

**West Midlands - Black Country Research Ethics  
Committee**

**Annual Report**

**01 April 2016 - 31 March 2017**



## Part 1 – Committee Membership and Training

<b>Name of REC:</b>	West Midlands - Black Country Research Ethics Committee
<b>Type of REC:</b>	Authorised REC
<b>Type of Flag:</b>	Paediatric
<b>Chair:</b>	Dr Hilary Paniagua
<b>Vice-Chair:</b>	Dr Joseph Arumainayagam
<b>Alternate Vice-Chair:</b>	Mr Nanak Singh Sarhadi
<b>REC Manager:</b>	Carolyn Halliwell
<b>REC Assistant:</b>	Teagan Allen
<b>Committee Address:</b>	The Old Chapel Royal Standard Place Nottingham NG1 6FS
<b>Telephone:</b>	0207 1048098
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## Chair's overview of the past year:

This has been a busy year in which the committee has experienced some changes in terms of its members and REC management. We have been pleased to welcome two new members to the committee Dr Giridharan Rajaratnam and Miss Nicola Brooks who quickly became part of the group. We are now working with a new REC manager and assistant and the transition seems to be working well. The changeover to holding meetings on the last Monday of the month instead of at the beginning continues to be effective as regards to attracting applications as we have an average number of 4 proposals per full meeting. Between 2-3 proportionate reviews are undertaken prior to our main meetings and doing this face to face as opposed to online seems to be more efficient and practical. We also seem to remain timely in completing applications within the given time deadlines, although there is always room for improvement. I am sure next year will remain as productive as this and we look forward to another year of work and meetings within our excellent venue and hospitality.

## West Midlands - Black Country Research Ethics Committee Membership

Name	Profession	Expert or Lay	Dates	
			Appointed	Left
Dr Joseph Arumainayagam	Consultant and Honorary Senior Clinical Lecturer in HIV and GUM	Expert	01/04/2007	
Mrs Chris Bell	Board Member	Lay Plus	01/04/2007	
Miss Nicola Brooks	Solicitor	Lay Plus	13/02/2017	
Dr Nicola Erb	Consultant Rheumatologist	Expert	01/01/2009	
Reverend Keith Lackenby	Reverend	Lay Plus	21/03/2016	30/11/2016
Dr Aisha Malik	Tutor Medical Ethics/Distance Learning Tutor for OUDCE	Expert	23/11/2015	
Dr Hilary Paniagua	Senior Lecturer	Expert	01/04/2007	
Mrs Rita Patel	Contracts and Innovation Manager	Lay	22/09/2015	14/12/2016
Dr Giridharan Rajaratnam	Deputy Regional Director	Expert	23/11/2016	
Mr Nanak Singh Sarhadi	Consultant Plastic Surgeon	Expert	01/06/2009	
Dr Julian Sonksen	Consultant in Anaesthesia and Critical Care	Expert	01/01/2008	
Reverend Mark Stobert	Hospital Chaplain	Lay Plus	01/04/2007	
Mr David Vallance	Consultant Biochemist	Expert	01/04/2007	
Mrs Jennifer Walton	Retired Research Nurse	Lay	01/11/2010	
Dr Tony Zalin	Retired Consultant Physician	Expert	01/01/2009	

## West Midlands - Black Country Research Ethics Committee: Deputy Members

None

## West Midlands - Black Country Research Ethics Committee: Co-opted Members

Name	Profession	Status	Meeting date attended
Mr Chris Foy	Medical Statistician	Expert	25/07/2016
Mr Chris Foy	Medical Statistician	Expert	22/08/2016
Mr Chris Foy	Medical Statistician	Expert	20/09/2016 (SC)
Professor Paula McGee	Professor of Nursing	Expert	27/02/2017
Mrs Bernadette Roberts	Retired Finance Manager	Lay Plus	30/01/2017

