

**RES Committee South West - Exeter**

**Annual Report**

**01 April 2014 - 31 March 2015**



## Part 1 – Committee Membership and Training

<b>Name of REC:</b>	RES Committee South West - Exeter
<b>Type of REC:</b>	Authorised
<b>Type of Flag:</b>	Medical Devices Research Involving Children
<b>Chair:</b>	Dr Denise Sheehan
<b>Vice-Chair:</b>	Mrs Joan Ramsay
<b>Alternate Vice-Chair:</b>	Emeritus Professor Malcolm Cowburn
<b>REC Manager:</b>	Mrs Kirsten Peck
<b>REC Assistant:</b>	Miss Georgina Castledine
<b>Committee Address:</b>	Whitefriars Level 3 Block B Lewins Mead Bristol BS1 2NT
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## Chair's overview of the past year:

The Committee continues to work well together to review a wide variety of studies. We have welcomed new members to the committee in this past year, and would be keen to welcome new individuals to widen our pool of expertise.

We enjoyed a stimulating, wide-ranging training day in December.

I would like to thank all the members for their ongoing commitment and enthusiasm, and the team at the Bristol REC Centre for their support, and for all the work they do in the background to ensure that meetings are efficient and effective.

## RES Committee South West - Exeter Membership

Name	Profession	Expert or Lay	Dates	
			Appointed	Left
Mrs Rosamund Bagnald	Retired Store Manager	Lay Plus	01/11/2014	
Mrs Isobel Brooks	Retired Social Care Manager	Lay Plus	01/04/2010	
Dr Lee Burton	GP	Expert	01/04/2010	30/04/2014
Emeritus Professor Malcolm Cowburn	Emeritus Professor of Applied Social Science	Lay Plus	16/06/2014	
Dr Nicole Dorey	Consultant Clinical Oncologist	Expert	05/02/2009	
Mr Christoph Lohan	Pharmacist	Expert	15/07/2011	04/07/2014
Dr. Roy J. Powell	Research Design Consultant	Expert	01/04/2010	
Mrs Joan Ramsay	Retired Associate Director of Nursing (Women and Children)	Lay	01/03/2009	
Mr Phil Regan	Minister of Religion	Lay Plus	05/06/2009	
Mrs Carol Richardson	Senior Nurse (Retired)	Lay	01/05/2009	
Dr Denise Sheehan	Consultant Oncologist	Expert	01/04/2010	
Dr Jo Thompson Coon	Senior Research Fellow in Health Services Research	Lay	01/11/2014	
Dr Chris Vallance	Retired chemist (non-research)	Lay Plus	01/04/2010	
Mr Royston Van Tromp	Retired Head Teacher	Lay Plus	01/07/2011	

## RES Committee South West - Exeter: Deputy Members

Name	Profession	Status	Meeting date attended

## RES Committee South West - Exeter: Co-opted Members

Name	Profession	Status	Meeting date attended
Mr Brian Pixton	Retired Solicitor	Lay Plus	03/04/2014, 04/09/2014
Dr Sheila Dziobhan	Retired lecturer in Law	Lay Plus	04/09/2014

**RES Committee South West - Exeter: Members' Declarations of Interest:**

<b>Name</b>	<b>Declaration of Interest</b>	<b>Date</b>
Mrs Rosamund Bagnald	Joint ownership of 26 AstraZenica shares with husband Anthony Bagnald	30/10/2014
Mrs Isobel Brooks	None	04/12/2014
Emeritus Professor Malcolm Cowburn	Emeritus Professor of Applied Social Science, Sheffield Hallam University. Honorary Professor of Criminology, University of Exeter. Membership of ESRC-3 Prisons Research Ethics Committee	04/12/2014
Dr Nicole Dorey	Consultant Clinical Oncologist. Involved in R&D as part of clinical work.	31/03/2015
Dr. Roy J. Powell	None	03/07/2014
Mrs Joan Ramsay	None	04/12/2014
Mr Phil Regan	None	04/12/2014
Mrs Carol Richardson	Preparing to pursue a PhD in Medical Law incorporating a medically focussed empirical study which will require REC approval.	04/12/2014
Dr Denise Sheehan	Consultant Oncologist entering patients into clinical trials	04/12/2014
Mr Royston Van Tromp	None	03/07/2014
Dr Jo Thompson Coon	Senior research fellow and deputy director of ESMI at university of Exeter medical school. (Not a charity but involved in research everyday as part of employment). Member of the NIHR RFPB committee in the southwest.	07/11/2014
Dr Chris Vallance	Shareholder in: Astra ZenecaGlaxoSmithKleineDechra	04/12/2014

