

**South West - Frenchay Research Ethics  
Committee**

**Annual Report**

**01 April 2017 - 31 March 2018**





## Part 1 – Committee Membership and Training

<b>Name of REC:</b>	South West - Frenchay Research Ethics Committee
<b>Type of REC:</b>	Authorised
<b>Type of Flag:</b>	None
<b>Chair:</b>	Mr Stephen Draper
<b>Vice-Chair:</b>	Miss Wendy Bertram
<b>Alternate Vice-Chair:</b>	Mr Paul Allen
<b>REC Manager:</b>	Miss Natasha Bridgeman
<b>REC Assistant:</b>	Lidia Gonzalez – April 2017 Stacey Bamford – January 2018 - Present
<b>Committee Address:</b>	Level 3, Block B Whitefriars Lewins Mead, Bristol BS1 2NT Email: nrescommittee.southwest-frenchay@nhs.net
<b>Telephone:</b>	0207 104 8041
<b>Email:</b>	nrescommittee.southwest-frenchay@nhs.net



## Chair's overview of the past year:



## 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	Senior Research Fellow	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	
Mr Aadam Hashmi	Pharmacist	Expert	24/11/2017	
Dr Tarnjit Kaur Khera	Clinical Research Manager	Expert	28/04/2017	
Mrs Kerstin Kubiak	Solicitor	Lay Plus	01/07/2008	
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	13/10/2017

## 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
Mr Brian Pixton	Retired solicitor	Lay Plus	09/02/2018 PRSC 19/06/2018
Mr Chris Foy	Medical Statistician	Expert	14/06/2017 PRSC 09/06/2017



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

Mr Paul Allen	Member of Dentists Provident Society. No interest in Share portfolio/investment	09/03/2018
Mr Gordon Baxter	Employee of GE Healthcare Ltd as a Nuclear Safety Case Manager as well as Shareholder	09/03/2018
Miss Wendy Bertram	Active running of research for North Bristol NHS Trust and University of Bristol	09/03/2018
Miss Laura Birch	None	31/03/2018
Dr Alison Diaper	Senior Research Fellow - UWE Senior Research Fellow - Avon Primary Care Research Collaborative (BSSNG CCG R&E)	09/03/2018
Mr Stephen Draper	None	09/03/2018
Mrs Jane Elias	None	09/03/2018
Dr Tarnjit Kaur Khera	Works on the ProtecT study	05/04/2017
Mrs Kerstin Kubiak	None	31/03/2018
Dr Faye Noble	None	31/03/2018
Mr Jeremy Ruddock	Reviewer of data and summariser for National Council of Osteopathic research	09/03/2018



### Meetings for Full Ethical Review 01 April 2017 - 31 March 2018:

Month	Date	Number of Members Present at Meeting
April	07/04/2017	10
May	12/05/2017	8
June	09/06/2017	7
August	11/08/2017	8
September	08/09/2017	9
October	13/10/2017	7
November	10/11/2017	7
December	08/12/2017	8
February	09/02/2018	8

9 full committee meetings were held during the reporting period.

### Proportionate Review Sub-Committee Meetings held during 01 April 2017 - 31 March 2018:

Month	Date	Number of Members Present at Meeting
April	07/04/2017	9
April	11/04/2017	3
May	10/05/2017	3
May	12/05/2017	9
June	09/06/2017	7
July	11/07/2017	3
September	04/09/2017	3
October	10/10/2017	3
November	14/11/2017	2
December	12/12/2017	3

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

### Sub-Committee Meetings held during 01 April 2017 - 31 March 2018:

Month	Date	Number of Members Present at Meeting
April	12/04/2017	2
April	26/04/2017	2
May	10/05/2017	2
May	20/05/2017	3
May	24/05/2017	2
May	31/05/2017	3
June	07/06/2017	2
June	09/06/2017	6
June	21/06/2017	2
July	19/07/2017	2
August	06/08/2017	2
August	16/08/2017	2



