

**South West - Frenchay Research Ethics
Committee**

Annual Report

01 April 2016 - 31 March 2017



Part 1 – Committee Membership and Training

Name of REC:	South West - Frenchay Research Ethics Committee
Type of REC:	Authorised
Type of Flag:	None
Chair:	Mr Stephen Draper
Vice-Chair:	Miss Wendy Bertram
Alternate Vice-Chair:	Mr Paul Allen
REC Manager:	Miss Natasha Bridgeman
REC Assistant:	Miss Lidia Gonzalez
Committee Address:	Level 3, Block B Whitefriars Lewins Mead, Bristol BS1 2NT Email: nrescommittee.southwest-frenchay@nhs.net
Telephone:	020 7104 8041
Email:	nrescommittee.southwest-frenchay@nhs.net

Chair's overview of the past year:

The REC has welcomed several new members this year who are already making a strong contribution to its work. Other members have moved on and we thank them for their efforts in their time with us. However the Committee retains a core of very experienced members whose expertise and judgement is extremely valuable.

There appear to have been fewer projects for the Committee to review during the last twelve months and it is not clear why that would be so.

The Committee also feels that it would benefit from the return of its Mental Capacity flag having undergone training for that in the previous year.

The Committee had an excellent local REC Training day on Genetics and also took part in a trial video training session with Hugh Davies.

The Committee would like to thank their manager Natasha Bridgeman for her excellent help and support during the year as also her assistant Lidia Gonzalez.

South West - Frenchay Research Ethics Committee Membership

Name	Profession	Expert or Lay	Dates	
			Appointed	Left
Mr Paul Allen	Consultant Oral Surgeon	Expert	01/04/2011	
Mr Gordon Baxter	Safety Case Technical Leader	Lay Plus	01/02/2016	
Miss Wendy Bertram	Orthopaedic Research Fellow	Lay	15/10/2010	
Miss Laura Birch	Research Dietician	Expert	17/02/2014	
Dr Alison Diaper	Research Associate	Lay	21/06/2011	
Mr Stephen Draper	Retired Head teacher	Lay Plus	01/04/2011	
Mrs Jane Elias	Mediator/Professional Practice Consultant	Lay Plus	22/08/2016	
Dr Penny Kehagioglou	Consultant Clinical Oncologist	Expert	08/01/2015	29/09/2016
Mrs Kerstin Kubiak	Solicitor	Lay Plus	01/07/2008	
Dr Kristyn Manley	Research Fellow (O&G)	Expert	08/08/2014	
Dr James Morgan	Clinical Research Fellow	Expert	03/12/2015	30/11/2016
Dr Faye Noble	Emergency Care Physician	Expert	01/12/2015	
Mr Jeremy Ruddock	Osteopath	Expert	28/05/2013	
Mrs Judy Young	English Tutor	Lay Plus	02/09/2016	

South West - Frenchay Research Ethics Committee: Deputy Members

Name	Profession	Status	Meeting date attended
------	------------	--------	-----------------------

South West - Frenchay Research Ethics Committee: Co-opted Members

Name	Profession	Status	Meeting date attended
Dr Robert Beetham	Retired Consultant Clinical Biochemist	Lay	10/02/2017 and PRSC 10/02/2017
Miss Stephanie Ellis	Former Civil Servant	Lay Plus	08/04/2016
Mr Chris Foy	Medical Statistician	Expert	09/09/2016
Canon Ian Ainsworth-Smith	Retired Hospital Chaplain	Lay Plus	PR14/03/2017

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

Name	Declaration of Interest	Date
Mr Paul Allen	None	13/02/2017
Mr Gordon Baxter	Holds shares and in GE Healthcare.	13/02/2017
Mr Gordon Baxter	Employed by and holds shares and in GE Healthcare.	20/07/2016
Miss Wendy Bertram	Researcher and trial monitor at North Bristol Trust.	31/03/2017
Miss Laura Birch	None	31/03/2017
Dr Alison Diaper	None	13/02/2017
Mr Stephen Draper	None	13/02/2017
Mrs Jane Elias	None	31/03/2017
Mrs Kerstin Kubiak	None	31/03/2017
Dr Kristyn Manley	Research Fellow at St. Michael's Hospital (UHBristol)	31/03/2017
Dr Faye Noble	None	13/02/2017
Mr Jeremy Ruddock	Reviewer for "International Journal of Osteopathic Medicine"	31/03/2017
Mrs Judy Young	None	13/02/2017

