

**West Midlands - South Birmingham Research
Ethics Committee**

Annual Report

01 April 2017 - 31 March 2018



Part 1 – Committee Membership and Training

Name of REC:	West Midlands - South Birmingham Research Ethics Committee
Type of REC:	Authorised
Type of Flag:	Medical Devices, Research Involving Children
Chair:	Professor Paula McGee
Vice-Chair:	Vacant Position Dr John Cochrane to 20 February 2018
Alternate Vice-Chair:	Dr Kathryn Kinmond from 1 May 2017
REC Manager:	Ms Ellen Swainston from 8 May 2017 Ms Penelope Gregory until 8 May 2017
REC Assistant:	Ms Nicola Kohut from 10 July 2017
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Chair's overview of the past year:

South Birmingham Research Ethics Committee has undergone a considerable change in membership during the last year. In March 2017, the Chair, Professor Simon Bowman stepped down and left the REC to pursue another role. During the year, the Alternate Vice-Chair, Reverend Barry Clark, Dr Sunil Thomas, Dr Andal Thirumalai, Dr Mary Glover and Dr Dalvina Hanu-Cernat also left either because they had reached the end of their tenure or, in the case of Dr Thomas, because of changes in their work commitments. The REC Manager was also redeployed. Alongside these changes was the death of another long-serving member, Mr Michael Andrews in May 2017.

Professor Paula McGee was appointed as the new Chair in April 2017 and Dr Kathryn Kinmond agreed to become Alternate Vice-Chair. There has been no Vice Chair since Dr Cochrane left in February 2018. Ms Ellen Swainston is now REC Manager and has formed a very good, supportive working relationship with the Chair and the members.

The reduction in the number of members posed a challenge. The remaining members launched a recruitment campaign targeting local hospitals, university departments, the GP network and individual professional networks. Five new members were recruited: two experts and three lay plus. More experienced members act as buddies to enable new people to settle into the committee. Despite the improvement in numbers, only three members are doctors, a marked reduction from seven. Efforts continue to try to address this issue.

South Birmingham REC normally meets every month, with the exception of February and July. However, meetings were cancelled in November and December 2017 owing to a shortage of applications. Discussion is constructive and robust. Applicants are made welcome and feedback is positive: 'very good service' 'no concerns – very fair and thorough'. Several observers have attended and have found the experience useful. The REC was audited in December 2017 and received full accreditation for the next three years.

Members have attended training events throughout the year and shared the slides at meetings. Articles circulated at Chairs' meetings, e.g. on vulnerability, have also been shared. More could be done with this information and the REC will address the best way to address this issue.

West Midlands - South Birmingham Research Ethics Committee Membership

Name	Profession	Expert or Lay	Dates	
			Appointed	Left
Mr Michael Andrews	Retired Company Secretary	Lay Plus	17/10/2007	08/05/2017
Ms Philippa Burgon	Retired Local Government Officer	Lay Plus	01/05/2010	
Dr John David Cochrane	Retired GP	Expert	20/02/2007	20/02/2018
Dr Mary Glover	University Lecturer and Psychotherapist	Lay	20/09/2005	21/11/2017
Dr Peter Guest	Retired Consultant Radiologist	Expert	31/01/2014	
Dr Dalvina Hanu-Cernat	Consultant in Anaesthesia and Pain Medicine	Expert	01/10/2007	01/10/2017
Mr Liviu Marius Hanu-Cernat	Consultant Maxillofacial Surgeon	Expert	18/08/2011	
Dr Elizabeth Hensel	Consultant Clinical Psychologist	Expert	01/10/2014	
Dr Kathryn Kinmond	Psychologist and University Lecturer	Lay Plus	01/09/2014	
Mr Ben Kirsch	Business Support Policy Advisor	Lay Plus	24/10/2017	
Professor Paula McGee	Professor of Nursing	Expert	21/04/2015	
Mr Felix Petrou	Student	Lay Plus	19/12/2017	
Miss Charlotte Playll	Student	Lay Plus	21/03/2018	
Mr Daniel Shaw	Radiographer	Expert	01/03/2018	
Dr Robert Stevenson	Consultant Clinical Oncologist	Expert	05/03/2018	
Mrs Andal Thirumalai	Plastic Surgeon	Expert	01/02/2009	31/12/2017