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

Month	Date	Number of Members Present at Meeting
April	03/04/2014	8
May	01/05/2014	9
June	05/06/2014	7
July	03/07/2014	8
September	04/09/2014	9
October	02/10/2014	9
November	06/11/2014	9
February	05/02/2015	10
March	05/03/2015	10

9 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	16/04/2014	3
May	12/05/2014	3
June	16/06/2014	3
September	15/09/2014	3
October	13/10/2014	3
November	06/11/2014	8
December	15/12/2014	3
January	20/01/2015	3
February	17/02/2015	3
March	17/03/2015	3

10 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	09/04/2014	2
April	16/04/2014	3
April	17/04/2014	2
April	29/04/2014	5
May	09/05/2014	2
May	20/05/2014	2
May	30/05/2014	2
June	23/06/2014	3
July	01/07/2014	2
July	16/07/2014	2
July	24/07/2014	2
July	25/07/2014	2

August	08/08/2014	2
August	15/08/2014	2
August	29/08/2014	2
September	10/09/2014	2
September	18/09/2014	2
September	26/09/2014	2
October	03/10/2014	2
October	15/10/2014	2
October	30/10/2014	2
November	12/11/2014	2
November	21/11/2014	2
December	19/12/2014	2
January	05/01/2015	3
January	23/01/2015	2
January	30/01/2015	2
February	20/02/2015	2
February	27/02/2015	2
March	05/03/2015	3
March	13/03/2015	2
March	20/03/2015	3
March	26/03/2015	3
March	27/03/2015	3

34 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
Mrs Rosamund Bagnald	3
Mrs Isobel Brooks	8
Dr Lee Burton	1
Emeritus Professor Malcolm Cowburn	3
Dr Nicole Dorey	6
Mr Christoph Lohan	2
Dr Roy J. Powell	8
Joan Ramsay	8
Mr Phil Regan	8
Mrs Carol Richardson	8
Dr Denise Sheehan	6
Dr Jo Thompson Coon	1
Dr Chris Vallance	8
Mr Royston Van Tromp	6

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

Name	Number of Meetings Attended
Mrs Rosamund Bagnald	1
Mrs Isobel Brooks	8
Dr Nicole Dorey	4
Mrs Joan Ramsay	10
Mrs Carol Richardson	3
Dr Denise Sheehan	7
Dr Chris Vallance	1
Mr Royston Van Tromp	1

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

Name	Number of Meetings Attended
Mrs Isobel Brooks	1
Dr Lee Burton	1
Dr Nicole Dorey	3
Dr Roy J. Powell	1
Mrs Joan Ramsay	32
Mrs Carol Richardson	3
Dr Denise Sheehan	33
Dr Jo Thompson Coon	1