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

Month	Date	Number of Members Present at Meeting
April	08/04/2016	7
May	13/05/2016	7
July	08/07/2016	10
September	09/09/2016	7
October	14/10/2016	8
November	11/11/2016	8
February	10/02/2017	7
March	10/03/2017	8

8 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	16/05/2016	3
June	13/06/2016	3
July	18/07/2016	3
August	15/08/2016	3
September	19/09/2016	3
November	14/11/2016	3
December	08/12/2016	3
January	16/01/2017	3
February	10/02/2017	7
February	14/02/2017	3
March	14/03/2017	3

12 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	06/04/2016	2
April	13/04/2016	2
April	27/04/2016	2
May	11/05/2016	2
May	25/05/2016	2
June	07/06/2016	2
June	21/06/2016	2
June	22/06/2016	2
July	06/07/2016	2
July	20/07/2016	2
July	25/07/2016	3

August	17/08/2016	2
September	01/09/2016	2
September	17/09/2016	3
October	05/10/2016	2
October	17/10/2016	2
October	19/10/2016	2
November	02/11/2016	2
November	17/11/2016	2
December	15/12/2016	2
January	04/01/2017	2
January	18/01/2017	2
January	31/01/2017	2
February	15/02/2017	2
February	28/02/2017	2
March	16/03/2017	3
March	30/03/2017	2

27 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
Mr Paul Allen	6
Mr Gordon Baxter	8
Miss Wendy Bertram	7
Miss Laura Birch	2
Dr Alison Diaper	7
Mr Stephen Draper	7
Mrs Jane Elias	4
Dr Penny Kehagioglou	2
Mrs Kerstin Kubiak	4
Dr James Morgan	5
Dr Faye Noble	5
Mr Jeremy Ruddock	4
Mrs Judy Young	5

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

Name	Number of Meetings Attended
Mr Paul Allen	6
Mr Gordon Baxter	5
Miss Wendy Bertram	3
Miss Laura Birch	4
Dr Alison Diaper	4
Mr Stephen Draper	5
Dr Penny Kehagioglou	2
Dr James Morgan	3
Dr Faye Noble	2
Mr Jeremy Ruddock	2
Mrs Judy Young	2

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

Name	Number of Meetings Attended
Mr Paul Allen	8
Mr Gordon Baxter	4
Miss Wendy Bertram	11
Miss Laura Birch	3
Dr Alison Diaper	8
Mr Stephen Draper	12

Dr Penny Kehagioglou	1
Dr Kristyn Manley	1
Dr James Morgan	1
Dr Faye Noble	3
Mr Jeremy Ruddock	4
Mrs Judy Young	1

Training 01 April 2016 - 31 March 2017

Name of Member	Date	Event(s) attended
Mr Paul Allen	24/02/2017	Local Training - Bristol REC
Mr Gordon Baxter	06/12/2016	Members Induction
Miss Wendy Bertram	19/05/2016	NREAP REC Chairs Network Meeting - South West
Miss Wendy Bertram	30/06/2016	Training for new REC chairs
Miss Wendy Bertram	14/09/2016	Training - Handling Health-Related Findings in Research (Joint MRC/HRA)
Miss Wendy Bertram	11/11/2016	Qualitative VC training - Hugh Davies
Dr Alison Diaper	24/02/2017	Local Training - Bristol REC
Mr Stephen Draper	19/05/2016	NREAP Chairs' Network Meeting South West
Mr Stephen Draper	11/11/2016	Qualitative VC training - Hugh Davies
Mr Stephen Draper	01/12/2016	National Training Day for Chairs
Mr Stephen Draper	24/02/2017	Local Training - Bristol REC
Mrs Jane Elias	01/12/2016	Members Induction
Mrs Jane Elias	16/02/2017	National Members Training Day
Mrs Kerstin Kubiak	24/02/2017	Local Training - Bristol REC
Mr Jeremy Ruddock	24/02/2017	Local Training - Bristol REC
Mrs Judy Young	10/11/2016	Qualitative training
Mrs Judy Young	01/12/2016	Members 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	0	0.00
Phase 1	0	0.00
Gene Therapy	0	0.00
Research Tissue Bank (including renewals)	0	0.00
Research Database (including renewals)	0	0.00
Others	34	100.00
Total Applications Reviewed	34	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	15
Number of paediatric applications reviewed	5
Number of device applications reviewed	0
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	0
Number of qualitative applications reviewed	8

