

**RES Committee South West - Frenchay**

**Annual Report**

**01 April 2014 - 31 March 2015**



## Part 1 – Committee Membership and Training

<b>Name of REC:</b>	RES Committee South West - Frenchay
<b>Type of REC:</b>	Authorised
<b>Type of Flag:</b>	Research involving adults lacking capacity * Please note, this flag has been suspended since January 2014 to the members requiring additional training in this specialism.
<b>Chair:</b>	Mr Peter Jones
<b>Vice-Chair:</b>	Mr Stephen Draper
<b>Alternate Vice-Chair:</b>	Mr Paul Allen
<b>REC Manager:</b>	Mrs Naazneen Nathoo
<b>REC Assistant:</b>	Miss Lidia Gonzalez (up to May 2014) Miss Tanya Muravyeva (May 2014 to February 2015) Miss Fran Race (from February 2015)
<b>Committee Address:</b>	Level 3, Block B Whitefriars Lewins Mead, Bristol BS1 2NT Email: nrescommittee.southwest-frenchay@nhs.net
<b>Telephone:</b>	0117 342 1335
<b>Email:</b>	nrescommittee.southwest-frenchay@nhs.net

## Chair's overview of the past year:

This has been a period of positive changes for the committee. I was appointed Chair in February, 2014, and stated then that there were changes that I would like to see in order to make the working of the committee more equitable and inclusive. It is pleasing to report that the measures I was hoping to see put in place have come to fruition.

For these changes to be effective it was crucial that we had the same REC Manager for all meetings, something that was not happening previously. It is very pleasing, therefore, to report that Mrs Naaz Nathoo has been our REC Manager for this period. She has provided the experience and expertise needed to support myself and the committee during this period of change. There have been three REC Assistants; Lidia Gonzalez, Tanya Muravyeva and Fran Race. I thank them for their help.

As stated in the first paragraph, my aim was to make the work of the committee more equitable and inclusive, and to this end we have successfully introduced the following:

We now have Lead Reviewers and committee members are carrying out this role with diligence and total professionalism. The Ethics Review Form has proved to be very useful in enabling the Lead Reviewers to present full reports to the committee.

The work of Sub Committees dealing with Substantial Amendments is now undertaken by a larger number of Committee members, so sharing the workload in a far fairer way.

Since January 2015, the Committee has been undertaking Proportionate Reviews. Once again, a large number of Committee members are doing this work.

From my own point of view, I was delighted that Stephen Draper was appointed as Vice- Chair, and Paul Allen as Alternate Vice- Chair. Both are highly experienced professionals, who add a great deal to the stability of the Committee.

We have also welcomed new members to the Committee, and their contributions have already made an impact. Mrs A. Clarke transferred from Central Bristol in June 2014. Dr. P. Kehagioglou joined in January, 2015. Dr. K. Manley joined in August, 2014. Sadly, two Committee members, Dr. I Thomas and Miss S Hirons have left.

Finally, there was a local Training Day, which concentrated on the Mental Capacity Act. It was very successful and means that consideration can be given to reinstating the flag for research applications involving adults lacking capacity.

This period has, therefore, been successful in the aims I was hoping to achieve. As in all cases of implementing new procedures, there have been occasional problems, but none of these proved insurmountable. This was due to the hard work and commitment of all involved and I wish to record my sincere thanks to the Committee, Mrs Nathoo and the REC Assistants.

