BAP1 and Histone Deacetylase Expression in Uveal Melanoma V1	18
16/SW/0220	Improving Caries and Toothwear 1	10
16/SW/0221	Terahertz-frequency imaging system for skin diagnostics	7
16/SW/0226	Clearing Haemoglobin In Superficial Siderosis (CHISS)	6
16/SW/0228	Reliability and Feasibility of using a Hand Held Dynamometer in HTLV	5

Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
16/SW/0107	Personality Profiles	22
17/SW/0048	FLEX-HD	17

Unfavourable Opinion

REC Reference	Title	Number of Days on Clock
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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
16/SW/0122	Exertional Heat Stroke in London Marathon Runners: inherited disorder?	12

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/Q2006/102/AM12	Natural History Study of the development of Type 1 Diabetes - May 2004	15.0	24/02/2016	30
06/Q2001/197/AM05	Vascular progenitor cells in human vessels	5	17/12/2015	31
06/Q2001/197/AM06	Vascular progenitor cells in human vessels	Amendment 6	23/11/2016	47
06/Q2002/80/AM07	TRIOs	7	16/05/2016	24
08/H0106/28+5/AM02	South West Dementia Brain Bank	1	20/12/2016	31
09/H0102/64/AM16	DUTY: The Diagnosis of UTI in Young Children Study. v 1.0	15	29/04/2016	36
09/H0106/19+5/AM05	(duplicate) SPLDv3	2	16/05/2016	15
09/H0106/19+5/AM06	(duplicate) SPLDv3	3	12/04/2016	15
09/H0106/80/AM06	National Study of Steroid Resistant Nephrotic Syndrome in Childhood	4	12/12/2016	3
09/H0106/80/AM07	National Study of Steroid Resistant Nephrotic Syndrome in Childhood	Substantial Amendment 5,	14/02/2017	31
11/SW/0036/AM28	TABLET	24	03/06/2016	13
11/SW/0036/AM29	TABLET	25	13/04/2016	14
11/SW/0345/AM02	Bristol Bladder Trial	2	04/03/2016	25
12/SW/0055/AM08	COCO90s Version 1.0	8	18/04/2016	28
12/SW/0055/AM09	COCO90s Version 1.0	9	05/10/2016	16
12/SW/0055/AM10	COCO90s Version 1.0	10	01/11/2016	17
12/SW/0084/AM09	Study of Intravitreal LFG316 in patients with multifocal choroiditis	11	13/12/2016	30
13/SW/0064/AM05	The Cleft Collective Cohort Studies - v1	5	20/04/2016	28
13/SW/0064/AM06	The Cleft Collective Cohort Studies - v1	6	31/05/2016	23
13/SW/0096/AM01	The Bath Spondyloarthritis (SpA) Biobank	1	25/07/2016	37
13/SW/0159/AM06	NN304-4016 Diabetes Pregnancy Registry	4	01/08/2016	21
13/SW/0163/AM01	The Veteran Athlete's Heart (Version 2)	1	20/01/2017	13
13/SW/0199/AM05	EVRA (Early Venous Reflux Ablation) Ulcer trial Version 1.0	5	16/03/2016	27
13/SW/0247/AM04	Buparlisib or placebo, plus paclitaxel, in head and neck carcinoma	Changes to IB version 8 & 9	08/08/2016	20
13/SW/0247/AM06	Buparlisib or placebo, plus paclitaxel, in head and neck carcinoma	3	30/08/2016	25

13/SW/0300/AM06	CoolXenon3	5	16/08/2016	27
13/SW/0300/AM07	CoolXenon3	2.2	22/09/2016	9
14/SW/0030/AM04	Feeding and Autoimmunity in Down's syndrome Evaluation Study (FADES)	5	04/08/2016	29
14/SW/0033/AM02	V1: Development of a PRO Measure in Haematological Practice	2	29/06/2016	18
14/SW/0075/AM05	REDUCE Trial	4	25/05/2016	31
14/SW/0112/AM04	The Bristol Archive Project	3	02/02/2016	37
14/SW/1061/AM04	TrialNet TN18 Abatacept Prevention	3	12/04/2016	31
14/SW/1061/AM05	TrialNet TN18 Abatacept Prevention	4	12/08/2016	16
14/SW/1084/AM01	Newborn Hearing Screening and the risk of SIDS	1	22/03/2016	33
14/SW/1084/AM03	Newborn Hearing Screening and the risk of SIDS	2	10/01/2017	14
14/SW/1085/AM06	Placebo controlled Radium-223, plus exemestane and everolimus in mBC	4	26/04/2016	30
14/SW/1085/AM07	Placebo controlled Radium-223, plus exemestane and everolimus in mBC	5	13/05/2016	10
14/SW/1085/AM08	Placebo controlled Radium-223, plus exemestane and everolimus in mBC	6	05/07/2016	20
14/SW/1088/AM01	National Registry for Rare Kidney Diseases (RaDaR)	1	20/05/2016	24
14/SW/1108/AM05	Equivalence in analgesic efficacy & bowel function taking OXN tablets.	3.0	06/04/2016	21
14/SW/1148/AM01	University of Birmingham Dentistry Research Tissue Bank	1	27/01/2016	27
14/SW/1164/AM12	MEDI4736 in Recurrent or Metastatic PD-L1 Positive SCCHN	9	19/12/2016	23
15/SW/0084/AM01	PUMA-Paediatric early warning systems: Utility and Mortality Avoidance	1	24/03/2016	28
15/SW/0084/AM02	PUMA-Paediatric early warning systems: Utility and Mortality Avoidance	2	12/08/2016	11
15/SW/0086/AM07	Daratumumab + rd vs rd in subjects with previously untreated MM	Substantial amendmen 04	04/07/2016	21
15/SW/0086/AM08	Daratumumab + rd vs rd in subjects with previously untreated MM	N/A	20/10/2016	15
15/SW/0086/AM09	Daratumumab + rd vs rd in subjects with previously untreated MM	Protocol amendment INT-3/UK-1,	23/02/2017	27
15/SW/0144/AM02	Energy Expenditure Study Version 1.0	2	19/05/2016	23