August	30/08/2017	2
September	13/09/2017	2
September	27/09/2017	2
October	11/10/2017	2
October	12/10/2017	2
October	25/10/2017	2
November	08/11/2017	2
December	08/12/2017	2
December	20/12/2017	2
January	03/01/2018	2
January	11/01/2018	2
February	11/02/2018	2
February	25/02/2018	2
March	11/03/2018	2
March	22/03/2018	2
March	25/03/2018	2

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

#### Details of inquorate meeting held:01 April 2017 - 31 March 2018

None



### Attendance of Members at full committee meetings: 01 April 2017 - 31 March 2018

Name	Number of Meetings Attended
Mr Paul Allen	7
Mr Gordon Baxter	7
Miss Wendy Bertram	8
Miss Laura Birch	3
Dr Alison Diaper	6
Mr Stephen Draper	7
Mrs Jane Elias	4
Dr Tarnjit Kaur Khera	4
Mrs Kerstin Kubiak	8
Dr Faye Noble	6
Mr Jeremy Ruddock	6
Mrs Judy Young	3

### Attendance of Members at proportionate review sub-committee meetings: 01 April 2017 - 31 March 2018

Name	Number of Meetings Attended
Mr Paul Allen	4
Mr Gordon Baxter	3
Miss Wendy Bertram	5
Miss Laura Birch	1
Dr Alison Diaper	5
Mr Stephen Draper	5
Mrs Jane Elias	2
Dr Tarnjit Kaur Khera	2
Mrs Kerstin Kubiak	3
Dr Faye Noble	5
Mr Jeremy Ruddock	5
Mrs Judy Young	3

### Attendance of Members at sub-committee meetings: 01 April 2017 - 31 March 2018

Name	Number of Meetings Attended
Mr Paul Allen	7
Mr Gordon Baxter	2
Miss Wendy Bertram	11
Miss Laura Birch	2
Dr Alison Diaper	9
Mr Stephen Draper	11



Mrs Jane Elias	3
Dr Tarnjit Kaur Khera	2
Mrs Kerstin Kubiak	1
Dr Faye Noble	6
Mr Jeremy Ruddock	5
Mrs Judy Young	2



## Training 01 April 2017 - 31 March 2018

Name of Member	Date	Event(s) attended
Mr Paul Allen	09/03/2018	Local Training Day
Mr Gordon Baxter	09/03/2018	Local Training Day
Miss Wendy Bertram	09/03/2018	Local Training Day
Dr Alison Diaper	09/03/2018	Local Training Day
Mr Stephen Draper	24/11/2017	National Chairs Training Day
Mr Stephen Draper	09/03/2018	Local Training Day
Mrs Jane Elias	09/03/2018	Local Training Day
Mr Aadam Hashmi	09/03/2018	Local Training Day
Dr Tarnjit Kaur Khera	16/11/2017	Training - Committee Members Induction
Dr Tarnjit Kaur Khera	09/03/2018	Local Training Day
Mr Jeremy Ruddock	09/03/2018	Local Training Day



## PART 2: REC WORKLOAD AND ACTIVITY DURING THE REPORTING PERIOD

**Table 1: Applications assigned to a full committee meeting held within the reporting period:**

<b>Applications for full ethical review – Study Type</b>	<b>Number</b>	<b>%</b>
Clinical Trial of Investigational Medicinal Product	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	31	100.00
<b>Total Applications Reviewed</b>	<b>31</b>	<b>100</b>

**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	10
Number of paediatric applications reviewed	3
Number of device applications reviewed	7
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	0
Number of qualitative applications reviewed	3

**Table 3: Decisions given at meetings held within the reporting period**

<b>Decisions taken at meetings following review of applications</b>	<b>Number</b>	<b>%</b>
Favourable Opinion with Standard Conditions	0	0.00
Favourable Opinion with Additional Conditions	5	16.13
Unfavourable Opinion	2	6.45
Provisional Opinion	24	77.42
Provisional Opinion Pending Consultation with Referee	0	0.00
<b>Total</b>	<b>31</b>	<b>100</b>
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**