Peter Jones  
Chair

## RES Committee South West - Frenchay Membership

Name	Profession	Expert or Lay	Dates	
			Appointed	Left
Mr Paul Allen	Consultant Oral Surgeon	Expert	01/04/2011	
Miss Wendy Bertram	Spine Research Fellow	Lay	15/10/2010	
Miss Laura Birch	Research Dietician	Expert	17/02/2014	
Mrs Angela Clarke	Retired social worker	Lay Plus	20/06/2014	
Dr Alison Diaper	Research Associate	Lay	21/06/2011	
Mr Alex Drake	Assistant Psychologist	Lay	15/10/2010	
Mr Stephen Draper	Retired Head teacher	Lay Plus	01/04/2011	
Miss Sarah Hirons	PhD Student	Lay Plus	01/05/2011	31/03/2015
Mrs Alexandra F. Jensen	Exam Invigilator	Lay	17/02/2014	
Mr Peter Jones	Retired Head teacher	Lay Plus	01/03/2013	
Dr Penny Kehagioglou	Consultant Clinical Oncologist	Expert	08/01/2015	
Mrs Kerstin Kubiak	Solicitor	Lay Plus	01/07/2008	
Dr Kristyn Manley	Research Fellow (O&G)	Expert	08/08/2014	
Dr Ruth Morse	Senior Lecturer in Molecular Biomedicine	Expert	01/04/2012	
Dr Lettie E Rawlins	Junior Doctor	Expert	01/03/2014	
Mr Jeremy Ruddock	Osteopath	Expert	28/05/2013	
Dr Ian Thomas	Consultant in Intensive Care Medicine	Expert	01/04/2007	10/11/2014

## RES Committee South West - Frenchay: Deputy Members

Name	Profession	Status	Meeting date attended
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## RES Committee South West - Frenchay: Co-opted Members

Name	Profession	Status	Meeting date attended
Mr Brian Pixton	Retired Solicitor	Lay Plus	12/12/2014, 13/06/2014

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

<b>Name</b>	<b>Declaration of Interest</b>	<b>Date</b>
Mr Paul Allen	Member of Dentists Provident Society Member of British Dental Association Member of Royal College of Surgeons England	22/12/2014
Miss Wendy Bertram	Monitoring of NBT sponsored CTIMPs under NBT R&D management.	22/12/2014
Miss Laura Birch	None	23/04/2014
Mrs Angela Clarke	None	22/12/2014
Dr Alison Diaper	Research associate for the University of Bristol Research Coordinator for Bioinduction Ltd. Lay member of the UWE REC Peer reviewer for NIHR and Pharmacy Research UK grants applications	14/01/2015
Mr Alex Drake	None	22/12/2014
Mr Stephen Draper	None	22/12/2014
Miss Sarah Hirons	Director of City Road Management Co-Trustee at Bristol Centre for Deaf People Volunteer at National Deaf Children's Society Researcher at University of Bristol	01/04/2014
Mrs Alexandra F. Jensen	None.	10/07/2014
Mr Peter Jones	None	22/12/2014
Dr Penny Kehagioglou	None	31/03/2015
Mrs Kerstin Kubiak	None	17/12/2014
Dr Ruth Morse	Secretary to UK Environmental Mutagen Society	22/12/2014
Dr Lettie E Rawlins	None	23/04/2014
Dr Ian Thomas	None	28/04/2014
Dr Jay Ruddock	Reviewer for "International Journal of Osteopathic Medicine"	31/03/2015
Dr Kristyn Manley	Research Fellow at St. Michael's Hospital	31/03/2015

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

Month	Date	Number of Members Present at Meeting
April	11/04/2014	9
May	09/05/2014	8
June	13/06/2014	8
August	08/08/2014	7
September	12/09/2014	10
October	10/10/2014	8
November	14/11/2014	10
December	12/12/2014	9
January	09/01/2015	9
February	13/02/2015	10

10 full committee meetings were held during the reporting period.