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	2	5.88
Favourable Opinion with Additional Conditions	6	17.65
Unfavourable Opinion	5	14.71
Provisional Opinion	20	58.82
Provisional Opinion Pending Consultation with Referee	1	2.94
Total	34	100
Number of studies sent back to full committee meeting for final opinion	1	

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	18	52.94
Further Information Favourable Opinion with Additional Conditions	3	8.82
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	2	5.88
Favourable Opinion with Additional Conditions	6	17.65
Unfavourable Opinion	5	14.71
Provisional Opinion	0	0.00
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	0	0.00
Total	34	100

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

Total Applications Reviewed	29
------------------------------------	-----------

Table 6: Breakdown of PRS applications and other activity during reporting period:

Number of applications made invalid by the REC Manager	3
Number of studies withdrawn prior to the meeting	1
Number of student applications reviewed	10
Number of paediatric applications reviewed	1
Number of device applications reviewed	1
Number of qualitative applications reviewed	4

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	17.24
Favourable Opinion with Additional Conditions	2	6.90
No Opinion transfer to full committee for review	5	17.24
Provisional Opinion	14	48.28
Unfavourable Opinion	3	10.34
Total	29	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	3.78
Number of completed applications for full ethical review	34
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	8
Number of completed applications over 40 days as a % of total	23.53%
Number of days taken to final decision – average (mean)	34
Number of completed proportionate review applications for ethical review	24
Number of completed proportionate review applications for ethical review over 14 days (Please note, the timeline for the review of PR applications was extended from 14 to 21 calendar days in December 2016)	16
Number of completed proportionate review applications for ethical review over 21 days	4
Number of completed proportionate review applications over 14 days as a % of total	66.67%
Number of SSAs (non-Phase 1) reviewed	3
Number of completed applications for SSA review over 25 days	0
Number of completed 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 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	42
Number of completed substantial amendments over 35 days	8
Number of completed substantial amendments over 35 days as a % of total substantial amendments	19.05%
Number of completed substantial amendments over 28 days	11
Number of completed substantial amendments over 28 days as a % of total substantial amendments	26.19%
Number of modified amendments reviewed	4
Number of completed modified amendments over 14 days	1
Number of completed modified amendments over 14 days as a % of total modified amendments	25.00%
Number of non substantial amendments received	54

Number of substantial amendments received for information	0
Number of substantial amendments received for new sites/PIs	0
Number of annual progress reports received	6
Number of safety reports received	0
Number of Serious Adverse Events received	11
Number of final reports received	1

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/0099	The REJUVENATE Study v1	34
16/SW/0103	SSOD: Patient opinions and utilisation	60
16/SW/0136	Depression in Paediatric Chronic Fatigue Syndrome (CFS/ME)	39
16/SW/0138	Sleep Disordered Breathing and Arrhythmias	44
16/SW/0141	Experiences of CBT therapy in South Asian men with problem gambling	39
16/SW/0195	Longitudinal Study of Autonomic Function and Cancer	35
16/SW/0196	Childhood sexual abuse: Change and recovery	26
16/SW/0197	Oral Hygiene Study BL01	45
16/SW/0198	Neurodynamic Pilot Study	39
16/SW/0268	FITNET-NHS: How effective is FITNET-NHS for children and young adults	37
16/SW/0269	Study to evaluate prevalence of meningococcal carriage in teenagers	30
16/SW/0276	Crisis Response for Psychosis	27
16/SW/0277	Evaluation of retinal blood flow in primary open angle glaucoma	29
16/SW/0296	Increasing participation in self-harm research	42
16/SW/0300	Does 'Exercise Snacking' improve muscle function in older adults?	30
16/SW/0309	Exploring the Cognitions underlying OCD in Children with Autism	29
17/SW/0030	ICG Cell Imaging Study	44
17/SW/0033	Drug use in street sex workers (DUSK) study	36