Dr Chris Vallance	2
Mr Royston Van Tromp	1

**Training 01 April 2014 - 31 March 2015**

<b>Name of Member</b>	<b>Date</b>	<b>Event(s) attended</b>
Mrs Isobel Brooks	17/11/2014	Equality and Diversity
Mrs Isobel Brooks	04/12/2014	Local REC Training Day
Emeritus Professor Malcolm Cowburn	04/12/2014	Local REC Training Day
Dr Nicole Dorey	04/12/2014	Local REC Training Day
Dr Roy J. Powell	04/12/2014	Local REC Training Day
Mrs Joan Ramsay	03/07/2014	Training for New REC Chairs
Mrs Joan Ramsay	04/12/2014	Local REC Training Day
Mrs Joan Ramsay	08/02/2015	Equality and Diversity
Mr Phil Regan	31/07/2014	Equality and Diversity
Mr Phil Regan	04/12/2014	Local REC Training Day
Mrs Carol Richardson	04/12/2014	Local REC Training Day
Dr Denise Sheehan	29/05/2014	NREAP Meeting
Dr Denise Sheehan	04/12/2014	Local REC Training Day
Dr Chris Vallance	04/12/2014	Local REC 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	44	100.00
<b>Total Applications Reviewed</b>	<b>44</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	1
Number of applications withdrawn prior to the meeting	1
Number of student applications reviewed	20
Number of paediatric applications reviewed	7
Number of device applications reviewed	7
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	2

**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	1	2.27
Favourable Opinion with Additional Conditions	2	4.55
Unfavourable Opinion	1	2.27
Provisional Opinion	40	90.91
Provisional Opinion Pending Consultation with Referee	0	0.00
<b>Total</b>	<b>44</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	37	84.09
Further Information Favourable Opinion with Additional Conditions	2	4.55
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	1	2.27
Favourable Opinion with Additional Conditions	2	4.55
Unfavourable Opinion	1	2.27
Provisional Opinion	1	2.27
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>44</b>	<b>100</b>

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

<b>Total Applications Reviewed</b>	<b>23</b>
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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	4
Number of studies withdrawn prior to the meeting	1
Number of student applications reviewed	9
Number of paediatric applications reviewed	3
Number of device applications reviewed	0
Number of qualitative applications reviewed	5

**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	8.70
Favourable Opinion with Additional Conditions	0	0.00
No Opinion transfer to full committee for review	0	0.00
Provisional Opinion	19	82.61
Unfavourable Opinion	2	8.70
<b>Total</b>	<b>23</b>	<b>100</b>

**Table 8: Other Management Information for the reporting period:**

<b>Average number of applications reviewed per full meeting</b>	4.89
<b>Number of applications for full ethical review</b>	44
<b>Number of applications for full ethical review over 60 days</b>	0
<b>Number of applications over 60 days as a % of total</b>	0.00%
<b>Number of applications for full ethical review over 40 days</b>	17
<b>Number of applications over 40 days as a % of total</b>	38.64%
<b>Number of days taken to final decision – average (mean)</b>	40
<b>Number of proportionate review applications for ethical review</b>	23
<b>Number of proportionate review applications for ethical review over 14 days</b>	5
<b>Number of proportionate review applications over 14 days as a % of total</b>	21.74%
<b>Number of SSAs (non-Phase 1) reviewed</b>	10
<b>Number of applications for SSA review over 25 days</b>	0
<b>Number of applications for SSA review over 25 days as % of all non- Phase 1 SSAs</b>	0.00%
<b>Number of SSAs (Phase 1) reviewed</b>	0
<b>Number of applications for SSA review over 14 days</b>	0
<b>Number of applications for SSA review over 14 days as % of all Phase 1 SSAs</b>	0.00%
<b>Number of substantial amendments reviewed</b>	71
<b>Number of substantial amendments over 35 days</b>	3
<b>Number of substantial amendments over 35 days as a % of total substantial amendments</b>	4.23%
<b>Number of substantial amendments over 28 days</b>	6
<b>Number of substantial amendments over 28 days as a % of total substantial amendments</b>	8.45%
<b>Number of modified amendments reviewed</b>	4
<b>Number of modified amendments over 14 days</b>	1
<b>Number of modified amendments over 14 days as a % of total modified amendments</b>	25.00%
<b>Number of minor amendments received</b>	42
<b>Number of substantial amendments received for information</b>	1
<b>Number of substantial amendments received for new sites/PIs</b>	5
<b>Number of annual progress reports received</b>	50
<b>Number of safety reports received</b>	8
<b>Number of Serious Adverse Events received</b>	4
<b>Number of final reports received</b>	19