West Midlands - South Birmingham Research Ethics Committee: Co-opted Members

Name	Profession	Status	Meeting date attended
Mrs Jeanne-Anne Charly	Staff Nurse	Expert	18/04/2017
Mrs Alison Parsons	Retired Senior Manager	Lay Plus	16/05/2017
Reverend Keith Lackenby	Reverend	Lay Plus	15/08/2017 15/03/2017 PR
Dr Ronald Jubb	Retired Consultant Rheumatologist	Expert	18/04/2017 15/08/2017
Mr Chris Foy	Medical Statistician	Expert	19/09/2017 17/10/2017
Mrs Lynne Gray	Senior Biomedical Scientist	Expert	20/03/2018
Dr Brenda Laverty	Retired Head of Research Governance	Lay	18/04/2017
Miss Chanan Berry	Student	Lay Plus	16/01/2018
Ms Julie Lockhart	PPI Representative	Lay Plus	16/05/2017

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

Name	Declaration of Interest	Date
Ms Philippa Burgon	Lay reviewer for N I H R Research Design Service South West	12/03/2018
Dr Peter Guest	Participant researcher in a number of studies usually as ARSAC licence holder or IRMER practitioner	30/03/2018
Mr Liviu Marius Hanu-Cernat	None declared	24/03/2018
Dr Elizabeth Hensel	Public Governor UHB ~Foundation Trust Honorary research psychologist Queen Elizabeth Hospital Birmingham	30/03/2018
Dr Kathryn Kinmond	Change indicated on DOI form: I took voluntary redundancy from Manchester metropolitan university in August 2017. I am still lecturing in HE at 2 institutions on a part time basis. I have retained my professional registrations with the British Psychological Society (BPS) and the British Association for Counselling & Psychotherapy (BACP)	24/03/2018
Mr Ben Kirsch	Member of the Investment Decision Group for the Smart Concept Fund (ERDF project University of Wolverhampton)	23/01/2018
Professor Paula McGee	Emerita Professor at Birmingham City University. Supervises PhD research projects. Edits professional journals (health and social care). Associate editor Journal of Transcultural Nursing, published by SAGE	14/03/2018
Mr Felix Petrou	None declared	23/01/2018
Miss Charlotte Playll	None declared	30/03/2018
Mr Daniel Shaw	None declared	30/03/2018
Dr Robert Stevenson	None declared	30/03/2018

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

Month	Date	Number of Members Present at Meeting
April	18/04/2017	8
May	16/05/2017	7
June	20/06/2017	8
August	15/08/2017	8
September	19/09/2017	8
October	17/10/2017	7
January	16/01/2018	7
March	20/03/2018	8

8 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	18/04/2017	3
May	16/05/2017	3
June	16/06/2017	3
August	15/08/2017	3
September	19/09/2017	3
October	17/10/2017	3
November	21/11/2017	3
December	12/12/2017	3
January	16/01/2018	3
February	20/02/2018	3
March	20/03/2018	3

11 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	08/04/2017	2
April	21/04/2017	2
May	05/05/2017	2
May	19/05/2017	2
June	02/06/2017	2
June	13/06/2017	2
June	16/06/2017	2
June	30/06/2017	2
July	14/07/2017	2
August	11/08/2017	2
August	25/08/2017	2
September	08/09/2017	2

September	15/09/2017	2
September	22/09/2017	2
October	06/10/2017	2
October	13/10/2017	2
October	20/10/2017	2
November	03/11/2017	2
November	10/11/2017	2
November	24/11/2017	2
December	01/12/2017	2
December	04/12/2017	2
December	15/12/2017	2
December	22/12/2017	2
January	05/01/2018	2
January	12/01/2018	2
January	18/01/2018	2
February	02/02/2018	2
February	12/02/2018	2
February	28/02/2018	2
March	12/03/2018	2
March	26/03/2018	2
March	26/03/2018	2

