

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

Annual Report

01 April 2016 - 31 March 2017



Part 1 – Committee Membership and Training

Name of REC:	West Midlands - South Birmingham Research Ethics Committee
Type of REC:	Authorised REC
Type of Flag:	Medical Device Study, Research Involving Children
Chair:	Professor Simon Bowman
Vice-Chair:	Dr John David Cochrane
Alternate Vice-Chair:	Vacant
REC Manager:	Ms Penelope Gregory (until February 2017)
REC Assistant:	Mr Tadeusz Jones (until February 2017)
Committee Address:	The Old Chapel Royal Standard Place Nottingham NG1 6FS
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Chair's overview of the past year:

West Midlands South Birmingham REC: Chairs annual report:

1. We have had another successful year in 2016-7. We reviewed 37 full applications and 37 proportionate reviews.
2. I would particularly like to thank Dr John Cochrane, Vice-Chair for his hard work and support as well as all of the committee members and the NRES team.
3. We also thank the following members who have left the committee for all their hard work:
 - a. Dr Barry Clark
 - b. Dr Sunil Thomas
4. I am due to step down at the end of March after 7 years as Chair and I am delighted that Professor Paula McGee is taking over.

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	
Professor Simon Bowman	Consultant Rheumatologist	Expert	01/10/2007	31/03/2017
Ms Philippa Burgon	Retired Local Government Officer	Lay Plus	01/05/2010	
Rev'd Dr Barry Clark	Retired Hospital Chaplain	Lay Plus	01/08/2009	15/11/2016
Dr John David Cochrane	Retired GP	Expert	20/02/2007	
Dr Mary Glover	University Lecturer and Psychotherapist	Lay	22/11/2012	
Dr Peter Guest	Consultant Radiologist	Expert	31/01/2014	
Dr Dalvina Hanu-Cernat	Consultant in Anaesthesia and Pain Medicine	Expert	01/10/2007	
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	
Professor Paula McGee	Professor of Nursing	Expert	21/04/2015	
Mrs Andal Thirumalai	Plastic Surgeon	Expert	01/02/2009	
Mr Sunil Solomon Thomas	Consultant Plastic Surgeon	Expert	01/01/2009	14/03/2017

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

Name	Profession	Status	Meeting date attended
Dr Nicola James	Independent Research Consultant	Lay Plus	13/12/2016
Dr Ronald Jubb	Retired Consultant Rheumatologist	Expert	17/01/2017
Ms Margret Vince	Translator	Lay Plus	21/03/2017
Dr Michael Wolffe	Optometrist	Expert	20/09/2016
Ms Yasumati Damodar	Pharmacist	Expert	19/04/2016 17/01/2017
Reverend Keith Lackenby	Reverend	Lay Plus	21/03/2017 PR

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

Name	Declaration of Interest	Date
Mr Michael Andrews	None declared	14/01/2017
Professor Simon Bowman	I have consulted for a number of Pharmaceutical Companies in the field of clinical trial design Sjogren's Syndrome (AstraZeneca/Medimmune, BMS, Celgene, Eli Lilly, Glenmark, GSK, MTPharma, Novartis, Ono, Pfizer, Takeda, UCB, xtlbio). Roche Pharma provided Rituximab free of charge for the TRACTISS study that I am CI ofTrustee of the British Sjogren's Syndrome Association (patient charity)I am PI or co-applicant on studies in Sjogren's through the NHS	07/03/2017
Ms Philippa Burgon	Lay reviewer for NIHR Research Design Service South West	16/01/2017
Dr John David Cochrane	None declared	13/01/2017
Dr Mary Glover	Shares in genus and dairy crestNewman university Health and Wellbeing counselling serviceActive researcher at Newman University, BirminghamMember of National Farmer's Union	08/03/2017
Dr Dalvina Hanu-Cernat	None declared	20/09/2016
Mr Liviu Marius Hanu-Cernat	None declared	20/09/2016
Dr Elizabeth Hensel	Honorary Clinical Research psychologist, UHB	12/01/2017
Dr Kathryn Kinmond	Any other activities or interests likely or possibly likely to be related to the conduct of research(Please include any involvement in local Research & Development management or support, Research & Development committees or peer review bodies) in my role as senior lecturer at Manchester Metropolitan University	23/03/2017
Professor Paula McGee	Emerita Professor at Birmingham City University. Supervises PhD research projects. Edits professional journals (health and social care).	16/01/2017
Mr Sunil Solomon Thomas	Vice Chairman - FOL - Friends of Ludhiana - Charity	25/01/2017