<b>Status of applications at date of generation of report</b>	<b>Number</b>	<b>%</b>
Further Information Favourable Opinion with Standard Conditions	22	70.97
Further Information Favourable Opinion with Additional Conditions	1	3.23
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	0	0.00
Favourable Opinion with Additional Conditions	5	16.13
Unfavourable Opinion	2	6.45
Provisional Opinion	1	3.23
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
<b>Total</b>	<b>31</b>	<b>100</b>



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

<b>Total Applications Reviewed</b>	<b>18</b>
------------------------------------	-----------

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

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

<b>Decisions taken at proportionate review sub-committee meetings</b>	<b>Number</b>	<b>%</b>
Favourable Opinion with Standard Conditions	2	11.11
Favourable Opinion with Additional Conditions	1	5.56
No Opinion transfer to full committee for review	3	16.67
Provisional Opinion	12	66.67
Unfavourable Opinion	0	0.00
<b>Total</b>	<b>18</b>	<b>100</b>



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

<b>Average number of applications reviewed per full meeting</b>	3.44
<b>Number of completed applications for full ethical review</b>	31
<b>Number of completed applications for full ethical review over 60 days</b>	1
<b>Number of completed applications over 60 days as a % of total</b>	3.23%
<b>Number of completed applications for full ethical review over 40 days</b>	17
<b>Number of completed applications over 40 days as a % of total</b>	54.84%
<b>Number of days taken to final decision – average (mean)</b>	42
<b>Number of completed proportionate review applications for ethical review</b>	15
<b>Number of completed proportionate review applications for ethical review over 21 days</b>	7
<b>Number of completed proportionate review applications over 21 days as a % of total</b>	46.67%
<b>Number of SSAs (non-Phase 1) reviewed</b>	2
<b>Number of completed applications for SSA review over 25 days</b>	2
<b>Number of completed applications for SSA review over 25 days as % of all non- Phase 1 SSAs</b>	100.00%
<b>Number of SSAs (Phase 1) reviewed</b>	0
<b>Number of completed applications for SSA review over 14 days</b>	0
<b>Number of completed applications for SSA review over 14 days as % of all Phase 1 SSAs</b>	0.00%
<b>Number of substantial amendments reviewed</b>	51
<b>Number of completed substantial amendments over 35 days</b>	10
<b>Number of completed substantial amendments over 35 days as a % of total substantial amendments</b>	19.61%
<b>Number of completed substantial amendments over 28 days</b>	24
<b>Number of completed substantial amendments over 28 days as a % of total substantial amendments</b>	47.06%
<b>Number of modified amendments reviewed</b>	0
<b>Number of completed modified amendments over 14 days</b>	0
<b>Number of completed modified amendments over 14 days as a % of total modified amendments</b>	0.00%
<b>Number of non substantial amendments received</b>	72
<b>Number of substantial amendments received for information</b>	0
<b>Number of substantial amendments received for new sites/PIs</b>	0
<b>Number of annual progress reports received</b>	24
<b>Number of safety reports received</b>	0
<b>Number of Serious Adverse Events received</b>	4



<b>Number of final reports received</b>	2
---	---



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

<b>Further Information Favourable Opinion with Standard Conditions</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
17/SW/0076	Aphasia and Spirituality Toolkit pilot study version 1	43
17/SW/0098	IRIS+ feasibility study	59
17/SW/0129	Enumerating plasma cells in circulation in myeloma patients	46
17/SW/0130	Woven OGMend Implant	47
17/SW/0171	Carotid Body Activity in Young Onset Hypertension	47
17/SW/0173	Acceptability of a Lycra sleeve for glenohumeral subluxation in stroke	34
17/SW/0175	'TPN CHEK' (Total Parenteral Nutrition Chloride Home Evaluation Kit)	57
17/SW/0179	Cognitive predictors of social anxiety in autistic adults	42
17/SW/0184	Biers v's Haematoma block - Patient and staff experiences/preferences	55
17/SW/0203	Eczema phenotypes	24
17/SW/0208	MyQuality - Measure What Matters	35
17/SW/0227	Evaluation of CPET use in IPF	59
17/SW/0236	Feeling sexual inside and out	45
17/SW/0255	CIP-2101-01	63
17/SW/0256	Peripal System - Human factors validation testing	42
17/SW/0257	NU-Burst Study	34
17/SW/0258	Caffeine, physical activity and mood study	38
17/SW/0264	Neuf Study 20160441	49
18/SW/0038	The LoDED Trial	23
18/SW/0042	Activage ageing & smoking cessation	46
18/SW/0043	Integrating smoking cessation treatment into IAPT care	46
18/SW/0046	Psychotic-Like Experiences in Young People with BPD Traits	45

