

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

**Annual Report**

**01 April 2015 - 31 March 2016**



## Part 1 – Committee Membership and Training

<b>Name of REC:</b>	West Midlands - South Birmingham Research Ethics Committee
<b>Type of REC:</b>	Authorised REC
<b>Type of Flag:</b>	Medical Devices Paediatrics
<b>Chair:</b>	Professor Simon Bowman
<b>Vice-Chair:</b>	Dr John David Cochrane
<b>Alternate Vice-Chair:</b>	Rev'd Dr Barry Clark
<b>REC Manager:</b>	Ms Penelope Gregory from 01/04/2015
<b>REC Assistant:</b>	Ms Nicola Kohut from 01/04/2015 to 31/01/2016 Mr Tadeuz Jones from 01/02/2016
<b>Committee Address:</b>	The Old Chapel Royal Standard Place Nottingham NG1 6FS
<b>Telephone:</b>	0207 1048097 / 0207 1048101
<b>Email:</b>	nrescommittee.westmidlands-southbirmingham@nhs.net

### **Chair's overview of the past year:**

We have had another productive year. I would like to thank John Cochrane (Vice-Chair) and Barry Clark (Alternate Vice-Chair) for their support and proportionate review contributions and all the committee members for their commitment and dedication to the work of the committee.

We were delighted to welcome Professor Paula McGee who joined the Committee.

We were similarly delighted to welcome Penelope Gregory the new REC Manager and Tad Jones the new REC Assistant.

We reviewed 51 applications for full ethical review and 32 applications for proportionate review.

## 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	
Ms Philippa Burgon	Support Worker	Lay Plus	01/05/2010	
Rev'd Dr Barry Clark	Retired Hospital Chaplain	Lay Plus	01/08/2009	
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	
Mr Liviu Marius Hanu-Cernat	Consultant Maxillofacial Surgeon	Expert	18/08/2011	
Dr Dalvina Hanu-Cernat	Consultant in Anaesthesia and Pain Medicine	Expert	01/10/2007	
Dr Elizabeth Hensel	Honorary Research Fellow/Clinical Lecturer	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	

## West Midlands - South Birmingham Research Ethics Committee: Deputy Members

Name	Profession	Status	Meeting date attended
None			

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

Name	Profession	Status	Meeting date attended
Dr Ronald Jubb	Retired Consultant Rheumatologist	Expert	15/09/2015
Reverend Keith Lackenby	Reverend	Lay Plus	15/09/2015
Mrs Lynne Gray	Senior Biomedical Scientist	Expert	18/08/2015 17/11/2015

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

<b>Name</b>	<b>Declaration of Interest</b>	<b>Date</b>
Mr Michael Andrews	None declared	11/12/2015
Professor Simon Bowman	SB has a special interest in a condition called 'Sjogren's Syndrome. In this capacity, SB has provided consultancy services for the following: Celgene, Eli Lilly, Glenmark, GSK, Medimmune, Novartis, Ono, Pfizer, Roche, Takeda, UCB. Roche provided Rituximab without charge for the TRACTISS study sponsored by Arthritis Research UK.  Trustee until 01.05.2016 of the British Society for Rheumatology.  Trustee British Sjogren's Syndrome Association	14/02/2016
Ms Philippa Burgon	Occasional lay reviewer for Research Design Service South West (project review committee)	06/12/2015
Rev'd Dr Barry Clark	Chair of Patient and Public Involvement Supervisory Committee for CLAHRC - WM. Member of Programme Executive Committee for CLAHRC - WM	10/12/2015
Dr John David Cochrane	None declared	15/12/2015
Dr Mary Glover	As University lecturer is involved in supervising undergraduate and postgraduate research. On occasions peer reviews research proposals.	01/06/2015
Dr Peter Guest	PI on some research projects. AMAL and IRMER activities for number of studies Participant on some research studies.	14/12/2015
Dr Elizabeth Hensel	Honorary clinical lecturer, School of psychology, University of Birmingham and Honorary clinical researcher, psychology dept, University Hospitals Foundation Trust, Birmingham. Public Governor, University Hospitals Birmingham Foundation Trust.	17/02/2016
Dr Kathryn Kinmond	Research with UHNM	02/02/2016
Professor Paula McGee	Emerita Professor at Birmingham City University	20/05/2015
Mrs Andal Thirumalai	None declared	15/12/2015
Mr Sunil Solomon Thomas	Vice Chairman - FOL - Friends of Ludhiana - Registered Charity	15/12/2015

### Meetings for Full Ethical Review 01 April 2015 - 31 March 2016:

Month	Date	Number of Members Present at Meeting
April	21/04/2015	12
May	19/05/2015	10
June	16/06/2015	10
August	18/08/2015	9
September	15/09/2015	10
October	20/10/2015	12
November	17/11/2015	10
December	15/12/2015	11
January	19/01/2016	8
March	15/03/2016	12

10 full committee meetings were held during the reporting period.