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

Month	Date	Number of Members Present at Meeting
April	19/04/2016	11
May	17/05/2016	9
June	21/06/2016	13
August	16/08/2016	10
September	20/09/2016	10
October	18/10/2016	9
December	13/12/2016	10
January	17/01/2017	9
March	21/03/2017	8

9 full committee meetings were held during the reporting period.

Proportionate Review Sub-Committee Meetings held during 01 April 2016 - 31 March 2017:

Month	Date	Number of Members Present at Meeting
April	19/04/2016	3
May	17/05/2016	3
June	21/06/2016	3
July	19/07/2016	4
August	16/08/2016	3
September	20/09/2016	3
October	18/10/2016	3
December	13/12/2016	3
January	17/01/2017	3
February	21/02/2017	3
March	15/03/2017	3

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

Sub-Committee Meetings held during 01 April 2016 - 31 March 2017:

Month	Date	Number of Members Present at Meeting
April	01/04/2016	2
April	08/04/2016	2
April	29/04/2016	2
May	06/05/2016	2
May	13/05/2016	2
May	26/05/2016	2
June	03/06/2016	2
June	17/06/2016	2
July	01/07/2016	5
July	05/07/2016	2
July	29/07/2016	2

August	12/08/2016	2
August	26/08/2016	2
September	02/09/2016	2
September	19/09/2016	2
September	23/09/2016	2
September	30/09/2016	2
October	07/10/2016	2
October	21/10/2016	2
November	04/11/2016	2
November	10/11/2016	2
November	18/11/2016	2
November	25/11/2016	2
December	02/12/2016	2
December	09/12/2016	2
December	16/12/2016	2
December	30/12/2016	2
January	27/01/2017	2
February	10/02/2017	2
February	17/02/2017	2
February	24/02/2017	2
March	11/03/2017	2

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

Details of inquorate meeting held:01 April 2016 - 31 March 2017

None

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

Name	Number of Meetings Attended
Mr Michael Andrews	7
Professor Simon Bowman	7
Ms Philippa Burgon	7
Rev'd Dr Barry Clark	4
Dr John David Cochrane	7
Dr Mary Glover	6
Dr Peter Guest	7
Dr Dalvina Hanu-Cernat	5
Mr Liviu Marius Hanu-Cernat	4
Dr Elizabeth Hensel	6
Dr Kathryn Kinmond	6
Professor Paula McGee	8
Mrs Andal Thirumalai	5
Mr Sunil Solomon Thomas	4

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

Name	Number of Meetings Attended
Professor Simon Bowman	11
Ms Philippa Burgon	1
Rev'd Dr Barry Clark	6
Dr John David Cochrane	9
Dr Mary Glover	2
Professor Paula McGee	3

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

Name	Number of Meetings Attended
Mr Michael Andrews	1
Professor Simon Bowman	32
Dr John David Cochrane	32
Dr Peter Guest	1
Professor Paula McGee	1