**West Midlands - Black Country Research Ethics Committee: Members' Declarations of Interest:**

<b>Name</b>	<b>Declaration of Interest</b>	<b>Date</b>
Dr Joseph Arumainayagam	None declared	31/03/2017
Mrs Chris Bell	None declared	31/03/2017
Miss Nicola Brooks	None declared	27/03/2017
Dr Giridharan Rajaratnam	Employee of Public Health England which undertakes research.	01/02/2017
Dr Nicola Erb	None declared	31/03/2017
Reverend Keith Lackenby	None declared	18/04/2016
Dr Aisha Malik	Working as a Research fellow at the Health services management centre, University of Birmingham, since January 2017	31/03/2017
Dr Hilary Paniagua	None declared	31/03/2017
Dr Julian Sonksen	Julian is a research active consultant and local PI for several NIHR portfolio studies, Chief Investigator for 1 local NIHR portfolio study.	31/03/2017
Reverend Mark Stobert	Member of Dudley Group R&D Directorate	31/03/2017
Mrs Jennifer Walton	None declared	31/03/2017
Dr Tony Zalin	Translation from French to English of French REC committee work and other regulatory authorities. The material often includes submissions by pharmaceutical companies.	31/03/2017
Dr David Vallance	Minor shareholdings in Astra-Zeneca Pharmaceuticals and GSK Pharmaceuticals. Total holding less than 100 shares per company. Trustee of The Robert Gaddie Fund. This charitable organisation (Charity no. 1016440) provides funding for research and educational activities in the field of clinical biochemistry.	21/12/2016

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

Month	Date	Number of Members Present at Meeting
May	23/05/2016	8
June	27/06/2016	8
July	25/07/2016	8
August	22/08/2016	9
September	26/09/2016	9
October	31/10/2016	7
November	28/11/2016	8
January	30/01/2017	8
February	27/02/2017	9
March	27/03/2017	9

10 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	25/04/2016	3
May	23/05/2016	3
June	27/06/2016	3
July	25/07/2016	3
August	22/08/2016	3
September	26/09/2016	5
October	31/10/2016	8
November	28/11/2016	3
February	27/02/2017	3
March	27/03/2017	3

10 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	15/04/2016	2
April	27/04/2016	2
May	12/05/2016	2
May	27/05/2016	2
June	10/06/2016	2
June	28/06/2016	2
July	08/07/2016	2
July	21/07/2016	2
August	05/08/2016	2
August	19/08/2016	2

September	02/09/2016	2
September	16/09/2016	2
September	20/09/2016	4
October	03/10/2016	2
October	28/10/2016	2
November	08/11/2016	2
December	09/12/2016	2
December	23/12/2016	2
January	06/01/2017	2
January	20/01/2017	2
February	01/02/2017	2
February	08/02/2017	2
February	20/02/2017	2
March	02/03/2017	2
March	16/03/2017	2
March	30/03/2017	2

27 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**

<b>Name</b>	<b>Number of Meetings Attended</b>
Dr Joseph Arumainayagam	7
Mrs Chris Bell	5
Miss Nicola Brooks	1
Dr Nicola Erb	7
Dr Aisha Malik	8
Dr Hilary Paniagua	8
Mrs Rita Patel	1
Dr Giridharan Rajaratnam	3
Mr Nanak Singh Sarhadi	2
Dr Julian Sonksen	4
Reverend Mark Stobert	7
Mr David Vallance	6
Mrs Jennifer Walton	7
Dr Tony Zalin	9

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

<b>Name</b>	<b>Number of Meetings Attended</b>
Dr Hilary Paniagua	1
Dr Joseph Arumainayagam	1
Mrs Chris Bell	5
Dr Nicola Erb	1
Dr Aisha Malik	4
Dr Hilary Paniagua	7
Mr Nanak Singh Sarhadi	1
Reverend Mark Stobert	3
Mr David Vallance	1
Mrs Jennifer Walton	3
Dr Tony Zalin	2

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

<b>Name</b>	<b>Number of Meetings Attended</b>
Dr Joseph Arumainayagam	26
Dr Hilary Paniagua	25
Mr Nanak Singh Sarhadi	2
Reverend Mark Stobert	1