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

Month	Date	Number of Members Present at Meeting
April	07/04/2014	3
September	12/09/2014	10
February	13/02/2015	3
March	02/03/2015	3
March	23/03/2015	3

5 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	03/04/2014	2
April	17/04/2014	2
May	01/05/2014	2
May	15/05/2014	2
May	29/05/2014	2
June	12/06/2014	2
June	20/06/2014	2
July	07/07/2014	2
July	29/07/2014	2
August	21/08/2014	3
September	04/09/2014	2
October	02/10/2014	2
October	16/10/2014	2
October	30/10/2014	2
November	06/11/2014	2
November	13/11/2014	2

December	04/12/2014	2
December	18/12/2014	2
January	05/01/2015	2
January	26/01/2015	2
February	03/02/2015	3
February	09/02/2015	2
February	23/02/2015	2
March	09/03/2015	2
March	23/03/2015	2

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

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

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

<b>Name</b>	<b>Number of Meetings Attended</b>
Mr Paul Allen	7
Miss Wendy Bertram	5
Miss Laura Birch	6
Mrs Angela Clarke	3
Dr Alison Diaper	6
Mr Alex Drake	5
Mr Stephen Draper	8
Mrs Alexandra F. Jensen	4
Mr Peter Jones	8
Dr Penny Kehagioglou	1
Mrs Kerstin Kubiak	5
Dr Kristyn Manley	5
Dr Ruth Morse	8
Dr Lettie E Rawlins	7
Mr Jeremy Ruddock	6
Dr Ian Thomas	2

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

<b>Name</b>	<b>Number of Meetings Attended</b>
Mr Paul Allen	3
Mrs Angela Clarke	2
Dr Alison Diaper	3
Mr Alex Drake	1
Mr Stephen Draper	2
Mrs Alexandra F. Jensen	1
Mr Peter Jones	2
Dr Penny Kehagioglou	1
Mrs Kerstin Kubiak	1
Dr Kristyn Manley	1
Dr Ruth Morse	2
Dr Lettie E Rawlins	1
Mr Jeremy Ruddock	1
Dr Ian Thomas	1



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

<b>Name</b>	<b>Number of Meetings Attended</b>
Mr Paul Allen	9
Miss Wendy Bertram	6
Mrs Angela Clarke	2
Dr Alison Diaper	8
Mr Alex Drake	4
Mr Stephen Draper	11
Mr Peter Jones	8
Mrs Kerstin Kubiak	1
Dr Ruth Morse	2
Dr Lettie E Rawlins	1

## Training 01 April 2014 - 31 March 2015

Name of Member	Date	Event(s) attended
Mr Paul Allen	05/09/2014	Oxford B Training Day
Mr Paul Allen	10/11/2014	Qualitative Research and Ethical Review
Mr Paul Allen	13/03/2015	Local Training Day for Frenchay REC members
Miss Wendy Bertram	19/02/2015	Complex cases
Miss Wendy Bertram	13/03/2015	Local Training Day for Frenchay REC members
Miss Laura Birch	21/07/2014	The Ethical Issues of Research Involving Children
Miss Laura Birch	29/07/2014	NRES Committee Members Induction
Miss Laura Birch	24/11/2014	Researcher Training Day
Miss Laura Birch	15/12/2014	Quantitative Research Methods and Statistics: A Health Research Authority Workshop.
Mrs Angela Clarke	01/06/2014	E&DT
Dr Alison Diaper	05/09/2014	Oxford B Training Day
Dr Alison Diaper	31/03/2015	Medical Devices Training Day
Dr Alison Diaper	13/03/2015	Local Training Day for Frenchay REC members
Mr Alex Drake	27/11/2014	Statistical advice for RECs
Mr Alex Drake	13/03/2015	Local Training Day for Frenchay REC members
Mr Stephen Draper	20/11/2014	South West NREAP/REC Chairs Network Meeting
Mr Stephen Draper	10/12/2014	National Training Day for NRES Committee Chairs
Mr Stephen Draper	26/02/2015	Training for new REC Chairs
Mr Stephen Draper	13/03/2015	Local Training Day for Frenchay REC members
Mrs Alexandra F. Jensen	14/01/2015	Committee members induction
Mr Peter Jones	10/12/2014	National Training Day for NRES Committee Chairs
Mr Peter Jones	19/02/2015	Complex cases
Mr Peter Jones	26/02/2015	Training for new REC Chairs
Mr Peter Jones	13/03/2015	Local Training Day for Frenchay REC members
Mrs Kerstin Kubiak	13/03/2015	Local Training Day for Frenchay REC members
Dr Ruth Morse	23/02/2015	Reading "Bad Pharma" by Ben Goldacre
Dr Lettie E Rawlins	26/04/2014	Equality & Diversity
Dr Lettie E Rawlins	12/06/2014	Induction
Dr Lettie E Rawlins	11/12/2014	Research in vulnerable groups
Dr Lettie E Rawlins	13/03/2015	Local Training Day for Frenchay REC members
Mr Jeremy Ruddock	28/04/2014	Equality & Diversity