Further Information Favourable Opinion with Additional Conditions		
REC Reference	Title	Number of Days on Clock
16/SW/0294	Shared decision making for cardiovascular conditions.	46
17/SW/0055	Sense of self and social identity in people with unusual experiences	27
17/SW/0059	CPET as a biomarker in FLD	41

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

Favourable Opinion with Standard Conditions

REC Reference	Title	Number of Days on Clock
16/SW/0109	The REFLECT Trial	25
16/SW/0142	Gastric Juice, Nitrite and C. Diff	32

Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
16/SW/0098	ROMIO: RCT of minimally invasive or open oesophagectomy	31
16/SW/0176	Dentine Hypersensitivity, could there be pulpal pathology?	28
17/SW/0025	Core outcomes for burn care research COSB version 1.0	28
17/SW/0058	Designing and Developing Integrated Therapist and Online CBT (Phase 1)	23
17/SW/0060	Singing for People with Aphasia (SPA) - version 1	24
17/SW/0061	Microbiota in Clostridium difficile infection	23

Unfavourable Opinion

REC Reference	Title	Number of Days on Clock
16/SW/0094	Longitudinal Study of Autonomic Function and Cancer	27
16/SW/0147	Utility of ACT self-help for PNES Final Version 1.0 date 01.04.16	42
16/SW/0185	Effect of negative mood on alcohol and heroin craving in prisoners	28
16/SW/0216	Post-void bladder scanning in acute cauda equina syndrome	23
17/SW/0062	Prelim	24

Provisional Opinion

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

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
---------------	-------	-------------------------

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/0116	Sebaceous activity in the aetiology of frontal fibrosing alopecia, 1	27
16/SW/0118	Men's experiences of their partner's breast cancer, version 1	27
16/SW/0144	IL-3 as an indicator of salicylate exacerbated chronic urticaria.	26
16/SW/0146	Impact of Artificial Feeding on Patient Reported Outcome Measures	17
16/SW/0178	Eat well feel well: qualitative development studies	12
16/SW/0180	Quality of Life Measures In Patients With Retinal Degeneration	21
16/SW/0206	FLIR One and assessment of epidural block	21
16/SW/0287	Parents' perceptions of using e-cigarettes around children in the home	14
16/SW/0288	Body Composition, Energy Intake and Energy Expenditure in PKU People	16
16/SW/0319	Work, Heroin and Opiate Substitution Treatment	13
16/SW/0320	HLA frequencies and relationship with red cell antibodies.	14
16/SW/0344	SAA1 as a CSF biomarker for neurosarcoidosis	15
16/SW/0346	Psychological Sequelae of Colonic Resections v1.0	65
17/SW/0041	Prehabilitation for CABG - a feasibility study	11

Further Information Favourable Opinion with Additional Conditions

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

Further Information Unfavourable Opinion

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

Favourable Opinion with Standard Conditions

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

16/SW/0208	JLA PSP - Healthcare associated infections survey	14
17/SW/0038	Optimising acute care for people with dementia: a mixed-methods study	8
17/SW/0057	Sigmoid WISE	21
17/SW/0063	Menstrual Fluid in Research and Diagnostics	19
17/SW/0065	Laser Activated Stem Cells	16

Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
16/SW/0286	The feasibility of HIV detection using primary care IT systems	11
17/SW/0064	Mapping out the patient pathway, for patients with PAD	16