**Training 01 April 2016 - 31 March 2017**

<b>Name of Member</b>	<b>Date</b>	<b>Event(s) attended</b>
Dr Joseph Arumainayagam	07/01/2017	Reviewing the Research Design of Clinical Trials
Dr Joseph Arumainayagam	08/01/2017	Training for non-commercial studies
Dr Joseph Arumainayagam	08/01/2017	Training for Commercial studies
Dr Joseph Arumainayagam	08/01/2017	Equality, Diversity and Human Rights
Dr Joseph Arumainayagam	08/01/2017	Reviewing research that uses quantitative methods
Dr Joseph Arumainayagam	09/01/2017	Adults lacking capacity on-line toolkit
Dr Aisha Malik	25/08/2016	Introduction to Informed Consent
Dr Aisha Malik	23/09/2016	Local Training Day - Regional
Dr Aisha Malik	15/11/2016	Bioethics for Beginners
Dr Hilary Paniagua	23/09/2016	Local Training Day - Regional
Dr Hilary Paniagua	12/01/2017	Diversity in the Workplace
Mrs Rita Patel	23/09/2016	Local Training Day Leicester
Mrs Rita Patel	19/10/2016	HARP Member's Portal Webinar
Mr Nanak Singh Sarhadi	23/09/2016	Local Training Day - Regional
Dr Julian Sonksen	19/04/2016	NREAP/Chairs Meeting – reading material
Dr Julian Sonksen	09/01/2017	Improving Healthcare through Clinical Research
Reverend Mark Stobert	19/04/2016	NREAP/Chairs Meeting – reading material
Mr David Vallance	23/09/2016	Local Training Day - Regional
Mrs Jennifer Walton	09/10/2016	Reading of ethical magazine article by BPS
Mrs Jennifer Walton	23/11/2016	Reading of Chairs Meeting Documents

## 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	4
Number of applications withdrawn prior to the meeting	0
Number of student applications reviewed	14
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	3

**Table 3: Decisions given at meetings held within the reporting period**

<b>Decisions taken at meetings following review of applications</b>	<b>Number</b>	<b>%</b>
Favourable Opinion with Standard Conditions	1	2.50
Favourable Opinion with Additional Conditions	5	12.50
Unfavourable Opinion	0	0.00
Provisional Opinion	34	85.00
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	0	

**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	28	70.00
Further Information Favourable Opinion with Additional Conditions	4	10.00
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	1	2.50
Favourable Opinion with Additional Conditions	5	12.50
Unfavourable Opinion	0	0.00
Provisional Opinion	2	5.00
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>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>21</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	8
Number of studies withdrawn prior to the meeting	0
Number of student applications reviewed	9
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	8	38.10
Favourable Opinion with Additional Conditions	6	28.57
No Opinion transfer to full committee for review	0	0.00
Provisional Opinion	6	28.57
Unfavourable Opinion	1	4.76
<b>Total</b>	<b>21</b>	<b>100</b>

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

<b>Average number of applications reviewed per full meeting</b>	4.00
<b>Number of completed applications for full ethical review</b>	40
<b>Number of completed applications for full ethical review over 60 days</b>	0
<b>Number of completed applications over 60 days as a % of total</b>	0.00%
<b>Number of completed applications for full ethical review over 40 days</b>	3
<b>Number of completed applications over 40 days as a % of total</b>	7.50%
<b>Number of days taken to final decision – average (mean)</b>	29
<b>Number of completed proportionate review applications for ethical review over 21 days</b>	21
<b>Number of completed proportionate review applications for ethical review over 14 days</b>	1
<b>Number of completed proportionate review applications over 14 days as a % of total</b>	4.76%
<b>Number of SSAs (non-Phase 1) reviewed</b>	3
<b>Number of completed applications for SSA review over 25 days</b>	0
<b>Number of completed 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 completed applications for SSA review over 14 days</b>	0
<b>Number of completed applications for SSA review over 14 days as % of all Phase 1 SSAs</b>	0.00%
<b>Number of substantial amendments reviewed</b>	68
<b>Number of completed substantial amendments over 35 days</b>	0
<b>Number of completed substantial amendments over 35 days as a % of total substantial amendments</b>	0.00%
<b>Number of completed substantial amendments over 28 days</b>	1
<b>Number of completed substantial amendments over 28 days as a % of total substantial amendments</b>	1.47%
<b>Number of modified amendments reviewed</b>	0
<b>Number of completed modified amendments over 14 days</b>	0
<b>Number of completed modified amendments over 14 days as a % of total modified amendments</b>	0.00%
<b>Number of non substantial amendments received</b>	67
<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>	42