Training 01 April 2016 - 31 March 2017

Name of Member	Date	Event(s) attended
Mr Michael Andrews	23/09/2016	Local Training Day - Regional
Professor Simon Bowman	01/12/2016	National Training Day for Chairs
Ms Philippa Burgon	14/09/2016	Training - Handling Health Related Findings in Research (Joint MRS/HRA)
Dr John David Cochrane	01/12/2016	National Training Day for Chairs
Dr John David Cochrane	16/02/2017	National Members Training Day
Dr Mary Glover	12/07/2016	Training - Research involving adults who lack capacity (including research in emergency situations)
Dr Peter Guest	01/02/2017	Medical Devices Training Day
Dr Elizabeth Hensel	04/04/2016	Logical and Critical Thinking
Dr Elizabeth Hensel	01/05/2016	Research Survey Review - Cancer patients at UHB
Professor Paula McGee	14/07/2016	Personal Data in Research - A Workshop
Professor Paula McGee	23/09/2016	Local Training Day - Regional
Mrs Andal Thirumalai	23/09/2016	Local Training Day - Regional
Mr Sunil Solomon Thomas	01/05/2016	BMJ personal reading
Mr Sunil Solomon Thomas	20/05/2016	E&D training
Mr Sunil Solomon Thomas	01/06/2016	Personal reading BMJ
Mr Sunil Solomon Thomas	01/07/2016	Personal reading BMJ
Mr Sunil Solomon Thomas	01/08/2016	Personal reading BMJ
Mr Sunil Solomon Thomas	01/09/2016	Personal reading BMJ
Mr Sunil Solomon Thomas	01/10/2016	Personal reading BMJ
Mr Sunil Solomon Thomas	01/11/2016	Coaching workshop
Mr Sunil Solomon Thomas	01/11/2016	Personal reading BMJ
Mr Sunil Solomon Thomas	01/11/2016	Coaching workshop
Mr Sunil Solomon Thomas	01/12/2016	Personal reading BMJ

PART 2: REC WORKLOAD AND ACTIVITY DURING THE REPORTING PERIOD

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

Applications for full ethical review – Study Type	Number	%
Clinical Trial of Investigational Medicinal Product	0	0.00
Phase 1	0	0.00
Gene Therapy	0	0.00
Research Tissue Bank (including renewals)	0	0.00
Research Database (including renewals)	0	0.00
Others	37	100.00
Total Applications Reviewed	37	100

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

Number of applications made invalid by the REC Manager	7
Number of applications withdrawn prior to the meeting	1
Number of student applications reviewed	11
Number of paediatric applications reviewed	2
Number of device applications reviewed	6
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	5

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	0	0.00
Favourable Opinion with Additional Conditions	3	8.11
Unfavourable Opinion	1	2.70
Provisional Opinion	33	89.19
Provisional Opinion Pending Consultation with Referee	0	0.00
Total	37	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	26	70.27
Further Information Favourable Opinion with Additional Conditions	1	2.70
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	0	0.00
Favourable Opinion with Additional Conditions	3	8.11
Unfavourable Opinion	1	2.70
Provisional Opinion	5	13.51
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	1	2.70
Total	37	100

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

Total Applications Reviewed	37
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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	6
Number of studies withdrawn prior to the meeting	0
Number of student applications reviewed	14
Number of paediatric applications reviewed	3
Number of device applications reviewed	2
Number of qualitative applications reviewed	1

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	6	16.22
Favourable Opinion with Additional Conditions	3	8.11
No Opinion transfer to full committee for review	0	0.00
Provisional Opinion	28	75.68
Unfavourable Opinion	0	0.00
Total	37	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	4.11
Number of completed applications for full ethical review	36
Number of completed applications for full ethical review over 60 days	0
Number of completed applications over 60 days as a % of total	0.00%
Number of completed applications for full ethical review over 40 days	1
Number of completed applications over 40 days as a % of total	2.70%
Number of days taken to final decision – average (mean)	25
Number of completed proportionate review applications for ethical review	37
Number of completed proportionate review applications for ethical review over 14 days. (Please note, the timeline for the review of PR applications was extended from 14 to 21 days in December 2016)	7
Number of completed proportionate review applications for ethical review over 21 days.	0
Number of completed proportionate review applications over 14 days as a % of total	18.92%
Number of SSAs (non-Phase 1) reviewed	3
Number of completed applications for SSA review over 25 days	0
Number of completed applications for SSA review over 25 days as % of all non- Phase 1 SSAs	0.00%
Number of SSAs (Phase 1) reviewed	0
Number of completed applications for SSA review over 14 days	0
Number of completed applications for SSA review over 14 days as % of all Phase 1 SSAs	0.00%
Number of substantial amendments reviewed	68
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 completed substantial amendments over 28 days	0
Number of completed substantial amendments over 28 days as a % of total substantial amendments	0.00%
Number of modified amendments reviewed	0
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	68