Mr Jeremy Ruddock	12/02/2015	Adults lacking capacity - including emergency research - advanced
Mr Jeremy Ruddock	13/03/2015	Training Day for Frenchay REC Members

## 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	40	100.00
<b>Total Applications Reviewed</b>	<b>40</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	11
Number of paediatric applications reviewed	4
Number of device applications reviewed	1
Number of prisoner applications reviewed	0
Number of applications involving adults unable consent reviewed	0
Number of applications reviewed that are funded by the US DHHS	0
Number of qualitative applications reviewed	0

**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	6	15.38
Unfavourable Opinion	2	5.13
Provisional Opinion	32	79.49
Provisional Opinion Pending Consultation with Referee	0	0.00
<b>Total</b>	<b>40</b>	<b>100</b>
Number of studies sent back to full committee meeting for final opinion	2	

**Table 4: Summary of current status of applications reviewed during the reporting period**

<b>Status of applications at date of generation of report</b>	<b>Number</b>	<b>%</b>
Further Information Favourable Opinion with Standard Conditions	24	60.00
Further Information Favourable Opinion with Additional Conditions	7	17.50
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	0	0.00
Favourable Opinion with Additional Conditions	6	15.00
Unfavourable Opinion	2	5.00
Provisional Opinion	0	0.00
Provisional Opinion Pending Consultation with Referee	0	0.00
Further Information response not complete	1	2.50
No decision entered on system	0	0.00
Number of studies withdrawn after the meeting	0	0.00
<b>Total</b>	<b>40</b>	<b>100</b>

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

<b>Total Applications Reviewed</b>	<b>9</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	3
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	0
Number of qualitative applications reviewed	0

**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	1	11.11
Favourable Opinion with Additional Conditions	0	0.00
No Opinion transfer to full committee for review	1	11.11
Provisional Opinion	7	77.78
Unfavourable Opinion	0	0.00
<b>Total</b>	<b>9</b>	<b>100</b>

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

<b>Average number of applications reviewed per full meeting</b>	4.00
<b>Number of applications for full ethical review</b>	40
<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>	9
<b>Number of applications over 40 days as a % of total</b>	22.50%
<b>Number of days taken to final decision – average (mean)</b>	34
<b>Number of proportionate review applications for ethical review</b>	8
<b>Number of proportionate review applications for ethical review over 14 days</b>	2
<b>Number of proportionate review applications over 14 days as a % of total</b>	25.00%
<b>Number of SSAs (non-Phase 1) reviewed</b>	4
<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>	58
<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>	5.17%
<b>Number of substantial amendments over 28 days</b>	7
<b>Number of substantial amendments over 28 days as a % of total substantial amendments</b>	12.07%
<b>Number of modified amendments reviewed</b>	1
<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>	100.00%
<b>Number of minor amendments received</b>	20
<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>	13
<b>Number of safety reports received</b>	0
<b>Number of Serious Adverse Events received</b>	10
<b>Number of final reports received</b>	4