33 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
Ms Philippa Burgon	6
Dr John David Cochrane	7
Dr Mary Glover	2
Dr Peter Guest	5
Mr Liviu Marius Hanu-Cernat	5
Dr Dalvina Hanu-Cernat	2
Dr Elizabeth Hensel	6
Dr Kathryn Kinmond	6
Mr Ben Kirsch	2
Professor Paula McGee	7
Mr Felix Petrou	2
Mrs Andal Thirumalai	1

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

Name	Number of Meetings Attended
Ms Philippa Burgon	5
Dr John David Cochrane	9
Dr Kathryn Kinmond	6
Professor Paula McGee	11

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

Name	Number of Meetings Attended
Ms Philippa Burgon	4
Dr John David Cochrane	27
Dr Kathryn Kinmond	3
Professor Paula McGee	32

Training 01 April 2017 - 31 March 2018

Name of Member	Date	Event(s) attended
Ms Philippa Burgon	06/03/2018	Training - Assessing the Consequences (benefits and harms) of Research: a Health Research Authority workshop
Dr John David Cochrane	24/11/2017	HRA National Chairs' Day and Policy Event
Dr John David Cochrane	12/05/2017	Chairs' Meeting - West Midlands
Dr John David Cochrane	02/11/2017	Chairs' Meeting – East/West Midlands
Dr Peter Guest	30/03/2018	Regular (60 minutes monthly) reading of the BMJ with reference to research ethics related articles
Mr Liviu Marius Hanu-Cernat	01/04/2017	Information Governance
Mr Liviu Marius Hanu-Cernat	18/12/2017	Mental Capacity Act
Mr Liviu Marius Hanu-Cernat	18/12/2017	PREVENT Awareness
Mr Liviu Marius Hanu-Cernat	18/12/2017	Equality and Diversity
Dr Elizabeth Hensel	22/05/2017	Read HRA EU clinical trial regulations – info for RECS
Dr Elizabeth Hensel	25/08/2017	Read “could unconscious bias be hindering diversity in your workplace” by Elizabeth Scholes Update magazine April/May 2017 A magazine for law professionals
Dr Elizabeth Hensel	15/01/2018	Equality and Diversity
Dr Kathryn Kinmond	01/05/2017	Equality and Diversity
Dr Kathryn Kinmond	01/06/2017	Research Integrity
Dr Kathryn Kinmond	23/08/2017	Ethical tensions of research in Clinical Hypnosis
Dr Kathryn Kinmond	28/01/2018	Buddy
Mr Ben Kirsch	15/02/2018	Committee Members Induction
Professor Paula McGee	22/08/2017	Equality and Diversity
Professor Paula McGee	29/09/2017	Regional Training Day - Nottingham
Professor Paula McGee	30/11/2017	Generic and Genomic Research
Professor Paula McGee	16/01/2018	Training for New REC Chairs
Professor Paula McGee	07/02/2018	Training - Introduction to Phase 1 Research - Trials & Regulations
Professor Paula McGee	13/02/2018	The Ethical Issues of Research Involving Children
Professor Paula McGee	20/02/2018	Human Tissue Act (Use of Human Samples in Research) - An Introductory Level
Professor Paula McGee	12/05/2017	Chairs' Meeting - West Midlands
Professor Paula McGee	02/11/2017	Chairs' Meeting – East/West Midlands
Mrs Andal Thirumalai	29/09/2017	Local Regional Training Day
Mr Felix Petrou	29/12/2017	Mental disorders and decision

		making
Mr Felix Petrou	29/12/2017	Autonomy and ethics
Mr Felix Petrou	04/01/2018	Ethics of assisted suicide
Mr Felix Petrou	09/01/2018	Surrogacy and ethics
Mr Felix Petrou	09/01/2018	Organ donations and ethics

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)	1	2.56
Others	38	97.44
Total Applications Reviewed	39	100

Table 2: Breakdown of full applications and other activity during reporting period