<b>Further Information Favourable Opinion with Additional Conditions</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
18/SW/0048	Isobar ECS v Sigvaris compression post ulcer healing (thermotrak)	38

<b>Further Information Unfavourable Opinion</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>



**Favourable Opinion with Standard Conditions**

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

**Favourable Opinion with Additional Conditions**

REC Reference	Title	Number of Days on Clock
17/SW/0112	Clinical Feasibility of M-Mark	55
17/SW/0260	Unilateral cochlear implantation in adults with residual hearing	28
17/SW/0271	HEATABLE CLOTHING FOR IMPROVING THERMAL COMFORT IN STROKE	35
17/SW/0287	Healthy Vending in Hospitals	31
18/SW/0047	DIPLOMA trial version 1.0	25

**Unfavourable Opinion**

REC Reference	Title	Number of Days on Clock
17/SW/0176	Predictors of Eating Behaviours in Young People with Asthma	23
17/SW/0204	Identifying anxiety in primary care	24

**Provisional Opinion**

REC Reference	Title	Number of Days on Clock
17/SW/0288	ARTISTIC	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
---------------	-------	-------------------------



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

<b>Further Information Favourable Opinion with Standard Conditions</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
17/SW/0081	CP-0010 Evas-Global Version 2.0	35
17/SW/0085	PKU Go - ACCEPTABILITY AND TOLERANCE	30
17/SW/0087	Patient Experience of Recovering from Pneumonia	33
17/SW/0091	People with dementia in Public Space using Everyday Technology: PIPSET	17
17/SW/0093	Focus on Dopamine	35
17/SW/0131	Neuroendocrine tumours	20
17/SW/0150	VIM Klebsiella virulence potentials	26
17/SW/0210	Assessment of nasogastric tube placement using deep learning	20
17/SW/0230	Validation of Quality of Life Measures in older people with frailty	24
17/SW/0282	Engaging patients in early inflammatory arthritis clinics	21
17/SW/0285	Engaging the Emotional Aspects of Patients' Audiological needs. v. 1.0	22

<b>Further Information Favourable Opinion with Additional Conditions</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>

<b>Further Information Unfavourable Opinion</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
17/SW/0084	2 year plus follow up of 'Live Life Better' (Tier 3) patients	14

<b>Favourable Opinion with Standard Conditions</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
17/SW/0148	Retrospective Burden of Illness Study of FCS Patients on volanesorsen	14
17/SW/0284	Development of a qPCR-based assay for STI detection	13

<b>Favourable Opinion with Additional Conditions</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
17/SW/0095	Pregnancy Lifestyle Survey 2017 V1.0	8



<b>Unfavourable Opinion</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>

<b>Provisional Opinion</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>

<b>Further information response not complete</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>

<b>Withdrawn after the meeting</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>