### Proportionate Review Sub-Committee Meetings held during 01 April 2015 - 31 March 2016:

Month	Date	Number of Members Present at Meeting
April	21/04/2015	3
May	19/05/2015	3
July	21/07/2015	3
August	18/08/2015	3
September	15/09/2015	3
October	20/10/2015	3
November	17/11/2015	3
December	15/12/2015	3
January	19/01/2016	3
February	16/02/2016	3
March	15/03/2016	3

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

### Sub-Committee Meetings held during 01 April 2015 - 31 March 2016:

Month	Date	Number of Members Present at Meeting
April	10/04/2015	2
April	17/04/2015	2
April	24/04/2015	2
May	01/05/2015	2
May	08/05/2015	2
May	22/05/2015	2
June	12/06/2015	2
June	19/06/2015	2
June	26/06/2015	2
July	03/07/2015	2

July	10/07/2015	2
July	17/07/2015	3
July	31/07/2015	2
August	07/08/2015	2
August	14/08/2015	2
August	21/08/2015	2
September	25/09/2015	2
October	02/10/2015	2
October	09/10/2015	2
October	16/10/2015	2
October	30/10/2015	2
December	04/12/2015	2
December	11/12/2015	2
December	18/12/2015	2
December	22/12/2015	2
January	08/01/2016	2
January	22/01/2016	2
January	29/01/2016	2
February	05/02/2016	2
February	12/02/2016	2
February	19/02/2016	2
March	04/03/2016	2
March	11/03/2016	2
March	25/03/2016	2

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

#### Details of inquorate meeting held: 01 April 2015 - 31 March 2016

None

### Attendance of Members at full committee meetings: 01 April 2015 - 31 March 2016

Name	Number of Meetings Attended
Mr Michael Andrews	8
Professor Simon Bowman	9
Ms Philippa Burgon	8
Rev'd Dr Barry Clark	9
Dr John David Cochrane	9
Dr Mary Glover	5
Dr Peter Guest	9
Dr Dalvina Hanu-Cernat	6
Mr Liviu Marius Hanu-Cernat	7
Dr Elizabeth Hensel	6
Dr Kathryn Kinmond	5
Professor Paula McGee	8
Mrs Andal Thirumalai	3
Mr Sunil Solomon Thomas	8

### Attendance of Members at proportionate review sub-committee meetings: 01 April 2015 - 31 March 2016

Name	Number of Meetings Attended
Mr Michael Andrews	1
Professor Simon Bowman	10
Ms Philippa Burgon	1
Rev'd Dr Barry Clark	11
Dr John David Cochrane	9
Professor Paula McGee	1

### Attendance of Members at sub-committee meetings: 01 April 2015 - 31 March 2016

Name	Number of Meetings Attended
Professor Simon Bowman	34
Rev'd Dr Barry Clark	2
Dr John David Cochrane	33