Number of substantial amendments received for information	0
Number of substantial amendments received for new sites/PIs	0
Number of annual progress reports received	65
Number of safety reports received	1
Number of Serious Adverse Events received	1
Number of final reports received	9

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

Further Information Favourable Opinion with Standard Conditions		
REC Reference	Title	Number of Days on Clock
16/WM/0189	PanOptix Trifocal IOL (ILH297-P003)	26
16/WM/0191	Measure of engagement of epilepsy patients in messaging groups	17
16/WM/0195	Frailty Assessment in Elderly Patients with Ischemic Heart Disease(V1)	17
16/WM/0196	Circulating cells in advanced cancer (CICATRIx)	22
16/WM/0226	PROMOTER Trial	22
16/WM/0235	SAFE study	26
16/WM/0242	The effects of hyperglycaemia on the response to acute exercise (v2)	22
16/WM/0267	Macroprolactinaemia: epidemiology, pathophysiology, clinical relevance	24
16/WM/0271	Contour Neurovascular System, IA study	34
16/WM/0277	COSMIST	24
16/WM/0278	Qualitative retrospective study of FGM women accessing UK maternity	25
16/WM/0339	TREAT-2: Oral anticoagulation in AF stratified by SAME-TT2R2 score	27
16/WM/0361	Use of chest x-ray in the estimation of the tracheal diameter size	30
16/WM/0394	Exercise for people with multiple sclerosis	20
16/WM/0397	Co-designing dementia care to improve value (v4)	22
16/WM/0407	Effect of a new toothpaste on dentine hypersensitivity	20
16/WM/0410	Reproductive issues in SA female patients with IBD - Version 1	23
16/WM/0412	UK national study on referral time to hospice care before death	28
16/WM/0423	Tommy's Birmingham - Miscarriage Research Project	22
16/WM/0434	REFRAME RPD	28
16/WM/0439	EndoStim CS-100 FDA study	29
16/WM/0482	Men's experiences of engaging with psychological therapy.	34
16/WM/0502	Cognitive Behavioural Therapy to reduce anxiety and depression in AF	22
16/WM/0505	MAP (Movement through Active Personalised engagement)	24
17/WM/0004	Routes into the breast clinic v001	42
17/WM/0028	PROTECT NEURO	20

Further Information Favourable Opinion with Additional Conditions		
REC Reference	Title	Number of Days on Clock
16/WM/0223	Use of patient experience data in inpatient mental health services	24

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
None		

Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
16/WM/0288	Feasibility of a psychological intervention for rDKA	20
16/WM/0489	LCI RESCUE	20
17/WM/0013	AF-GEN-UK: UK extension of Long-term Registry of Atrial Fibrillation	22

Unfavourable Opinion

REC Reference	Title	Number of Days on Clock
16/WM/0234	Antibiotic prescribing and resistance	22

Provisional Opinion

REC Reference	Title	Number of Days on Clock
16/WM/0492	Arterial reperfusion first in DCD liver transplantation	n/a
17/WM/0030	Prospective Observational Study of Innovotherapy.	n/a
17/WM/0091	DNACPR Decisions: Perceptions of older patients and their families	n/a
17/WM/0111	The COSUMO study- Defining a Core Outcome Set in patients with Uveitis	n/a
17/WM/0114	Phenylalanine supplementation in Tyrosinemia type 1	n/a