**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>
14/SW/0061	Muscle metabolic, pH and blood oxygenation exercise response in CF	30
14/SW/0068	Adjustment and Psychological Flexibility in T2 Diabetes V1.0	59
14/SW/0072	Understanding Treatment of Infection after Joint Replacement(v1.0)	31
14/SW/0079	DEFLECT III	19
14/SW/0080	Study of Pseudomonas Strains in Bronchiectasis	30
14/SW/0081	A PILOT STUDY OF DIETARY NITRATE SUPPLEMENTATION IN ANAEMIC PATIENTS	53
14/SW/0092	dietary nitrate, effects on hepatic perfusion	33
14/SW/0093	GLP-1 receptor blocker study	41
14/SW/0101	Yo-Yo dieting and adipose tissue dysfunction	51
14/SW/0106	Health benefits of a home-based exercise intervention in MWU_V1	30
14/SW/0108	Measuring visual structure and function after optic nerve compression	33
14/SW/0115	VIRTUS – OUS	37
14/SW/0139	CADENCE Study version 1	59
14/SW/1004	The psychological adjustment of family members of children with ABI	58
14/SW/1016	Validity of the Children's Cognitive Screening Instrument (CCoSI)	53
14/SW/1026	Exercise as a intervention in endometrial cancer survivors (1.0)	34
14/SW/1052	Unity Total Knee Replacement:prospective single centre clinical study	45
14/SW/1066	Fathers experience of their child's life limiting condition. Version 1	39
14/SW/1076	Observational Study Utilizing Harmonic ACEA®+7 Shears (ENG-14-001)	56
14/SW/1077	Raman spectroscopy in premalignant and malignant disease of the vulva	32
14/SW/1079	Pilot study into the use of Needle arthroscopy for joint assessment.	44
14/SW/1090	coronary assessment for mortality prediction v4	50
14/SW/1096	Use of DGEMRIC to assess shoulder cartilage - pilot study.	44
14/SW/1101	The effect of plasma proteins on dry socket healing	38
14/SW/1104	Cystatin C as renal marker in patients receiving fenofibrate	25
14/SW/1110	"PremieStart" maternal & infant programme: Feasibility study Version 1	46
14/SW/1122	Oculomotor training in Multiple Sclerosis	33
14/SW/1139	A study of the effectiveness of different kinds of hip replacements	36
15/SW/0003	The Association between Adiposity and Crohn's Disease	36
15/SW/0017	Study of Immune Drug Side Effects-SIDEX. Version 1.0	39
15/SW/0021	fATDIVA-Exeter (for Adipose Tissue Diabetes Variants)	31
15/SW/0022	Reward Processing and Childhood Abuse - V1	33

15/SW/0025	A Randomised intra-patient Comparison of toric Intraocular lenses	29
15/SW/0026	Evaluation & Development of Peninsula Alcohol and Violence Programme	29
15/SW/0044	Association of anxiety and depression with Oral Epithelial Dysplasia	41
15/SW/0054	Ageing and Oral Health in Subjects with Cleft Lip and Palate	56
15/SW/0068	CTCA feasibility in routine CTTAP version 1, 25/08/2014	59

#### Further Information Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
14/SW/0109	Investigating a role for IGFII in adipocyte regulation	57
14/SW/1018	Assessing the effect of caffeine on attention in Dementia. Version 2	36

#### 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/0064	The anti-erosion effects of 2 toothpastes on enamel	21

#### Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
14/SW/0125	IEU Metabolomics Facility	40
15/SW/0028	The anti-erosion effects of toothpaste on tooth enamel	27

#### Unfavourable Opinion

REC Reference	Title	Number of Days on Clock
14/LO/0856	An Investigation of Beliefs in Compulsive Hoarding	31

#### Provisional Opinion

REC Reference	Title	Number of Days on Clock
14/SW/1103	Profiling Mantle cell Lymphoma version SRPLYM001	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**