**Training 01 April 2015 - 31 March 2016**

<b>Name of Member</b>	<b>Date</b>	<b>Event(s) attended</b>
Mr Michael Andrews	25/09/2015	HRA Regional Training Day
Professor Simon Bowman	07/05/2015	NREAP Meeting
Professor Simon Bowman	09/12/2015	National Training Day for Committee Chairs
Ms Philippa Burgon	19/11/2015	Personal Data in Research
Rev'd Dr Barry Clark	13/01/2016	Assessing the consequences (benefits and harms) of Research: a HRA workshop
Dr John David Cochrane	07/05/2015	NREAP Meeting
Dr John David Cochrane	25/09/2015	HRA Members Training Day
Dr John David Cochrane	09/12/2015	National Training Day for Committee Chairs
Dr Mary Glover	01/03/2016	SDL - Teaching - Ethical, Professional and Contextual Issues
Dr Mary Glover	14/03/2016	SDL - Professional Meeting - United Kingdom Council Psychotherapists Ethics committee internal consultation
Dr Mary Glover	31/03/2016	SDL - Reading
Dr Peter Guest	29/09/2015	Training - Genetic and Genomic Research (prev HTA advanced)
Dr Elizabeth Hensel	04/11/2015	Committee Member Induction
Dr Kathryn Kinmond	30/09/2015	Preparation and submission of NIHR i4i funded project
Dr Kathryn Kinmond	14/01/2016	Reading and preparation of lecture material for PG session on research ethics
Dr Kathryn Kinmond	10/03/2016	Faculty Chair of Ethics at MMU in Crewe - preparation / reading
Professor Paula McGee	25/09/2015	HRA Regional Training Day
Professor Paula McGee	04/11/2015	Committee Members Induction
Professor Paula McGee	13/01/2016	Assessing the consequences (benefits and harms) of Research: a HRA workshop
Mrs Andal Thirumalai	25/09/2015	HRA Regional 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)	1	1.96
Others	50	98.04
<b>Total Applications Reviewed</b>	<b>51</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	3
Number of applications withdrawn prior to the meeting	2
Number of student applications reviewed	26
Number of paediatric applications reviewed	7
Number of device applications reviewed	11
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	9

**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	2	3.92
Favourable Opinion with Additional Conditions	6	11.76
Unfavourable Opinion	1	1.96
Provisional Opinion	42	82.35
Provisional Opinion Pending Consultation with Referee	0	0.00
<b>Total</b>	<b>51</b>	<b>100</b>
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	33	64.71
Further Information Favourable Opinion with Additional Conditions	9	17.65
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	2	3.92
Favourable Opinion with Additional Conditions	6	11.76
Unfavourable Opinion	1	1.96
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
<b>Total</b>	<b>51</b>	<b>100</b>

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

<b>Total Applications Reviewed</b>	<b>32</b>
------------------------------------	-----------

**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	5
Number of student applications reviewed	9
Number of paediatric applications reviewed	3
Number of device applications reviewed	1
Number of qualitative applications reviewed	9

**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	5	15.63
Favourable Opinion with Additional Conditions	15	46.88
No Opinion transfer to full committee for review	1	3.13
Provisional Opinion	10	31.25
Unfavourable Opinion	1	3.13
<b>Total</b>	<b>32</b>	<b>100</b>

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

Average number of applications reviewed per full meeting	5.10
Number of completed applications for full ethical review	51
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	0
Number of completed applications over 40 days as a % of total	0.00%
Number of days taken to final decision – average (mean)	25
Number of completed proportionate review applications for ethical review	31
Number of completed proportionate review applications for ethical review over 14 days	0
Number of completed proportionate review applications over 14 days as a % of total	0.00%
Number of SSAs (non-Phase 1) reviewed	0
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	67
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	1
Number of completed substantial amendments over 28 days as a % of total substantial amendments	1.49%
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 minor amendments received	55
Number of substantial amendments received for information	0
Number of substantial amendments received for new sites/PIs	0
Number of annual progress reports received	104

<b>Number of safety reports received</b>	2
<b>Number of Serious Adverse Events received</b>	2
<b>Number of final reports received</b>	47

**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>
15/WM/0105	Pilot study testing feasibility of creatinine clearance in PICU	26
15/WM/0138	Vestibular Function in Patients with Vestibular Schwannoma	26
15/WM/0142	Feasibility of Other Orthosis for Talipes (FOOT) trial	26
15/WM/0147	AMPSIM	23
15/WM/0168	Shared Decision Making in Rheumatoid Arthritis Care . V1	28
15/WM/0170	GTPS: does shockwave therapy help?	24
15/WM/0174	Impact of stoma for constipation	27
15/WM/0176	Communicating Genetic Research in Complex Neurological Diseases	25
15/WM/0194	BOOST	29
15/WM/0196	The experience of arranging a marriage for a son / daughter with a LD	27
15/WM/0198	Managing spasticity and contracture with vibration and standing frames	27
15/WM/0201	Development of Imaging Techniques for MRI Scanners.	26
15/WM/0260	ACUte effects of SITting time in older adults (ACUSIT)	27
15/WM/0267	The 1,000 Families Study	25
15/WM/0271	Pornography use in Men with learning disabilities.	23
15/WM/0273	Proteomic effects of metformin on myocardial ischaemia-reperfusion	28
15/WM/0277	IRTIVA v1.3	24
15/WM/0305	Men's experiences of living with a diagnosis of Bipolar Disorder	23
15/WM/0306	The QUBES Study	34
15/WM/0313	Understanding the challenges and impact of parenting with epilepsy	23
15/WM/0378	Birmingham Objective Scar Scale Study	23
15/WM/0416	Shame, psychological flexibility, substance use and mental health	23
15/WM/0417	Cortical electrical stimulation for the treatment of focal epilepsy	33
15/WM/0446	Young offenders in transition from child to adult services	36
15/WM/0452	Dietary carbohydrate and substrate oxidation during exercise	22
15/WM/0465	Measurement of preplatelets in inherited and acquired thrombocytopenia	24
15/WM/0466	Development of the PES-PD	34
16/WM/0022	Performance of RapidRhythm for Atrial Fibrillation in Primary Care V1	25
16/WM/0028	HeartLight Pulse Study	36
16/WM/0029	Bumps and Babies Longitudinal Study 'BaBBLeS'	22
16/WM/0032	Young people's views of an intensive home treatment service in Enfield	22
16/WM/0104	Adolescents and Carers experience of Dialectical Behaviour Therapy	22