Unfavourable Opinion

REC Reference	Title	Number of Days on Clock
16/SW/0240	Returning to sport following ankle sprain Version 1.0	19
16/SW/0242	leukaemia immunology	15
16/SW/0343	Associative learning in alcohol dependence	15

Provisional Opinion

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
----------------------	--------------	--------------------------------

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
09/H0107/18/AM07	Decision making in basal ganglia disease	5, 08/06/2016	08/06/2016	14
09/H0107/72/AM02	Reactive Oxygen Species in Central Nervous System Inflammation	amendment 1	01/09/2016	21
10/H0107/57/AM19	HeadandNeck5000	13	02/11/2016	12
11/H0107/9/AM11	Effect of CPB on Ultradian Rhythms of Cortisol in Man. v1.0	9	26/05/2016	58
11/H0107/9/AM12	Effect of CPB on Ultradian Rhythms of Cortisol in Man. v1.0	10	26/10/2016	11
11/SW/0248/AM15	By-Band-Sleeve	8.0	04/05/2016	40
12/SW/0186/AM05	Cortisol profiles in the critically ill after cardiac surgery	5 17/05/2016	17/05/2016	20
12/SW/0340/AM10	Hippocampal changes in early Alzheimer's disease	9. 07.02.17	17/02/2017	29
12/SW/0354/AM01	Back pain and vertebral fractures	AM01	06/04/2016	22
13/SW/0132/AM11	MASTER	AM14 21st Mar 2016	21/03/2016	23
13/SW/0256/AM02	MRI in Acute Stroke	3	19/09/2016	17
14/SW/0011/AM10	The 3D Study: Improving care for multimorbidity patients v1.0	11. 09/06/2016	09/06/2016	10
14/SW/0011/AM11	The 3D Study: Improving care for multimorbidity patients v1.0	12.	19/10/2016	11
14/SW/0029/AM04	Metformin and colorectal cancer.	1.3. August 2016	31/08/2016	15
14/SW/1140/AM02	Diabetes VArants (DIVA)- Exeter	2	22/02/2017	40
14/SW/1165/AM01	Vasculopathy and fibrosis in Systemic sclerosis v1.0	1.0 02.02.16	02/02/2016	38
14/SW/1166/AM02	INFORM - Surgery after Hip Infection Project	2 28.06.2016	28/06/2016	43
15/SW/0008/AM02	The Bluebelle Study: Phase B	2.0	30/06/2016	26
15/SW/0009/AM01	OPTIMISE	V6 30/09/14	14/09/2016	7
15/SW/0093/AM01	Bacterial proteins in semen	1	27/10/2016	7
15/SW/0098/AM02	The VISICORT Study	2	28/10/2016	13
15/SW/0124/AM03	MAGENTA: Graded Exercise Therapy Vs Activity Management	3. 16/06/2016	16/06/2016	14
15/SW/0124/AM04	MAGENTA: Graded Exercise Therapy Vs Activity Management	4	31/08/2016	48
15/SW/0212/AM01	Grip strength implementation in routine practice (GRImP)	1	06/12/2016	7
15/SW/0244/AM01	Ester vs Salt Study (ESS)	1- 19th September 2016	19/09/2016	8
15/SW/0291/AM05	Sleep and Wellbeing - Version 1	2	14/10/2016	27
15/SW/0331/AM01	The PIP studies	1, 31/10/16	31/10/2016	12
15/SW/0343/AM01	Reducing oral bacteria in those with mild dementia	1	14/04/2016	24