Provisional Opinion Pending Consultation with Referee

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
16/WM/0357	Tommy's Miscarriage Research in Birmingham	47

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

Further Information Favourable Opinion with Standard Conditions		
REC Reference	Title	Number of Days on Clock
16/WM/0182	Morphology in Supraventricular Tachycardia (MIST)	18
16/WM/0202	Simulation Training – The Patient and Public Perspective	8
16/WM/0240	Investigation of set shifting in bariatric surgery patients	9
16/WM/0247	APPRECIATE (Apremilast clinical treatment experience in psoriasis)	2
16/WM/0292	Patients' expectations and experiences of total knee replacement.	11
16/WM/0295	SELFIE	5
16/WM/0335	Influenza vaccination and COPD phenotypes	6
16/WM/0336	Effect of spirometry with reversibility testing on the vasculature	6
16/WM/0338	Health sensing technologies in people with inflammatory bowel disease.	8
16/WM/0376	Mindfulness for sleep disturbance in dementia	13
16/WM/0377	Workforce capability and capacity for integrated working in Vanguard	12
16/WM/0418	The detection of circulating tumour cells by immunohistochemistry	12
16/WM/0422	Characterising Immunocytochemical Expression Levels of Survivin	10
16/WM/0443	Ploidy and stroma in early rectal cancer	15
16/WM/0447	Tissue engineering approaches to treat COPD	13
16/WM/0449	Understanding Autism Spectrum Disorder in Adulthood	13
16/WM/0517	Initial validation of the SPANS in an ID sample	8
16/WM/0518	Identifying untreated hearing loss in MCI	12
16/WM/0519	Mindful Yoga for Young People with Skin disease	12
16/WM/0522	Feasibility study of a new peripheral oedema monitor for heart failure	12
17/WM/0034	VICTOR Study	13
17/WM/0035	Improving Detection of AF in patients after TIA (ID-AF)	9
17/WM/0036	“My Life After Stroke” - a feasibility study	18
17/WM/0037	Quality of life and attitudes towards ageing among older adults	10
17/WM/0073	Recruitment- Healthy volunteers	21

Further Information Favourable Opinion with Additional Conditions		
REC Reference	Title	Number of Days on Clock
16/WM/0184	Impact of Modern Oral Health Education on Oral Microbiota	21
16/WM/0337	Use of MRI assessment in patients with renal disease.	8
16/WM/0416	ACP RACPC	12

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

Favourable Opinion with Standard Conditions		
REC Reference	Title	Number of Days on Clock
16/WM/0187	OCEAN Study	16
16/WM/0236	Using My Extracted Teeth For Research	13
16/WM/0238	Antimicrobial resistance for Neisseria gonorrhoeae version 9 18/02/16	9
16/WM/0372	Placental Changes in Diabetic Pregnancies Resulting in Stillbirth	12
16/WM/0419	Socio-economic status and prognosis in pulmonary hypertension	10
16/WM/0441	Mental health of mothers of children with intellectual disabilities v1	13

Favourable Opinion with Additional Conditions		
REC Reference	Title	Number of Days on Clock
17/WM/0072	Diagnostic Study for abbreviated oral plaque and bleeding scores	15
17/WM/0112	Validation of a POEM (patient reported outcome and experience measure)	8
17/WM/0113	How does PCF relate to spirometry in lung transplantation?	8