Number of applications made invalid by the REC Manager	0
Number of applications withdrawn prior to the meeting	1
Number of student applications reviewed	17
Number of paediatric applications reviewed	5
Number of device applications reviewed	13
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	7

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	1	2.56
Favourable Opinion with Additional Conditions	14	35.90
Unfavourable Opinion	6	15.38
Provisional Opinion	18	46.15
Provisional Opinion Pending Consultation with Referee	0	0.00
Total	39	100
Number of studies sent back to full committee meeting for final opinion	0	

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

Status of applications at date of generation of report	Number	%
Further Information Favourable Opinion with Standard Conditions	12	30.77
Further Information Favourable Opinion with Additional Conditions	6	15.38
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	1	2.56
Favourable Opinion with Additional Conditions	14	35.90
Unfavourable Opinion	6	15.38
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	39	100

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

Total Applications Reviewed	17
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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	1
Number of studies withdrawn prior to the meeting	6
Number of student applications reviewed	11
Number of paediatric applications reviewed	1
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

Decisions taken at proportionate review sub-committee meetings	Number	%
Favourable Opinion with Standard Conditions	5	29.41
Favourable Opinion with Additional Conditions	2	11.76
No Opinion transfer to full committee for review	1	5.88
Provisional Opinion	9	52.94
Unfavourable Opinion	0	0.00
Total	17	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	4.33
Number of completed applications for full ethical review	39
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 days taken to final decision – average (mean)	30
Number of completed proportionate review applications for ethical review	16
Number of completed proportionate review applications for ethical review over 21 days	8
Number of completed proportionate review applications over 21 days as a % of total	50.00%
Number of SSAs (non-Phase 1) reviewed	3
Number of completed applications for SSA review over 25 days	1
Number of completed applications for SSA review over 25 days as % of all non- Phase 1 SSAs	33.33%
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	69
Number of completed substantial amendments over 35 days	0
Number of completed substantial amendments over 35 days as a % of total substantial amendments	0.00%
Number of modified amendments reviewed	2
Number of completed modified amendments over 14 days	0
Number of completed modified amendments over 14 days as a % of total modified amendments	0.00%
Number of non substantial amendments received	79
Number of substantial amendments received for information	0
Number of substantial amendments received for new sites/PIs	0
Number of annual progress reports received	49
Number of safety reports received	1
Number of Serious Adverse Events received	0
Number of final reports received	10

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
17/WM/0103	Pulsed magnetic stimulation Managing spasticity in spinal cord injury	34
17/WM/0141	Relatedness & connectedness of young people recovering from psychosis.	34
17/WM/0154	BERI study	37
17/WM/0157	Affordable, robotic prostheses in the NHS	36
17/WM/0194	DISCOVERY	20
17/WM/0200	Hyperpolarized Myocardial 13C Imaging of Human Ischaemic Heart Disease	32
17/WM/0219	Use of the STAK Tool in treatment of arthrofibrosis post TKR	28
17/WM/0288	Experiences of DBT for individuals with Learning Disabilities	45
17/WM/0314	Clinical comparison of silicone hydrogel monthly lenses (CLL541-P001)	40
17/WM/0453	Tracking Immune Changes In Children with Cancer (TRICICL) version 1.0	55
18/WM/0017	Post-Market Clinical Investigation of the Clareon® IOL	42
18/WM/0082	PKU Lophlex Evaluation	36

Further Information Favourable Opinion with Additional Conditions		
REC Reference	Title	Number of Days on Clock
17/WM/0158	RCT to compare two functional appliances for class II malocclusions1.7	23
17/WM/0235	Young people's lived experiences of cancer	28
17/WM/0312	Factors which influence hepatitis C testing in prison	37
17/WM/0316	TREO Registry	34
17/WM/0350	The lived experiences of severe postnatal psychiatric illness	30
17/WM/0382	Implantation test for endometrial receptivity v1.0	26

Further Information Unfavourable Opinion		
REC Reference	Title	Number of Days on Clock
None		

Favourable Opinion with Standard Conditions		
REC Reference	Title	Number of Days on Clock
17/WM/0433	KIMAL Delta Lactate Project	57