16/WM/0126	Baseline cortical haemodynamics in MS	22
------------	---------------------------------------	----

#### Further Information Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
15/WM/0137	Intelligent oxygen therapy in type II respiratory failure during sleep	24
15/WM/0171	Sleep & Daytime Physical Activity in People with Chronic Pain	27
15/WM/0295	Scratch in Miscarriage	30
15/WM/0319	Repeatability and reproducibility of ArcScan Insight 100	25
15/WM/0338	Cognitive performance among men receiving ADT	27
15/WM/0348	Small incision lenticule extraction (SMILE) for high myopia	24
15/WM/0463	Guilt, Shame and Treatment in Mentally Disordered Offenders	20
16/WM/0031	Supported employment in primary and community care: a RCT	30
16/WM/0127	Zika Virus in Pregnancy Registry	24

#### 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
15/WM/0193	Warwick Spinal Immobiliser, stage 2	23
15/WM/0379	Alzheimer's disease pathology in Down's syndrome	19

#### Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
15/WM/0373	Parental experiences version 1	20
15/WM/0412	A study of fall prevention in people with memory problems	22
15/WM/0415	PRIMAL	23
15/WM/0464	cad:trauma study	21
16/WM/0033	Blood-borne Virus Testing in the ED	22
16/WM/0130	Version 1:Housing experiences of women with ID in locked care settings	20

<b>Unfavourable Opinion</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
15/WM/0408	Ethnographic study of a mental health and football project.	22

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

<b>Provisional Opinion Pending Consultation with Referee</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>

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

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

**Table 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>
15/WM/0153	The 'Lived Experience' of patients having a Cervical/Lumbar MRI scan	12
15/WM/0307	DARE v1	12
15/WM/0396	HUMUS	11
15/WM/0397	Filtered Out: Dialysis transition - patient experiences.	11
16/WM/0090	Allergy and stress in pregnancy	6
16/WM/0142	Decision aid for tinnitus	12
16/WM/0143	RESIST: Understanding the role of depression in heart disease v1.0	13

Further Information Favourable Opinion with Additional Conditions		
REC Reference	Title	Number of Days on Clock
15/WM/0431	Possible predictors of Major Adverse Cardiac Events	10
15/WM/0479	Important issues of research focus in children with ENT conditions.	14
16/WM/0145	Database Development for Newborn Screening Disorders.	13

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
15/WM/0344	eNewborn: European Neonatal Benchmarking and Evaluation Programme	8
15/WM/0429	Chimeric Antigen Receptor Selectivity - v1	9
15/WM/0430	Red cell HbA1c, reticulocytes and sialic acid	9
16/WM/0093	Pancreas physiology and pathology	10
16/WM/0094	Pedometers and healing Diabetic Foot Ulcers.	10

Favourable Opinion with Additional Conditions		
REC Reference	Title	Number of Days on Clock
15/WM/0158	1-DAY ACUVUE® Moist Multifocal Real World Through Focus Curve	8
15/WM/0189	MSK-HQ, Version 1.0	10
15/WM/0192	Patient perceptions of shared decision-making in minor injury care	9
15/WM/0269	Spectral Doppler ultrasound in the investigation of thyroid nodules	6
15/WM/0303	Standardised outcomes in nephrology- Haemodialysis (SONG-HD)	7
15/WM/0308	Seasonal variation hypo & hyperthyroidism	7
15/WM/0345	PATH-GP	7
15/WM/0347	Measuring General Practice Productivity	8
15/WM/0388	MicroRNA Expression and Function in Psoriasis III	7
15/WM/0395	Process Evaluation of a Quality Improvement Project	8
15/WM/0478	Understanding the barriers to a healthy lifestyle in T2DM patients	9
16/WM/0047	Investigation of PH nurses' knowledge about sexting and young people	7
16/WM/0051	Late follow-up with MRI of patients with corrected TAPVD v1.0	8
16/WM/0091	Trunk motor control	10