**Table 10.1: Breakdown of current status of all substantial amendments reviewed within the reporting period**

<b>Favourable opinion</b>				
<b>Amendment REC Reference</b>	<b>Title</b>	<b>Version</b>	<b>Date</b>	<b>Number of Days on Clock</b>
10/H0107/14/AM02	Structure/function relationships in cancellous bone	am1	07/06/2017	27
10/H0107/49/AM04	Protection 1	4	14/11/2017	48
11/SW/0248/AM16	By-Band-Sleeve	9	06/06/2017	39
11/SW/0254/AM06	Renal Denervation for Resistant Hypertension	6	02/08/2017	33
12/SW/0340/AM12	Hippocampal changes in early Alzheimer's disease	SA11	04/05/2017	31
14/SW/0011/AM12	The 3D Study: Improving care for multimorbidity patients v1.0	13. 06/04/2017	06/04/2017	4
14/SW/1091/AM09	IMPROVE 2	16 dated 30th March 2017	30/03/2017	44
14/SW/1173/AM05	ALSPAC Focus @ 24+ Clinic	SA7	30/03/2017	34
14/SW/1173/AM06	ALSPAC Focus @ 24+ Clinic	8	05/07/2017	9
14/SW/1173/AM07	ALSPAC Focus @ 24+ Clinic	5.6.	19/10/2017	21
15/SW/0124/AM05	MAGENTA: Graded Exercise Therapy Vs Activity Management	5	08/02/2017	29
15/SW/0263/AM01	A study to refine the CAR burns scales	1 09/02/2017	09/02/2017	1
15/SW/0263/AM02	A study to refine the CAR burns scales	2	12/04/2017	13
15/SW/0263/AM03	A study to refine the CAR burns scales	SA3	19/05/2017	29
15/SW/0263/AM05	A study to refine the CAR burns scales	SA4	22/09/2017	15
15/SW/0263/AM06	A study to refine the CAR burns scales	5	08/12/2017	39
15/SW/0263/AM08	A study to refine the CAR burns scales	Substantial Amendment 6	07/02/2018	2
15/SW/0294/AM03	TIGAR	1.3	15/05/2017	13
15/SW/0316/AM02	Coping in children and adolescents with food allergy.	2	14/06/2017	22
15/SW/0343/AM05	Reducing oral bacteria in those with mild dementia	3	25/09/2017	29
15/SW/0352/AM05	Case series evaluation of wellbeing augmented CBT for depression	4	15/01/2018	25
15/SW/0352/AM06	Case series evaluation of wellbeing augmented CBT for depression	Substantial Amendment 5	26/02/2018	15
16/SW/0059/AM03	Evaluation of cognitive motor system for measurement of fatigue in MS	3	06/04/2017	33
16/SW/0069/AM03	Dynamic hormone diagnostics (ULTRADIAN)	3 01/04/2017	01/04/2017	31
16/SW/0069/AM04	Dynamic hormone diagnostics (ULTRADIAN)	4 19/07/2017	19/07/2017	27
16/SW/0098/AM03	ROMIO: RCT of minimally invasive or open oesophagectomy	SA2	26/05/2017	24



16/SW/0098/AM04	ROMIO: RCT of minimally invasive or open oesophagectomy	3.0	22/06/2017	14
16/SW/0099/AM02	The REJUVENATE Study v1	16.3.17	16/03/2017	27
16/SW/0116/AM04	Sebaceous activity in the aetiology of frontal fibrosing alopecia, 1	SA1	24/01/2018	21
16/SW/0136/AM04	Depression in Paediatric Chronic Fatigue Syndrome (CFS/ME)	4	23/08/2017	14
16/SW/0142/AM01	Gastric Juice, Nitrite and C. Diff	01/02/2017, Version 2	01/02/2017	31
16/SW/0146/AM04	Impact of Artificial Feeding on Patient Reported Outcome Measures	SA2	03/05/2017	43
16/SW/0178/AM01	Eat well feel well: qualitative development studies	SA1	29/03/2017	47
16/SW/0208/AM01	JLA PSP - Healthcare associated infections survey	2	28/09/2017	45
16/SW/0268/AM02	FITNET-NHS: How effective is FITNET-NHS for children and young adults	SA1	01/08/2017	62
16/SW/0276/AM02	Crisis Response for Psychosis	SA1	11/04/2017	13
16/SW/0287/AM03	Parents' perceptions of using e-cigarettes around children in the home	2.0	17/08/2017	35
17/SW/0030/AM01	ICG Cell Imaging Study	1	26/07/2017	3
17/SW/0038/AM04	Optimising acute care for people with dementia: a mixed-methods study	1	10/01/2018	37
17/SW/0060/AM01	Singing for People with Aphasia (SPA) - version 1	SA1	18/04/2017	34
17/SW/0060/AM02	Singing for People with Aphasia (SPA) - version 1	3	18/07/2017	24
17/SW/0060/AM05	Singing for People with Aphasia (SPA) - version 1	Amendment 6	25/01/2018	11
17/SW/0063/AM01	Menstrual Fluid in Research and Diagnostics	SA1	26/04/2017	28
17/SW/0064/AM01	Mapping out the patient pathway, for patients with PAD	SA1	03/05/2017	35
17/SW/0095/AM02	Pregnancy Lifestyle Survey 2017 V1.0	SA/07/17 21st July 2017	21/07/2017	24
17/SW/0095/AM04	Pregnancy Lifestyle Survey 2017 V1.0	SA/11/17	06/11/2017	28
17/SW/0098/AM01	IRIS+ feasibility study	1.0	05/10/2017	30
17/SW/0098/AM02	IRIS+ feasibility study	2	09/02/2018	20
17/SW/0130/AM01	Woven OGMend Implant	1	04/12/2017	41
17/SW/0131/AM01	Neuroendocrine tumours	1	19/01/2018	16
17/SW/0171/AM01	Carotid Body Activity in Young Onset Hypertension	1	10/10/2017	35