Favourable Opinion with Additional Conditions		
REC Reference	Title	Number of Days on Clock
17/WM/0180	Birdshot-ABC	21
17/WM/0217	Qualities valued in nursing staff: a multiperspective study. V1.	23
17/WM/0233	Improving Diabetic Education in Adults with Cystic Fibrosis (IDEA-CF)	23
17/WM/0237	Patients' Experiences of Restrictive Practice in an NHS Secure Service	23
17/WM/0241	BUMP	23
17/WM/0305	Spatial and non-spatial binding in ageing and Alzheimer's disease	29
17/WM/0309	The ICU CHAT Feasibility Study (Version 1.0)	29
17/WM/0342	Impact of specialist led integrated care in COPD	27
17/WM/0343	Rectal Cancer Oncological Complete Response Database (OnCoRe)	27
17/WM/0381	Frailty Intervention Trial In End-Stage Patients on Dialysis	16
17/WM/0384	Improving respiratory motion management using a mechanical ventilator.	16
18/WM/0027	SATURN 1.4 version 2	16
18/WM/0083	Comparing two real-ear measurement methods Version 3	35
18/WM/0086	Night Vision in RP	29

Unfavourable Opinion		
REC Reference	Title	Number of Days on Clock
17/WM/0156	TREO Registry	28
17/WM/0307	Needs and Experiences of Women with FGM in the Post-partum Period	29
17/WM/0336	Head injury & impulsive aggression in personality disorder - version 1	27
17/WM/0362	IMPROVE V1.0	27
17/WM/0383	EMHeP: Efficiency, cost and quality of mental healthcare provision	29
18/WM/0085	CHAPAS	29

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
17/WM/0145	Functional Assessment for Burns - Critical Care (FAB-CC)	26
17/WM/0188	Follow Up Study (PREPARE): Long Term Lifestyle Habits	26
17/WM/0189	Mindfulness, parental stress and child behaviour in neurodisability	22
17/WM/0320	An Investigation of Attentional Functions in Stable COPD	20
17/WM/0359	The effect of cataract on colour vision	32
17/WM/0427	V-HIT and VEMP findings in vestibular disorders	18
17/WM/0428	Understanding chemotherapy resistance in Mixed Lineage Leukaemia	24
18/WM/0028	Social networks & weight management in pregnancy/postpartum (SNIP)v1.0	36
18/WM/0074	GIFT study - Glucose in fertility testing	29

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

17/WM/0143	Examining the effects of acute stress on executive attention	22
17/WM/0147	Mental health and treatment needs of UK ex-service personnel: v1	18
17/WM/0242	PET-CT and the staging of SSNs	8
17/WM/0322	Optimal pre-operative duration of Continuous Positive Airway Pressure	6
17/WM/0392	DESCRIBEIII: Retrospective Chart Review for Patients in IPP	17

Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
17/WM/0357	Sleep telemetry services: a feasibility study (v1)	18
17/WM/0461	Ultrasound Imaging to Characterise Muscle in Spinal Cord Injury	20