<b>Number of safety reports received</b>	1
<b>Number of Serious Adverse Events received</b>	4
<b>Number of final reports received</b>	18

**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>
16/WM/0232	Inactivity, excess body weight, and the muscle secretome (v3)	28
16/WM/0243	Enhancing the capture and use of patient experience data	35
16/WM/0273	AQUEDUCT (v1)	38
16/WM/0289	NSMM-5001, the INSIGHT-MM study	30
16/WM/0296	The role of protein turnover in muscle responses to aerobic exercise	39
16/WM/0301	The impact of female pattern hair loss on quality of life	31
16/WM/0320	Comparison of RO with standard dressings for treatment of ulcers	35
16/WM/0352	Educational intervention for the management of constipation	39
16/WM/0368	Hoarding behaviours in ADHD	27
16/WM/0371	Sedentary behaviour and physical activity in RA and OA	26
16/WM/0374	Fatigue in Vasculitis - FAB-V	30
16/WM/0375	Blood sampling method for sleep studies v2	28
16/WM/0414	A loaded self-managed exercise programme for patellofemoral pain	34
16/WM/0420	Psychological factors, pain and fatigue in cancer survivors	29
16/WM/0457	CODEC Study	22
16/WM/0483	Preventing bed-rest induced muscle loss in the elderly	43
16/WM/0490	Communicating information from MRI - patient and parent views v1.0	30
16/WM/0496	PBR28-PET in Crohn's disease	42
17/WM/0001	Nutrition and endurance training induced mitochondrial biogenesis	22
17/WM/0014	Body Composition of Rugby League Players V.1	31
17/WM/0019	Foot assessment in people with Diabetes	25
17/WM/0038	Spiritual & emotional needs of siblings of a child with a rare disease	30
17/WM/0058	Home-based HIIT in people with T1D	25
17/WM/0068	LYSOTRACK-ageing	28
17/WM/0070	Physiological characteristics of elite Taekwondo players	23
17/WM/0084	Alphavbeta6 PET in Radiation induced Lung fibrosis (EARL)	29
17/WM/0125	ADIE to prevent development of anxiety disorders in autism - version 1	19
17/WM/0128	Feasibility study of an app-based intervention to improve wellbeing	21



17/WM/0129	Face Mask Human Factors Formative Study	18
17/WM/0130	EDISON	18

#### Further Information Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
16/WM/0303	Gellan Contact Study (Gellan sheet and fluid gel)	33
16/WM/0316	Reducing misdiagnosis of urinary tract infection in older adults	41
16/WM/0327	Evaluation of Practical Body Image therapy for Anorexia Nervosa V2	37
17/WM/0082	PBR28-PET in Inflammatory Joint disease (ASTRID)	28

#### 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
16/WM/0291	Patterns, meanings and mindsets of revenge v.1	25

#### Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
16/WM/0245	SortED - Use of a tablet application for initial clinical assessment	22
16/WM/0321	KinematicTKR Pilot Study KARMA	33
16/WM/0413	Human arteries as biological scaffolds in islet transplantation	21
17/WM/0039	IDENTIFY-HF Study, Version 1.0	22
17/WM/0127	Living With and Beyond Cancer study	17

#### Unfavourable Opinion

REC Reference	Title	Number of Days on Clock
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<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>
16/WM/0387	Cognitive Function & Type 2 Diabetes: A Study of Working Age Adults	11
16/WM/0388	Extra renal involvement in Polycystic Kidney Disease	9
16/WM/0390	The feasibility of using telemedicine for vestibular rehabilitation V1	9
16/WM/0466	Telephone Delivery of a Health Coaching Service	14
17/WM/0085	Explore Weight Post Heart Transplantation Study	13
17/WM/0124	Vascular stiffness in end-stage kidney disease	13