Further Information Favourable Opinion with Standard Conditions		
REC Reference	Title	Number of Days on Clock
14/SW/0105	Prolongation PREFER in AF Registry	24
14/SW/0107	Neutrophil-to-lymphocyte ratio in cancer of the larynx and pharynx	14
14/SW/0119	Identifying + validating molecular targets in low grade brain tumours	13
14/SW/0120	School-based Asthma Project (SAP)	20
14/SW/1011	VOLUME4b	12
14/SW/1013	Arabin Pessary in women with twin pregnancy, Pilot	11
14/SW/1015	Screening for pre-eclampsia; exploring women's views	13
14/SW/1095	Validating the 4AT: A triage tool for delirium	12
14/SW/1100	The Role of circulating and disseminated cells in metastases	7
14/SW/1102	Social Interaction in Autism Spectrum Presentation	10
14/SW/1129	Lifestyle in Later Life	20
14/SW/1130	Text messages to improve adherence to nebulised medication in CF	7
14/SW/1183	Sustaining physical activity levels in inflammatory joint disease	19
15/SW/0023	Measuring Reticulocyte Parameters in Haemodialysis Patients	11
15/SW/0024	The AVVQ study	10
15/SW/0036	Increasing physical activity for people with schizophrenia	11

15/SW/0082	ThinkActive: Designing for Health (Version 1)	14
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#### Further Information Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
14/SW/1145	Q Sense Acceptability Study	15
15/SW/0078	Experiences_and_Expectations_of_a_Psychodermatology_Service_Version 1	14

#### 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/1014	Emergency and Urgent Care Demand:Retrospective data analysis:Version 1	13
15/SW/0081	Clinical outcomes in cardiac rehabilitation patients	10

#### Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
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#### Unfavourable Opinion

REC Reference	Title	Number of Days on Clock
14/SW/1185	Intensive Community Care for Anorexia Nervosa (ICCAN study)	9
15/SW/0037	Salivary cortisol in sedated children version 1	14

#### 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**

<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>
04/6/004/AM28	Trial of Celecoxib vs Placebo in Patients with Primary Breast Cancer	22	01/04/2014	7
04/6/004/AM29	Trial of Celecoxib vs Placebo in Patients with Primary Breast Cancer		04/06/2014	20
04/6/004/AM29	Trial of Celecoxib vs Placebo in Patients with Primary Breast Cancer	3.5	04/06/2014	20
04/6/004/AM30	Trial of Celecoxib vs Placebo in Patients with Primary Breast Cancer	24	03/09/2014	14
04/6/005/AM12	OE05	12	16/07/2014	7
04/MRE06/4/AM06	TEXT Tamoxifen and Exemestane Trial, Version 1.1, 17 April 2003		13/05/2014	17
05/MRE06/32/AM07	NET 01 Version 1	9	17/06/2014	13
05/Q2102/22/AM04	The Encephalitis Study	4	30/05/2014	34
06/MRE06/41/AM12	UK Genetics of Testicular Cancer Study	3.1	06/04/2014	6
06/MRE06/41/AM13	UK Genetics of Testicular Cancer Study	10	01/08/2014	19
06/MRE06/65/AM31	New EPOC Version 1.0	32	11/02/2015	13
07/H0206/60/AM13	CA180-188: Long Term Safety and Effectiveness of Dasatinib	13	22/09/2014	17
08/H0206/4/AM22	Adolescent Diabetes Intervention Trial (AdDIT)	20	06/11/2014	32
08/H0206/4/AM24	Adolescent Diabetes Intervention Trial (AdDIT)	21	22/02/2015	5
10/H0206/43/AM13	A UK immunogenicity & safety study comparing 2 dTpa-IPV vaccines		14/05/2014	25
11/SW/0199/AM02	Does the structure of small blood vessels change in diabetes?	1	12/05/2014	35
12/SW/0143/AM02	Observational study of patients prescribed pazopanib for renal cancer	1	16/04/2014	6
12/SW/0206/AM13	SPUtNik	9	13/06/2014	14
12/SW/0240/AM01	Exome Sequencing in Families with Primary Ovarian Insufficiency (POI)		19/09/2014	15
12/SW/0254/AM07	Oxidative stress and obstructive sleep apnoea.	5.0	25/04/2015	6
12/SW/0265/AM01	Assessing renal denervation success(pilot)		25/03/2014	17
12/SW/0281/AM01	REVERT study version 1	1	17/06/2014	6
12/SW/0302/AM01	Use of Machine Perfusion for Improving Allograft Viability	1	12/06/2014	22