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

Favourable opinion				
Amendment REC Reference	Title	Version	Date	Number of Days on Clock
08/H1207/80/AM16	Ocrelizumab .v. Avonex .v. placebo in patients with RRMS.	WA21493/G	24/08/2017	7
08/H1207/80/AM17	Ocrelizumab .v. Avonex .v. placebo in patients with RRMS.	Protocol WA21493 version	27/09/2017	27
11/WM/0287/AM03	DESKTOP III	Amendment 8	20/12/2017	11
12/WM/0414/AM03	A prospective study of late-onset myasthenia gravis	2	30/08/2017	8
13/WM/0435/AM03	The use of GMP in the dietary management of PKU	SA3	27/07/2017	9
13/WM/0486/AM01	Prediction of inappropriate myometrial function	SA1	20/09/2017	15
14/WM/0094/AM02	Post Authorisation Safety Study of Perampanel in Epilepsy	3	27/03/2017	9
14/WM/0094/AM03	Post Authorisation Safety Study of Perampanel in Epilepsy	SA4	12/10/2017	12
14/WM/0094/AM04	Post Authorisation Safety Study of Perampanel in Epilepsy	Amendment 5	27/11/2017	11
14/WM/0109/AM03	Molecular markers of fat use and storage in myocardial tissue	3	24/03/2017	9
15/WM/0052/AM12	The MILESTONE Study: Improving Transition from CAMHS to AMHS v1.0	5	07/03/2017	17
15/WM/0052/AM14	The MILESTONE Study: Improving Transition from CAMHS to AMHS v1.0	6	26/01/2018	11
15/WM/0093/AM03	Quality of life measures for NPD type C	2	24/08/2017	34
15/WM/0138/AM01	Vestibular Function in Patients with Vestibular Schwannoma	SA1.2	19/07/2017	7
15/WM/0267/AM02	The 1,000 Families Study	1.1	30/01/2018	7
15/WM/0338/AM08	Cognitive performance among men receiving ADT	2.1	30/03/2017	2
15/WM/0338/AM09	Cognitive performance among men receiving ADT	SA3	11/10/2017	7
15/WM/0347/AM03	Measuring General Practice Productivity	SA1 11.7.17	11/07/2017	5
15/WM/0347/AM04	Measuring General Practice Productivity	SA2	13/10/2017	4
15/WM/0415/AM04	PRIMAL	Substantial Amendment 4	23/08/2017	7
15/WM/0431/AM05	Possible predictors of Major Adverse Cardiac Events	2	25/01/2018	18
15/WM/0466/AM02	Development of the PES-PD	2	19/04/2017	6
15/WM/0466/AM03	Development of the PES-PD	SA3	08/06/2017	15
16/WM/0029/AM07	Bumps and Babies Longitudinal Study 'BaBBLeS'	SA6	29/06/2017	6
16/WM/0029/AM08	Bumps and Babies Longitudinal Study 'BaBBLeS'	SA7	23/08/2017	6
16/WM/0029/AM09	Bumps and Babies Longitudinal Study 'BaBBLeS'	08	14/09/2017	18
16/WM/0031/AM01	Supported employment in primary and community care: a RCT	SA1	26/07/2017	6

16/WM/0031/AM02	Supported employment in primary and community care: a RCT	SA2	03/10/2017	29
16/WM/0143/AM05	RESIST: Understanding the role of depression in heart disease v1.0	5	10/04/2017	32
16/WM/0145/AM08	Database Development for Newborn Screening Disorders.	SA 3, 18th December 2017	18/12/2017	23
16/WM/0196/AM02	Circulating cells in advanced cancer (CICATRIx)	2	24/04/2017	9
16/WM/0223/AM01	Use of patient experience data in inpatient mental health services	1	24/04/2017	1
16/WM/0236/AM03	Using My Extracted Teeth For Research	SA01	12/06/2017	9
16/WM/0242/AM03	The effects of hyperglycaemia on the response to acute exercise (v2)	SA3	01/05/2017	9
16/WM/0242/AM04	The effects of hyperglycaemia on the response to acute exercise (v2)	SA4	19/12/2017	11
16/WM/0271/AM05	Contour Neurovascular System™ IA study	2	29/11/2017	23
16/WM/0339/AM02	TREAT-2: Oral anticoagulation in AF stratified by SAME-TT2R2 score	SA2	01/04/2017	5
16/WM/0376/AM01	Mindfulness for sleep disturbance in dementia	1	30/03/2017	7
16/WM/0397/AM02	Co-designing dementia care to improve value (v4)	SA1	13/06/2017	1
16/WM/0397/AM03	Co-designing dementia care to improve value (v4)	2	17/01/2018	21
16/WM/0418/AM02	The detection of circulating tumour cells by immunohistochemistry	SA1	14/09/2017	14
16/WM/0423/AM01	Tommy's Birmingham - Miscarriage Research Project	SA1	29/08/2017	35
16/WM/0434/AM01	REFRAME RPD	1	07/03/2017	12
16/WM/0434/AM02	REFRAME RPD	SA2	02/10/2017	13
16/WM/0439/AM01	EndoStim CS-100 FDA study	1	01/03/2017	9
16/WM/0439/AM02	EndoStim CS-100 FDA study	SA#2	01/06/2017	4
16/WM/0449/AM01	Understanding Autism Spectrum Disorder in Adulthood	1	06/04/2017	6
16/WM/0502/AM01	Cognitive Behavioural Therapy to reduce anxiety and depression in AF	SA1 -Protocol v3	05/04/2017	7
16/WM/0502/AM02	Cognitive Behavioural Therapy to reduce anxiety and depression in AF	SA2	18/12/2017	7
16/WM/0505/AM02	MAP (Movement through Active Personalised engagement)	2	23/03/2017	7
16/WM/0505/AM04	MAP (Movement through Active Personalised engagement)	3	02/02/2018	25
17/WM/0034/AM01	VICTOR Study	SA1	06/12/2017	29
17/WM/0037/AM01	Quality of life and attitudes towards ageing among older adults	SA1	15/06/2017	8
17/WM/0103/AM01	Pulsed magnetic stimulation Managing spasticity in spinal cord	SA1	05/01/2018	7