**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/0010	timelines in early interventions version 1	29
14/SW/0058	Feasibility study of YP Face IT	25
14/SW/0063	The effect of arm position in perfusion SPECT	29
14/SW/0090	Independence - Intraocular Lens Patient Satisfaction Study	31
14/SW/0098	Influence of Antioxidant Supplementation During Exercise Heat Stress	29
14/SW/0133	Role of perseverative negative thinking in depression in CHD	57
14/SW/0135	Understanding non compliance in fertility treatment	42
14/SW/0138	VIBE-COSHIBA	36
14/SW/1047	Prohealth@home Feasibility Study	24
14/SW/1048	Development and validation of a novel visuospatial memory test	34
14/SW/1049	Glucose Response, Excursions and Treatment (GREAT)	31
14/SW/1053	Does ACL reconstruction without a thigh tourniquet reduce pain?	29
14/SW/1057	Admission and discharge care bundles for COPD	36
14/SW/1086	Bristol and Region Neuroendocrine Tumour Patient Opinion survey	18
14/SW/1087	Adverse Effects of Mindfulness-Based Cognitive Therapy. Version 1	50
14/SW/1091	IMPROVE 2	29
14/SW/1111	Experience of self conscious emotion in psychosis. Version 1.0	32
14/SW/1120	Fibrofix Meniscus	31
14/SW/1136	Group Dialectical Behavioural Therapy for Bipolar Disorder	33
14/SW/1147	TMT fusion RCT	44
14/SW/1165	Vasculopathy and fibrosis in Systemic sclerosis v1.0	41
14/SW/1176	Incidence of Permanent Childhood Hearing Impairment	26
15/SW/0007	Impact of intermittent fasting on energy balance (v 1.0)	35
15/SW/0009	OPTIMISE	39

<b>Further Information Favourable Opinion with Additional Conditions</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
14/SW/0074	Longitudinal follow up study of Mild Cognitive Impairment	36
14/SW/1002	The effects of pain medication on sleep and sensory testing	48
14/SW/1142	Mnemonic Neglect in Dementia	43
14/SW/1173	ALSPAC Focus @ 24+ Clinic	45



15/SW/0008	The Bluebelle Study: Phase B	44
15/SW/0012	EUROPA: Vesomni Quality of Life Non-Interventional Study	37
15/SW/0030	Peripheral chemosensitivity in exercise in human hypertension	26

#### 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
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#### Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
14/SW/0076	Successful drug treatment for street sex workers: a qualitative study	20
14/SW/1030	Investigation of Ultrasound Assessment:Cysts in Pre-menopausal women/1	21
14/SW/1099	Genes and platelets	28
14/SW/1140	Diabetes VARIants (DIVA)- Exeter	33
14/SW/1166	INFORM - Surgery after Hip Infection Project	20
15/SW/0005	Acoustic Neuroma Screening: MRI asymmetry criteria	31

#### Unfavourable Opinion

REC Reference	Title	Number of Days on Clock
14/SW/0066	Assessing the effect of caffeine on attention in Dementia. Version 1	17
14/SW/1121	Evaluating the effects of potential new drugs on human immune cells.	32

#### Provisional Opinion

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

REC Reference	Title	Number of Days on Clock
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<b>Further information response not complete</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
15/SW/0029	Evaluating the effects of potential new drugs on human immune cells.	n/a

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

**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>
14/SW/0086	MRI is the ultimate diagnostic tool for the paediatric MSK infection	14
14/SW/0087	Resource for Developing Laboratory Methods	15
14/SW/0088	Breast compression and reattendance	17
14/SW/1092	Observational research program in Immune Tolerance Induction (ITI) v2	10
15/SW/0041	Culture of Schistosomes in human blood	5
15/SW/0053	Spinal Cord Injury - cognitive dysfunction, activity limitation & QoL	10
15/SW/0093	Bacterial enzymes in semen	9

<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>

<b>Favourable Opinion with Standard Conditions</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
15/SW/0052	Machine perfusion effects on kidneys not suitable for transplantation.	6