15/SW/0194/AM06	Phase III study with Finerenone in Type II Diabetes and DKD, Renal	6	08/04/2016	28
15/SW/0194/AM07	Phase III study with Finerenone in Type II Diabetes and DKD, Renal	7	12/05/2016	31
15/SW/0194/AM11	Phase III study with Finerenone in Type II Diabetes and DKD, Renal	8	21/09/2016	20
15/SW/0194/AM13	Phase III study with Finerenone in Type II Diabetes and DKD, Renal	9	11/11/2016	26
15/SW/0196/AM02	GO29431 Phase III Study of MPDL3280A in Stage IV Non-Squamous NSCLC	5	29/06/2016	21
15/SW/0196/AM04	GO29431 Phase III Study of MPDL3280A in Stage IV Non-Squamous NSCLC	9	07/12/2016	3
15/SW/0197/AM03	GO29432 Phase III Study of MPDL3280A in Stage IV Squamous NSCLC	5	19/10/2016	35
15/SW/0220/AM02	Ustekinumab in Subjects With Nonradiographic Axial Spondyloarthritis	Amendment 2	24/06/2016	26
15/SW/0242/AM02	The cold-shock response induced by cold water swimming	2	08/08/2016	17
15/SW/0248/AM05	VX14-661-110 Cystic Fibrosis	4	14/07/2016	9
15/SW/0248/AM07	VX14-661-110 Cystic Fibrosis	SA5_IB (VX-661) v8.0, ICF, Pat	13/01/2017	16
15/SW/0268/AM02	Collection of Bone Marrow during Orthopaedic Surgery	2.0	02/08/2016	13
15/SW/0274/AM05	TITAN, Protocol 56021927PCR3002	Protocol Amendment 1	06/05/2016	34
15/SW/0274/AM06	TITAN, Protocol 56021927PCR3002	6	18/07/2016	7
15/SW/0274/AM09	TITAN, Protocol 56021927PCR3002	8	15/09/2016	26
15/SW/0274/AM12	TITAN, Protocol 56021927PCR3002	9	17/02/2017	24
15/SW/0275/AM01	Inflammatory Dendritic Cells in Arthritis	Substantial Amendment #2 09/02	09/02/2017	12
15/SW/0289/AM01	RHINO: Respiratory Health Outcomes in Neonates	1	01/07/2016	16
15/SW/0289/AM02	RHINO: Respiratory Health Outcomes in Neonates	2	21/09/2016	19
15/SW/0289/AM03	RHINO: Respiratory Health Outcomes in Neonates	3	06/12/2016	9
15/SW/0300/AM02	ARTIC PC	1	29/07/2016	23
15/SW/0300/AM04	ARTIC PC	2	03/10/2016	15
15/SW/0300/AM06	ARTIC PC	3	15/11/2016	10
15/SW/0300/AM08	ARTIC PC	5	02/03/2017	21