	injury			
17/WM/0141/AM01	Relatedness & connectedness of young people recovering from psychosis.	SA1	23/06/2017	6
17/WM/0154/AM01	BERI study	SA 1	31/05/2017	5
17/WM/0154/AM02	BERI study	2	05/02/2018	21
17/WM/0194/AM02	DISCOVERY	SA1	18/07/2017	10
17/WM/0219/AM02	Use of the STAK Tool in treatment of arthrofibrosis post TKR	4	06/02/2018	12
17/WM/0241/AM02	BUMP	SA1	06/10/2017	10
17/WM/0312/AM02	Factors which influence hepatitis C testing in prison	2.2	08/03/2018	13
17/WM/0316/AM01	TREO Registry	1	14/03/2018	12
17/WM/0343/AM01	Rectal Cancer Oncological Complete Response Database (OnCoRe)	1.0	17/11/2017	10
17/WM/0350/AM01	The lived experiences of severe postnatal psychiatric illness	3	22/01/2018	13
18/WM/0017/AM01	Post-Market Clinical Investigation of the Clareon® IOL	1	06/03/2018	5

Unfavourable opinion				
Amendment REC Reference	Title	Version	Date	Number of Days on Clock
15/WM/0147/AM04	AMPSIM	4	31/03/2017	19
16/WM/0029/AM06	Bumps and Babies Longitudinal Study 'BaBBLeS'	5	26/05/2017	5
17/WM/0189/AM03	Mindfulness, parental stress and child behaviour in neurodisability	SA1	11/08/2017	16
17/WM/0219/AM01	Use of the STAK Tool in treatment of arthrofibrosis post TKR	SA1	06/08/2017	14

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

15/WM/0147/AM04/1	AMPSIM	4	20/04/2017	7
16/WM/0029/AM06/1	Bumps and Babies Longitudinal Study 'BaBBLLeS'	SA#5	14/06/2017	2

Unfavourable opinion timeline				
Amendment REC Reference	Title	Version	Date	Number of Days on Clock

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
17/WM/0143	Examining the effects of acute stress on executive attention	22
17/WM/0145	Functional Assessment for Burns - Critical Care (FAB-CC)	26

17/WM/0188	Follow Up Study (PREPARE): Long Term Lifestyle Habits	26
17/WM/0189	Mindfulness, parental stress and child behaviour in neurodisability	22
17/WM/0359	The effect of cataract on colour vision	32
17/WM/0428	Understanding chemotherapy resistance in Mixed Lineage Leukaemia	24
18/WM/0028	Social networks & weight management in pregnancy/postpartum (SNIP)v1.0	36
18/WM/0074	GIFT study - Glucose in fertility testing	29

SSAs (non Phase 1) over 25 day timeline

REC Reference	Title	Number of Days on Clock
17/WM/0283	EndoStim CS-100 FDA study	27

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
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Modified Amendments over 14 day timeline

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
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