**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
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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
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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>
06/Q2005/132/AM02	Hyperspectral imaging of the retina	2	16/06/2014	9
07/Q2005/47/AM08	The Cohort for Skeletal Health in Bristol and Avon (COSHIBA) Study	11	10/04/2014	15
09/H0107/18/AM06	Decision making in basal ganglia disease	3, 20/2/14	20/02/2014	17
09/H0107/18/AM06	Decision making in basal ganglia disease	4	20/02/2014	17
10/H0107/43/AM10	Observational study of Alzheimer's disease in Europe	12	21/07/2014	10
10/H0107/57/AM12	HeadandNeck5000	7	12/03/2014	47
10/H0107/57/AM13	HeadandNeck5000	8	18/07/2014	37
11/H0107/9/AM07	Effect of CPB on Ultradian Rhythms of Cortisol in Man. v1.0	6	20/04/2014	27
11/H0107/9/AM08	Effect of CPB on Ultradian Rhythms of Cortisol in Man. v1.0	7	06/02/2015	9
11/SW/0051/AM08	Breast tissue composition at young ages and its determinants	6	07/07/2014	1
11/SW/0079/AM01	Stem cell, cytokine and epigenetic profile in CNS inflammation	1	03/09/2014	15
11/SW/0232/AM11	DAPA Trial	7	02/06/2014	28
11/SW/0232/AM13	DAPA Trial	8	13/01/2015	5
11/SW/0248/AM08	BY-BAND	4	28/08/2014	7
11/SW/0358/AM02	Learning motivational interviewing for use in pulmonary rehabilitation	2	24/09/2014	25
12/SW/0009/AM13	Healthlines Study Randomised Controlled Trial	10	09/06/2014	15
12/SW/0161/AM06	ROMIO feasibility: RCT of minimally invasive or open oesophagectomy v1	6, 2 April 2014	02/04/2014	14
12/SW/0161/AM08	ROMIO feasibility: RCT of minimally invasive or open oesophagectomy v1	7	06/05/2014	9
12/SW/0161/AM09	ROMIO feasibility: RCT of minimally invasive or open oesophagectomy v1	8	02/07/2014	12
12/SW/0183/AM05	Head and eye movements in hemianopia and neglect due to stroke	2	27/01/2015	15
12/SW/0186/AM02	Cortisol profiles in the critically ill after cardiac surgery	2	29/08/2014	17
12/SW/0186/AM03	Cortisol profiles in the critically ill after cardiac surgery	3	16/01/2015	21
12/SW/0325/AM02	HARC version 1	2	20/06/2014	27
12/SW/0340/AM04	Hippocampal changes in early Alzheimer's disease	Number 3. 4th of	04/02/2014	15