Unfavourable Opinion		
REC Reference	Title	Number of Days on Clock

Provisional Opinion		
REC Reference	Title	Number of Days on Clock

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
05/Q2707/8/AM11	Heart failure with preserved ejection fraction	SA10	27/07/2016	16
06/Q2707/124/AM04	Non-invasive markers of hepatic fibrosis in children	SA v7	13/09/2016	5
08/H1207/80/AM13	Ocrelizumab .v. Avonex .v. placebo in patients with RRMS.	SA WA21493 version E	08/04/2016	10
08/H1207/80/AM15	Ocrelizumab .v. Avonex .v. placebo in patients with RRMS.	WA21493 version F dated 22 Dec	15/12/2016	19
10/H1207/67/AM05	Molecular markers of organ dysfunction in transplantation	SA#04	03/10/2016	2
11/H1207/7/AM10	Cognitive assessment of paediatric neurodegenerative disease	SA#8	08/11/2016	6
11/WM/0041/AM03	Primary Immunodeficiencies (Version 1.0)	SA#04	21/06/2016	6
11/WM/0041/AM04	Primary Immunodeficiencies (Version 1.0)	SA#04-1	19/09/2016	10
11/WM/0237/AM03	Inflammation and metabolic disease	SA#03	05/07/2016	3
12/WM/0010/AM07	PRiDE Study ver.1	SA#06	22/04/2016	6
12/WM/0010/AM09	PRiDE Study ver.1	SA#08	21/12/2016	6
13/WM/0202/AM04	Leucopatch II	SA02_28 Oct 2016	30/11/2016	5
13/WM/0234/AM06	ESSBR – Effectiveness of Single Stage Breast Reconstruction	Amendment 6	11/10/2016	7
13/WM/0251/AM02	ToPiC-II: The Sensations Provoking Cough	SA#02	09/08/2016	3
13/WM/0369/AM02	The ChilSFree Trial	SA#02	11/03/2016	11
13/WM/0406/AM03	DuoDERM Extra Thin Film Layer Wear Test (CW-0066-13-U370)	SA#02	16/09/2016	7
14/WM/0002/AM01	Skin temperature sensor to identify hypoglycaemia.	SA#01	05/04/2016	2
14/WM/0109/AM02	Molecular markers of fat use and storage in myocardial tissue	SA#02	04/05/2016	5
14/WM/1007/AM01	Sealants for children having decayed teeth extracted under GA: v 1.0	SA#01	28/07/2016	4
14/WM/1008/AM01	Physiotherapy for children with dysfunctional breathing	SA#01	03/05/2016	2

14/WM/1075/AM02	Executive and social functioning in patients with Tyrosinemia Type 1	SA#01	16/10/2016	3
14/WM/1083/AM08	Cognitive Rehabilitation for Attention and Memory in people with MS	SA#05	08/12/2016	8
14/WM/1104/AM05	HEATHER	3	04/08/2016	5
14/WM/1136/AM06	Libre Performance Check, version 1.0	SA#02	04/08/2016	15
14/WM/1136/AM09	Libre Performance Check, version 1.0	SA#03	29/11/2016	4
14/WM/1204/AM04	Follow up of a cohort of young adults with Type 2 diabetes	SA#02	23/03/2016	13
14/WM/1263/AM02	EktoTherix Tissue Repair Scaffold - EKT01	SA#01	31/05/2016	2
15/WM/0052/AM08	The MILESTONE Study: Improving Transition from CAMHS to AMHS v1.0	SA#03	25/03/2016	15
15/WM/0052/AM10	The MILESTONE Study: Improving Transition from CAMHS to AMHS v1.0	SA#04	01/08/2016	1
15/WM/0053/AM01	Neural monitoring of the superior laryngeal nerve in thyroid surgery	SA#01	08/11/2016	2
15/WM/0098/AM02	Dilapan-S/Dilasoft E-Registry in Induction of Labour	SA#02	12/05/2016	4
15/WM/0105/AM01	Pilot study testing feasibility of creatinine clearance in PICU	SA#01	27/04/2016	4
15/WM/0137/AM01	Intelligent oxygen therapy in type II respiratory failure during sleep	SA#01	23/08/2016	23
15/WM/0142/AM02	Feasibility of Other Orthosis for Talipes (FOOT) trial	SA#01	07/09/2016	7
15/WM/0142/AM03	Feasibility of Other Orthosis for Talipes (FOOT) trial	SA#02	11/01/2017	4
15/WM/0147/AM02	AMPSIM	SA#02	06/05/2016	4
15/WM/0147/AM03	AMPSIM	SA#03	12/09/2016	8
15/WM/0194/AM01	BOOST	SA#01	01/12/2016	6
15/WM/0267/AM01	The 1,000 Families Study	SA 1	13/02/2017	7
15/WM/0295/AM01	Scratch in Miscarriage	SA#01	06/04/2016	6
15/WM/0338/AM05	Cognitive performance among men receiving ADT	SA 1	19/12/2016	2
15/WM/0378/AM03	Birmingham Objective Scar Scale Study	SA#02	28/04/2016	1
15/WM/0378/AM04	Birmingham Objective Scar Scale Study	SA#03	25/07/2016	8
15/WM/0396/AM01	HUMUS	SA#01	23/06/2016	1
15/WM/0396/AM02	HUMUS	SA#02	11/11/2016	2
15/WM/0415/AM02	PRIMAL	SA2	09/06/2016	8
15/WM/0417/AM01	Cortical electrical stimulation for the treatment of focal epilepsy	SA#01	22/11/2016	2
15/WM/0431/AM03	Possible predictors of Major Adverse Cardiac Events	SA#01	01/12/2016	18
15/WM/0466/AM01	Development of the PES-PD	1	15/07/2016	6
16/WM/0022/AM02	Performance of RapidRhythm for Atrial Fibrillation in Primary	SA#01	21/10/2016	3