#### Unfavourable opinion

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
-------------------------	-------	---------	------	-------------------------



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

<b>Favourable opinion timeline</b>				
<b>Amendment REC Reference</b>	<b>Title</b>	<b>Version</b>	<b>Date</b>	<b>Number of Days on Clock</b>

<b>Unfavourable opinion timeline</b>				
<b>Amendment REC Reference</b>	<b>Title</b>	<b>Version</b>	<b>Date</b>	<b>Number of Days on Clock</b>



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

REC Reference	Title	Number of Days on Clock
17/SW/0255	CIP-2101-01	63

**Proportionate review applications for ethical review over 21 day timeline**

REC Reference	Title	Number of Days on Clock
17/SW/0081	CP-0010 Evas-Global Version 2.0	35
17/SW/0085	PKU Go - ACCEPTABILITY AND TOLERANCE	30
17/SW/0087	Patient Experience of Recovering from Pneumonia	33
17/SW/0093	Focus on Dopamine	35
17/SW/0150	VIM Klebsiella virulence potentials	26
17/SW/0230	Validation of Quality of Life Measures in older people with frailty	24
17/SW/0285	Engaging the Emotional Aspects of Patients' Audiological needs. v. 1.0	22

**SSAs (non Phase 1) over 25 day timeline**

REC Reference	Title	Number of Days on Clock
17/SW/0286	Feasibility study to reduce or	29
17/SW/0298	Feasibility study to reduce or	29

**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
10/H0107/49/AM04	Protection 1	4	14/11/2017	48
11/SW/0248/AM16	By-Band-Sleeve –	9	06/06/2017	39
14/SW/1091/AM09	IMPROVE 2	16 dated 30th March 2017	30/03/2017	44



15/SW/0263/AM06	A study to refine the CAR burns scales	5	08/12/2017	39
16/SW/0146/AM04	Impact of Artificial Feeding on Patient Reported Outcome Measures	SA2	03/05/2017	43
16/SW/0178/AM01	Eat well feel well: qualitative development studies	SA1	29/03/2017	47
16/SW/0208/AM01	JLA PSP - Healthcare associated infections survey	2	28/09/2017	45
16/SW/0268/AM02	FITNET-NHS: How effective is FITNET-NHS for children and young adults	SA1	01/08/2017	62
17/SW/0038/AM04	Optimising acute care for people with dementia: a mixed-methods study	1	10/01/2018	37
17/SW/0130/AM01	Woven OGMend Implant	1	04/12/2017	41

Modified Amendments over 14 day timeline				
Amendment REC Reference	Title	Version	Date	Number of Days on Clock