12/SW/0317/AM01	Kneease; a new vibration therapy for osteoarthritis of the knee. 1	1	26/09/2014	15
12/SW/0323/AM05	Personalized Anti-TNF Therapy in Crohn's Disease (PANTS)	5	05/08/2014	14
13/SW/0001/AM01	RAPID version 2	1	22/09/2014	19
13/SW/0012/AM02	Themis: A Multi-site evaluation of hospital-based IDVA services	2	18/07/2014	12
13/SW/0037/AM04	PresVIEWâ„¢ SCLERAL IMPLANT TO IMPROVE NEAR VISUAL ACUITY IN PRESBYOPIA	4	18/12/2014	7
13/SW/0048/AM02	ML28642 - ACT OBSERVE - Retrospective chart review	1	28/04/2014	15
13/SW/0083/AM02	Physiotherapy for Hypermobility Trial (PHyT)	Substantial Amendment 2	11/06/2014	19
13/SW/0105/AM01	Men and Chronic Fatigue Syndrome (Version 1)	1	20/06/2014	5
13/SW/0105/AM02	Men and Chronic Fatigue Syndrome (Version 1)	2	22/09/2014	21
13/SW/0136/AM02	HeART of Stroke project V1	1	06/08/2014	24
13/SW/0136/AM03	HeART of Stroke project V1	2	26/09/2014	16
13/SW/0136/AM04	HeART of Stroke project V1	3	11/11/2014	13
13/SW/0162/AM01	Young people with ADHD in transition from CAMHS - v1		14/06/2014	25
13/SW/0162/AM02	Young people with ADHD in transition from CAMHS - v1	2	26/08/2014	12
13/SW/0186/AM04	EFFECT - Efficacy of Fluticasone/Formoterol in COPD Treatment	4	30/07/2014	43
13/SW/0186/AM05	EFFECT - Efficacy of Fluticasone/Formoterol in COPD Treatment	5	12/08/2014	18
13/SW/0186/AM06	EFFECT - Efficacy of Fluticasone/Formoterol in COPD Treatment	6	18/09/2014	6
13/SW/0186/AM07	EFFECT - Efficacy of Fluticasone/Formoterol in COPD Treatment	7	16/12/2014	20
13/SW/0186/AM08	EFFECT - Efficacy of Fluticasone/Formoterol in COPD Treatment	8	05/01/2015	9
13/SW/0186/AM09	EFFECT - Efficacy of Fluticasone/Formoterol in COPD Treatment	9	26/01/2015	9
13/SW/0186/AM11	EFFECT - Efficacy of Fluticasone/Formoterol in COPD Treatment	10	03/02/2015	12
13/SW/0219/AM01	Biomarkers of alcohol induced liver toxicity	1	03/11/2014	6
13/SW/0246/AM02	Evaluation of group walking in an exercise referral scheme	Substantial Amendment 2	13/06/2014	13
13/SW/0261/AM02	Effect of GSK1120212, GSK2118436 + Panitumumab in	3	30/06/2014	28