	Care V1			
16/WM/0029/AM01	Bumps and Babies Longitudinal Study 'BaBBLLeS'	SA#01	24/03/2016	11
16/WM/0029/AM02	Bumps and Babies Longitudinal Study 'BaBBLLeS'	SA#02	29/06/2016	8
16/WM/0029/AM03	Bumps and Babies Longitudinal Study 'BaBBLLeS'	SA#03	07/12/2016	12
16/WM/0029/AM05	Bumps and Babies Longitudinal Study 'BaBBLLeS'	SA#04	27/01/2017	6
16/WM/0033/AM02	Blood-borne Virus Testing in the ED	SA#01	13/06/2016	19
16/WM/0091/AM02	Trunk motor control	SA#01	16/06/2016	8
16/WM/0143/AM01	RESIST: Understanding the role of depression in heart disease v1.0	SA#01	05/07/2016	3
16/WM/0143/AM03	RESIST: Understanding the role of depression in heart disease v1.0	SA 2	06/02/2017	7
16/WM/0145/AM01	Database Development for Newborn Screening Disorders.	SA#01	30/06/2016	8
16/WM/0196/AM01	Circulating cells in advanced cancer (CICATRlx)	SA#01	24/10/2016	1
16/WM/0242/AM01	The effects of hyperglycaemia on the response to acute exercise (v2)	Amendment 1	01/07/2016	3
16/WM/0242/AM02	The effects of hyperglycaemia on the response to acute exercise (v2)	Amendment 2	25/10/2016	4
16/WM/0288/AM01	Feasibility of a psychological intervention for rDKA	SA#01	02/08/2016	11
16/WM/0335/AM01	Influenza vaccination and COPD phenotypes		23/08/2016	8
16/WM/0339/AM01	TREAT-2: Oral anticoagulation in AF stratified by SAME-TT2R2 score	SA 1	28/02/2017	2
16/WM/0505/AM01	MAP (Movement through Active Personalised engagement)	1	09/02/2017	5
16/WM/0518/AM01	Identifying untreated hearing loss in MCI	SA#01	26/01/2017	3
2003/242/AM05	Chemokines involved in the development of Primary Sclerosing Cholangitis, Idiopathic Inflammatory Bowel Disease and Colorectal Cancer	Amendment 4	18/07/2016	1

Unfavourable opinion

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
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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

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 21 day timeline

REC Reference	Title	Number of Days on Clock
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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
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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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