16/WM/0144	Seasonal flu vaccine health beliefs and intent post HSCT	12
------------	--	----

#### Unfavourable Opinion

REC Reference	Title	Number of Days on Clock
15/WM/0346	Patient Diaries in the Paediatric Intensive Care Unit	8

#### Provisional Opinion

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 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>
05/Q2707/8/AM09	Heart failure with preserved ejection fraction	SA8	01/06/2015	11
05/Q2707/8/AM10	Heart failure with preserved ejection fraction	SA9	13/08/2015	4
09/H1207/160/AM05	Paediatric UK Demyelinating Disease Longitudinal Study (PUDDLs)	SA3	27/03/2015	20
10/H1207/6/AM06	Determinants of progression of adult chronic kidney disease	SA#06	14/03/2016	19
10/H1207/67/AM04	Molecular markers of organ dysfunction in transplantation	SA3	22/06/2015	7
10/H1207/98/AM10	Help seeking behaviour in patients with new onset rheumatoid arthritis	SA8	13/07/2015	3
11/H1207/7/AM08	Cognitive assessment of paediatric neurodegenerative disease	6: 02/12/15	18/12/2015	12
11/H1207/7/AM09	Cognitive assessment of paediatric neurodegenerative disease	SA#07	10/03/2016	11
11/WM/0041/AM02	Primary Immunodeficiencies (Version 1.0)	SA03	09/12/2015	1
11/WM/0235/AM04	OPERA	SA5	09/07/2015	10
11/WM/0235/AM06	OPERA	SA06	18/12/2015	18
11/WM/0237/AM02	Inflammation and metabolic disease	SA2	03/03/2016	12
13/WM/0298/AM02	Intermittent cycle training in people with type 1 diabetes	SA1	28/04/2015	15
13/WM/0435/AM02	The use of GMP in the dietary management of PKU	SA2	29/06/2015	12
13/WM/0507/AM06	ETTAA	SA3	26/05/2015	6
13/WM/0507/AM09	ETTAA	4.0	18/12/2015	5
14/WM/0003/AM04	The HYDRUS V trial	Substantial Amendment - Hydrus	29/09/2015	19
14/WM/0003/AM05	The HYDRUS V trial	SA revision E	12/02/2016	10
14/WM/0045/AM06	PoC Feasibility Trial of ClinTouch-CareLoop Enhanced Management	SA6	05/05/2015	6
14/WM/0045/AM07	PoC Feasibility Trial of ClinTouch-CareLoop Enhanced Management	SA7	05/06/2015	4
14/WM/0045/AM08	PoC Feasibility Trial of ClinTouch-CareLoop Enhanced Management	SA8	26/06/2015	4
14/WM/0045/AM09	PoC Feasibility Trial of ClinTouch-CareLoop Enhanced Management	SA9	06/07/2015	4
14/WM/0109/AM01	Molecular markers of fat use and storage in myocardial tissue	SA1	01/04/2015	6