15/SW/0306/AM01	Online brain training intervention for over 50s	1	09/08/2016	28
15/SW/0312/AM02	KARE: Ketamine for reduction of Alcoholic Relapse Version 1	2	14/03/2016	20
15/SW/0312/AM04	KARE: Ketamine for reduction of Alcoholic Relapse Version 1	3	23/09/2016	26
15/SW/0326/AM04	ATLAS: JNJ56021927 (ARN509)	4	09/07/2016	26
15/SW/0326/AM06	ATLAS: JNJ56021927 (ARN509)	5	20/02/2017	20
15/SW/0328/AM01	The Treatment of Progressive Early Onset Spinal Deformities	1	08/03/2016	31
15/SW/0328/AM02	The Treatment of Progressive Early Onset Spinal Deformities	2	22/06/2016	28
15/SW/0328/AM03	The Treatment of Progressive Early Onset Spinal Deformities	3	06/10/2016	28
15/SW/0333/AM02	Sentinel Skin Flaps in Pancreas Transplantation	2	04/05/2016	17
16/SW/0013/AM02	Video Laryngoscopy in Newborn Babies V1	4	15/11/2016	13
16/SW/0020/AM01	MAPPING NEURODEVELOPMENTAL TRAJECTORIES FOR ADULT PSYCHIATRIC DISORDER	1	03/06/2016	10
16/SW/0028/AM01	DOPAMIND	SubAm1REC	27/06/2016	21
16/SW/0044/AM01	ENTO in Chronic Graft Versus Host Disease	1	20/04/2016	22
16/SW/0044/AM02	ENTO in Chronic Graft Versus Host Disease	amendment 2	28/06/2016	16
16/SW/0044/AM04	ENTO in Chronic Graft Versus Host Disease	3	29/09/2016	15
16/SW/0044/AM05	ENTO in Chronic Graft Versus Host Disease	SA#4	22/02/2017	19
16/SW/0090/AM02	Ustekinumab in Subjects with Radiographic Axial Spondyloarthritis	1	17/08/2016	26
16/SW/0090/AM03	Ustekinumab in Subjects with Radiographic Axial Spondyloarthritis	2	07/12/2016	27
16/SW/0120/AM01	EKOS and r-tPA thrombolysis in Pulmonary Embolism (OPTALYSE STUDY)	1	07/07/2016	13
16/SW/0120/AM03	EKOS and r-tPA thrombolysis in Pulmonary Embolism (OPTALYSE STUDY)	5	21/11/2016	12
16/SW/0126/AM01	Prevalence of PTSD in psychosis and at-risk mental states	1	13/06/2016	8
16/SW/0126/AM02	Prevalence of PTSD in psychosis and at-risk mental states	2	12/10/2016	7
16/SW/0154/AM01	STAR trial	1	06/07/2016	7
16/SW/0160/AM01	CHALLENGE-UK: A UK cohort of the CHALLENGE trial	1	25/10/2016	9
16/SW/0165/AM01	Exploring ways to support parents to look after their babies' teeth v1	1	15/06/2016	20

16/SW/0165/AM02	Exploring ways to support parents to look after their babies' teeth v1	2	24/01/2017	14
16/SW/0186/AM01	Peacock - A Paediatric Cortisol Study	1	01/02/2017	10
16/SW/0201/AM01	CENTERA	1	23/01/2017	23
16/SW/0205/AM01	DopaCon	1	17/01/2017	28
16/SW/0255/AM01	Low-intensity intervention for people with personality disorder	1	28/11/2016	35

Unfavourable opinion

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
05/Q2001/78/AM21	Molecular genetics of high bone mineral density	20	31/03/2016	29
15/SW/0330/AM01	Gender differences in ASD; communication and language skills	1.0	30/08/2016	35
16/SW/0005/AM01	HOPE: Help for people with money, employment and benefit problems	1	26/04/2016	31
16/SW/0202/AM02	A Clinical Trial in subjects with active Ankylosing Spondylitis	1	27/10/2016	35

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

Favourable opinion timeline

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
05/Q2001/78/AM21/1	Molecular genetics of high bone mineral density	20	01/08/2016	8
15/SW/0330/AM01/2	Gender differences in ASD; communication and language skills	1	16/09/2016	9
16/SW/0005/AM01/1	HOPE: Help for people with money, employment and benefit problems	1	26/04/2016	8
16/SW/0202/AM02/1	A Clinical Trial in subjects with active Ankylosing Spondylitis	3	14/12/2016	5

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
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Proportionate review applications for ethical review over 21 day timeline

REC Reference	Title	Number of Days on Clock
16/SW/0107	Personality Profiles	22

SSAs (non Phase 1) over 25 day timeline

REC Reference	Title	Number of Days on Clock
16/SW/0310	An evaluation of the British Heart Foundation's 'Active Heart, Healthy Heart' DVD as an adjunct to standard, centre-based cardiac rehabilitation.	29
16/SW/0322	An evaluation of the British Heart Foundation's 'Active Heart, Healthy Heart' DVD as an adjunct to standard, centre-based cardiac rehabilitation.	27
16/SW/0324	An evaluation of the British Heart Foundation's 'Active Heart, Healthy Heart' DVD as an adjunct to standard, centre-based cardiac rehabilitation.	29
17/SW/0066	Persona Partial Knee Clinical	26

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
06/Q2001/197/AM06	Vascular progenitor cells in human vessels	Amendment 6	23/11/2016	47
09/H0102/64/AM16	DUTY: The Diagnosis of UTI in Young Children Study. v 1.0	15	29/04/2016	36
13/SW/0096/AM01	The Bath Spondyloarthritis (SpA) Biobank	1	25/07/2016	37

14/SW/0112/AM04	The Bristol Archive Project	3	02/02/2016	37
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Modified Amendments over 14 day timeline				
Amendment REC Reference	Title	Version	Date	Number of Days on Clock