15/SW/0343/AM04	Reducing oral bacteria in those with mild dementia	2.0	01/09/2016	27
15/SW/0352/AM03	Case series evaluation of wellbeing augmented CBT for depression	v2 27/5/2016	27/05/2016	30
16/SW/0059/AM01	Evaluation of cognitive motor system for measurement of fatigue in MS	1. 20/08/2016	20/08/2016	18
16/SW/0059/AM02	Evaluation of cognitive motor system for measurement of fatigue in MS	2	30/11/2016	20
16/SW/0069/AM02	Dynamic hormone diagnostics (ULTRADIAN)	2 07/12/2016	07/12/2016	8
16/SW/0088/AM01	Multimedia Informed Consent & PROMS in Laparoscopic Cholecystectomy	2.1 STUDY PROTOCOL_versi on 3_2	20/11/2016	13
16/SW/0098/AM01	ROMIO: RCT of minimally invasive or open oesophagectomy	1	20/10/2016	14
16/SW/0144/AM02	IL-3 as an indicator of salicylate exacerbated chronic urticaria.	AM02	08/06/2016	22
16/SW/0146/AM02	Impact of Artificial Feeding on Patient Reported Outcome Measures	1 31/01/2017	31/01/2017	14
16/SW/0287/AM01	Parents' perceptions of using e-cigarettes around children in the home	1 date: 24/10/2016	24/10/2016	12

Unfavourable opinion

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
13/SW/0318/AM01	RCT of follow-up after cataract extraction	1	17/03/2016	30
15/SW/0148/AM01	Brain, heart & kidney assessment of cooled infants at 6-8 years	1.2	18/05/2016	41
15/SW/0273/AM01	Patients' Cancer Treatment Expectations and the Impact on Experiences	1	01/08/2016	43
15/SW/0316/AM01	Coping in children and adolescents with food allergy.	Number 1, 20th February 2017	20/02/2017	18

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
---------------	-------	---------	------	-------------------

Reference				Clock
13/SW/0318/AM01/1	RCT of follow-up after cataract extraction	1.1 modified 29.07.16	29/07/2016	15
15/SW/0148/AM01/2	Brain, heart & kidney assessment of cooled infants at 6-8 years	1.3 06.10.2016 (modification)	06/10/2016	5
15/SW/0273/AM01/1	Patients' Cancer Treatment Expectations and the Impact on Experiences	1, August 2016	18/10/2016	8

Unfavourable opinion timeline				
Amendment REC Reference	Title	Version	Date	Number of Days on Clock
15/SW/0148/AM01/1	Brain, heart & kidney assessment of cooled infants at 6-8 years	1.2 18/05/2016 (modification)	06/10/2016	11

Table 11: Items exceeding timelines**Full applications for ethical review over 60 day timeline**

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

Proportionate review applications for ethical review over 21 day timeline

REC Reference	Title	Number of Days on Clock
16/SW/0116	Sebaceous activity in the aetiology of frontal fibrosing alopecia, 1	27
16/SW/0118	Men's experiences of their partner's breast cancer, version 1	27
16/SW/0144	IL-3 as an indicator of salicylate exacerbated chronic urticaria.	26
16/SW/0346	Psychological Sequelae of Colonic Resections v1.0	65

SSAs (non Phase 1) over 25 day timeline

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

SSAs (Phase 1) over 14 day timeline

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

Substantial Amendments over 35 day timeline

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
11/H0107/9/AM11	Effect of CPB on Ultradian Rhythms of Cortisol in Man. v1.0	9	26/05/2016	58
11/SW/0248/AM15	By-Band-Sleeve	8.0	04/05/2016	40
14/SW/1140/AM02	Diabetes VARIants (DIVA)- Exeter	2	22/02/2017	40
14/SW/1165/AM01	Vasculopathy and fibrosis in Systemic sclerosis v1.0	1.0 02.02.16	02/02/2016	38
14/SW/1166/AM02	INFORM - Surgery after Hip Infection Project	2 28.06.2016	28/06/2016	43
15/SW/0124/AM04	MAGENTA: Graded Exercise Therapy Vs Activity Management	4	31/08/2016	48
15/SW/0148/AM01	Brain, heart & kidney assessment of cooled infants at 6-8 years	1.2	18/05/2016	41
15/SW/0273/AM01	Patients' Cancer Treatment Expectations and the Impact on Experiences	1	01/08/2016	43

Modified Amendments over 14 day timeline				
Amendment REC Reference	Title	Version	Date	Number of Days on Clock
13/SW/0318/AM01/1	RCT of follow-up after cataract extraction	1.1 modified 29.07.16	29/07/2016	15