14/WM/0118/AM03	Active Assistance for Psychological Therapy (ACTISSIST)-version 1	SA2	25/03/2015	22
14/WM/0118/AM04	Active Assistance for Psychological Therapy (ACTISSIST)-version 1	SA3	13/05/2015	6
14/WM/0118/AM05	Active Assistance for Psychological Therapy (ACTISSIST)-version 1	SA4	02/07/2015	2
14/WM/0119/AM01	Brain stimulation in movement disorders	SA01	31/07/2015	5
14/WM/0150/AM03	Prenatal Assessment of Genomes and Exomes (PAGE) Birmingham arm	SA3	29/07/2015	4
14/WM/1005/AM01	Effects of body position on lung function in humans. Version 2	1.0	18/09/2015	4
14/WM/1006/AM02	Validation of the Neuropsychological Assessment Battery Screening Tool	SA1	21/04/2015	5
14/WM/1006/AM03	Validation of the Neuropsychological Assessment Battery Screening Tool	SA02	20/11/2015	7
14/WM/1010/AM03	Revascularisation, microcirculation and diabetic foot disease	SA3	24/07/2015	12
14/WM/1010/AM04	Revascularisation, microcirculation and diabetic foot disease	4	23/12/2015	7
14/WM/1083/AM03	Cognitive Rehabilitation for Attention and Memory in people with MS	SA 2.0	17/08/2015	3
14/WM/1083/AM04	Cognitive Rehabilitation for Attention and Memory in people with MS	SA03	12/10/2015	4
14/WM/1083/AM05	Cognitive Rehabilitation for Attention and Memory in people with MS	SA04	11/02/2016	4
14/WM/1104/AM01	HEATHER	SA01	17/04/2015	4
14/WM/1104/AM04	HEATHER	Substantial Amendment 2 to create Version 3.0	08/10/2015	7
14/WM/1107/AM03	U-SLEEP: Qualitative Study Version 1.0	SA2	14/05/2015	3
14/WM/1134/AM05	POPS2	SA5	21/04/2015	6
14/WM/1134/AM06	POPS2	SA#06	29/02/2016	9
14/WM/1135/AM01	A study to evaluate the safety and effectiveness of TOPS system	SA01	04/08/2015	6
14/WM/1135/AM02	A study to evaluate the safety and effectiveness of TOPS system	SA02	04/08/2015	3
14/WM/1205/AM03	The Impact of Giant Cell Arteritis (GCA) Study	SA3	17/04/2015	5
14/WM/1219/AM01	Genetic sequencing for investigation of perinatal mortality	SA1	29/05/2015	8
14/WM/1221/AM02	ExG Version 1.2	SA01	12/11/2015	2

15/WM/0037/AM01	The molecular epidemiology of ESBL genes in returning travellers	SA1	13/05/2015	3
15/WM/0037/AM02	The molecular epidemiology of ESBL genes in returning travellers	SA#02	02/02/2016	4
15/WM/0052/AM01	The MILESTONE Study: Improving Transition from CAMHS to AMHS v1.0	SA1	15/04/2015	5
15/WM/0052/AM02	The MILESTONE Study: Improving Transition from CAMHS to AMHS v1.0	SA2	06/05/2015	7
15/WM/0066/AM01	How do people with COPD use rescue medication in primary care?	SA1	14/04/2015	10
15/WM/0093/AM01	Quality of life measures for NPD type C	SA01	31/07/2015	4
15/WM/0098/AM01	Dilapan-S/Dilasoft E-Registry in Induction of Labour	SA01	14/08/2015	2
15/WM/0099/AM01	Dilapan-S / Dilasoft E-Registry in Termination of Pregnancy	SA01	14/08/2015	2
15/WM/0099/AM02	Dilapan-S / Dilasoft E-Registry in Termination of Pregnancy	SA2	11/02/2016	4
15/WM/0147/AM01	AMPSIM	SA#01	24/02/2016	5
15/WM/0170/AM02	GTPS: does shockwave therapy help?	SA09	13/08/2015	2
15/WM/0170/AM04	GTPS: does shockwave therapy help?	SA10	22/09/2015	2
15/WM/0170/AM07	GTPS: does shockwave therapy help?	SA 11	23/10/2015	3
15/WM/0176/AM01	Communicating Genetic Research in Complex Neurological Diseases	2	03/12/2015	5
15/WM/0192/AM01	Patient perceptions of shared decision-making in minor injury care	SA01	04/01/2016	4
15/WM/0347/AM02	Measuring General Practice Productivity	SA01	04/01/2016	3
15/WM/0378/AM02	Birmingham Objective Scar Scale Study	1.0	12/01/2016	7
15/WM/0479/AM01	Important issues of research focus in children with ENT conditions.	SA#01	03/03/2016	7
3359a/AM06	alpha-1-antitrypsin deficiency assessment and programme for treatment	10	01/10/2015	7
CA/5175/AM07	Molecular Pathology of Human Genetic Disease	SA06	23/07/2015	2

#### Unfavourable opinion

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
2003/028/AM07	Birmingham Children's Hospital Liver Disease Registry	SA#06	22/01/2016	34

**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

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 14 day timeline**

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

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

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

**SSAs (Phase 1) over 14 day timeline**

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

**Substantial Amendments over 35 day timeline**

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

**Modified Amendments over 14 day timeline**

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