		February 2014		
12/SW/0340/AM05	Hippocampal changes in early Alzheimer's disease	4	17/11/2014	28
12/SW/0358/AM02	Assessment of Cellular Therapy in Multiple Sclerosis (ACTiMuS)	1	28/05/2014	39
12/SW/0380/AM03	SPACE Support for Parents with a Child with JIA	3, 27/03/2014	27/03/2014	8
12/SW/0380/AM04	SPACE Support for Parents with a Child with JIA	4	06/06/2014	9
13/SW/0008/AM02	Examining Interactions in Consultations for RTI in Children	Amendment No. 1	23/05/2014	15
13/SW/0008/AM03	Examining Interactions in Consultations for RTI in Children	2.0	12/08/2014	23
13/SW/0017/AM07	Risk factors for and faecal colonisation of multiresistant coliforms	8	09/09/2014	28
13/SW/0036/AM05	MALT Study - Phase 2	5 27/03/2014	27/03/2014	10
13/SW/0060/AM03	Evaluation of Community Intravenous Antibiotic Services (CIVAS)	3	24/05/2014	34
13/SW/0060/AM04	Evaluation of Community Intravenous Antibiotic Services (CIVAS)	4	16/01/2015	8
13/SW/0086/AM06	FIRST STEPS:Randomised Controlled Trial, Group FNP	4, April 14th 2014	14/04/2014	9
13/SW/0086/AM07	FIRST STEPS:Randomised Controlled Trial, Group FNP	5	20/06/2014	26
13/SW/0086/AM08	FIRST STEPS:Randomised Controlled Trial, Group FNP	6	04/11/2014	12
13/SW/0132/AM03	MASTER	2	20/03/2014	12
13/SW/0132/AM04	MASTER	3	17/07/2014	1
13/SW/0155/AM01	A Qualitative Evaluation of Feeling Well with True Colours (OXTEXT-7)	1	11/06/2014	15
13/SW/0228/AM02	Increasing standing time in non-ambulant children with cerebral palsy	1	29/09/2014	12
13/SW/0248/AM01	Exploring the spine and lower limb kinematics of trans-tibial amputees	1, 25/04/2014	25/04/2014	9
13/SW/0255/AM01	Repeat infusion of autologous bone marrow cells in multiple sclerosis	2	28/05/2014	26
13/SW/0285/AM01	The ENGAGE study	1	14/01/2015	7
13/SW/0298/AM01	Health benefits of a novel exercise intervention in Type 2 diabetes	1.1	01/06/2014	15
13/SW/0298/AM02	Health benefits of a novel exercise intervention in Type 2 diabetes	1.2	01/10/2014	22
13/SW/0303/AM01	Biological Implications of Polyomavirus Genomic Diversity	1	24/02/2015	18
13/SW/0316/AM02	Suicide and the Internet	1	04/12/2014	30
13/SW/0316/AM02	Suicide and the Internet	1	05/12/2014	30

13/SW/0321/AM01	The effect of breaking prolonged sitting on adipose tissue	Number 1. 21/05/14	06/05/2014	1
14/SW/0011/AM01	The 3D Study: Improving care for multimorbidity patients v1.0	1	08/10/2014	33
14/SW/0011/AM02	The 3D Study: Improving care for multimorbidity patients v1.0	2	24/11/2014	33
14/SW/0028/AM01	Improving diagnosis with endocervical curettage and P16 staining.	1.0	21/04/2014	16
14/SW/0029/AM02	Metformin and colorectal cancer.	1.2	15/10/2014	27
14/SW/0029/AM02	Metformin and colorectal cancer.	Protocol 1, version 1.1, May 2	01/05/2014	27
14/SW/0058/AM01	Feasibility study of YP Face IT	1	04/02/2015	14
14/SW/0133/AM01	Role of perseverative negative thinking in depression in CHD	1	29/09/2014	14
14/SW/0138/AM01	VIBE-COSHIBA	1	22/08/2014	14
14/SW/0138/AM02	VIBE-COSHIBA	2	10/10/2014	20
14/SW/1111/AM02	Experience of self conscious emotion in psychosis. Version 1.0	1.0	19/02/2015	15

#### Unfavourable opinion

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
11/SW/0050/AM04	Deep brain stimulation for resistant hypertension	7	21/08/2014	20

**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
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#### Unfavourable opinion timeline

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
11/SW/0050/AM04/1	Deep brain stimulation for resistant hypertension	8	15/01/2015	33

**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/0087	Resource for Developing Laboratory Methods	15
14/SW/0088	Breast compression and reattendance	17

**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
10/H0107/57/AM12	HeadandNeck5000	7	12/03/2014	47
10/H0107/57/AM13	HeadandNeck5000	8	18/07/2014	37
12/SW/0358/AM02	Assessment of Cellular Therapy in Multiple Sclerosis (ACTiMuS)	1	28/05/2014	39

**Modified Amendments over 14 day timeline**

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
11/SW/0050/AM04/1	Deep brain stimulation for resistant hypertension	8	15/01/2015	33