	colorectal cancer			
13/SW/0289/AM01	Imaging for reconstructive plastic surgery	1	09/01/2015	9
13/SW/0296/AM02	Measuring Abnormal movement Patterns in Parkinson's		04/07/2014	27
13/SW/0332/AM01	Patient Perceptions on Asthma and the Environment	1	06/10/2014	13
14/SW/0015/AM01	EQUAL-IOHEXOL study	1	13/11/2014	7
14/SW/0019/AM04	RELIEF v2.5	1	24/12/2014	37
14/SW/0034/AM01	Light Box study	1	02/02/2015	25
14/SW/0047/AM01	HRQOL in IPF	1	10/07/2014	1
14/SW/0061/AM01	Muscle metabolic, pH and blood oxygenation exercise response in CF	1	08/07/2014	18
14/SW/0068/AM01	Adjustment and Psychological Flexibility in T2 Diabetes V1.0	1	12/11/2014	27
14/SW/0081/AM01	A PILOT STUDY OF DIETARY NITRATE SUPPLEMENTATION IN ANAEMIC PATIENTS	3.5	22/01/2015	6
14/SW/0106/AM01	Health benefits of a home-based exercise intervention in MWU_V1	1	07/07/2014	20
14/SW/0115/AM03	VIRTUS – OUS	2	02/10/2014	12
14/SW/0115/AM04	VIRTUS – OUS	3	27/10/2014	7
14/SW/0120/AM01	School-based Asthma Project (SAP)	1.7	23/05/2014	24
14/SW/0120/AM02	School-based Asthma Project (SAP)	3.5	11/07/2014	10
14/SW/0120/AM03	School-based Asthma Project (SAP)	4	14/07/2014	20
14/SW/0120/AM04	School-based Asthma Project (SAP)	5	25/11/2014	27
14/SW/0125/AM01	IEU Metabolomics Facility		17/07/2014	7
14/SW/0139/AM01	CADENCE Study version 1	1	27/10/2014	3
14/SW/0139/AM01	CADENCE Study version 1	2	30/03/2015	3
14/SW/1077/AM01	Raman spectroscopy in premalignant and malignant disease of the vulva	1	03/11/2014	13
2002/7/118/AM10	Diabetes Alliance for Research in England (DARE)	12	31/03/2014	9

### Unfavourable opinion

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
09/H0206/45/AM22	RORCLL 009		28/03/2014	47
11/SW/0222/AM08	PREDICTING SERIOUS DRUG SIDE EFFECTS IN GASTROENTEROLOGY	5	21/11/2014	14
13/SW/0141/AM02	Preventing T2DM after GDM: focus group modelling study	2	06/01/2015	21
14/SW/1011/AM01	VOLUME4b	3.5	22/09/2014	17

**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>
09/H0202/52/AM02/1	Cardiolipin metabolism and mitochondrial dysfunction in Barth syndrome	2	04/04/2014	13
11/SW/0222/AM08/1	PREDICTING SERIOUS DRUG SIDE EFFECTS IN GASTROENTEROLOGY	Modified Amendment 5	05/01/2015	18
13/SW/0141/AM02/1	Preventing T2DM after GDM: focus group modelling study	Modified Amendment 2	11/02/2015	2
14/SW/1011/AM01/1	VOLUME4b		07/10/2014	13

<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
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**Proportionate review applications for ethical review over 14 day timeline**

REC Reference	Title	Number of Days on Clock
14/SW/0105	Prolongation PREFER in AF Registry	24
14/SW/0120	School-based Asthma Project (SAP)	20
14/SW/1129	Lifestyle in Later Life	20
14/SW/1145	Q Sense Acceptability Study	15
14/SW/1183	Sustaining physical activity levels in inflammatory joint disease	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
09/H0206/45/AM22	RORCLL 009		28/03/2014	47
13/SW/0186/AM04	EFFECT - Efficacy of Fluticasone/Formoterol in COPD Treatment	4	30/07/2014	43
14/SW/0019/AM04	RELIEF v2.5	1	24/12/2014	37



<b>Modified Amendments over 14 day timeline</b>				
<b>Amendment REC Reference</b>	<b>Title</b>	<b>Version</b>	<b>Date</b>	<b>Number of Days on Clock</b>
11/SW/0222/AM08/1	PREDICTING SERIOUS DRUG SIDE EFFECTS IN GASTROENTEROLOGY	Modified Amendment 5	05/01/2015	18