<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>
16/WM/0199	Risk of Infection Using Agluna Treated METS System	14
16/WM/0252	Human intervention study investigating the PRECIOUS Food intake tool.	8
16/WM/0312	Imaging characteristics of childhood brain ATRT molecular subgroups	7
16/WM/0344	Evaluation of a new PCR method for targeting carbapenemase-producers	8
16/WM/0469	Investigating the tumour microenvironment in prostate cancer	7
16/WM/0499	Linking childhood cognition to health and administrative data	8
16/WM/0500	Emergency Laparotomy and Frailty (ELF)	8
17/WM/0083	Effect of comorbid mental disorders on CVD and diabetes outcomes	17

<b>Favourable Opinion with Additional Conditions</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
16/WM/0203	Access to samples for development of new tests for bladder cancer	8
16/WM/0214	A role for immunology and nutrition in pancreatic cancer. 16/WM/0214	8
16/WM/0250	PGL14-001 (PREMIUM) - non-interventional study, safety of Esmya	8
16/WM/0308	Cardiometabolic health and IVF/ICSI outcome (Ver. 2.1)	8
16/WM/0425	Further insights into the management of type 2 diabetes	11
16/WM/0497	Natural History Study of C3 Glomerulopathy	7

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

16/WM/0427	Shame Memories, Identity and Well-being V1	10
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<b>Provisional Opinion</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 10.1: Breakdown of current status of all substantial amendments reviewed within the reporting period**

<b>Favourable opinion</b>				
<b>Amendment REC Reference</b>	<b>Title</b>	<b>Version</b>	<b>Date</b>	<b>Number of Days on Clock</b>
04/Q2604/10/AM13	ACTIVE Version 1	12	02/02/2016	3
06/Q2604/11/AM06	A study of lapatinib in breast cancer brain metastases	Substantial Amendment 10	10/02/2017	14
06/Q2702/63/AM03	Immune mechanisms in the ocular microenvironment	3	11/05/2016	11
09/H1204/30/AM07	IBD in Oxford: a prospective cohort	4	29/02/2016	7
11/WM/0224/AM01	Enzymatic deglycation - an explanation for variation in HbA1c	Substantial Amendment 1	27/03/2017	9
11/WM/0396/AM02	Exercise capacity & vascular function in HLHS patients	2	25/05/2016	35
12/WM/0049/AM02	Asthma, Obesity and Obstructive Sleep Apnoea Study	3	13/04/2016	8
12/WM/0049/AM03	Asthma, Obesity and Obstructive Sleep Apnoea Study	3	04/08/2016	15
12/WM/0049/AM04	Asthma, Obesity and Obstructive Sleep Apnoea Study	5	08/12/2016	23
12/WM/0166/AM03	A Prospective Multi-ethnic Cohort of Young Adults with Type 2 Diabetes	1	13/04/2016	19
12/WM/0228/AM03	E-IMD version 1	2	07/04/2016	14
12/WM/0258/AM05	Outcomes in patients with inflammatory arthritis	5	27/04/2016	8
12/WM/0258/AM07	Outcomes in patients with inflammatory arthritis	Substantial Amendment 6	09/11/2016	8
12/WM/0288/AM06	MRI in Portal Hypertension 1.0	2	08/06/2016	14
12/WM/0320/AM06	The metabolic effects of DNA epimutations in Growth Disorders V1.1	5	06/04/2016	26
13/WM/0006/AM04	Mortality study of UK hard-metal workers	2	17/04/2016	9
13/WM/0146/AM03	SCRAPS SCReening for Arthritis in Psoriasis	1	11/11/2016	20
13/WM/0382/AM02	Validation of the Modified Microlife Blood Pressure Monitor in PAF	Substantial Amendment 1	17/02/2017	17
13/WM/0470/AM04	glycaemic abnormalities in sleep apnoea	3	04/07/2016	6
14/WM/0010/AM06	LiverMultiscan with MRI – replacing liver biopsy	5	28/10/2016	15
14/WM/0011/AM09	IIH:WT	6	12/05/2016	15

14/WM/0011/AM10	IIH:WT	Substantial Amendment 7	17/02/2017	6
14/WM/1114/AM02	Infant feeding and the body burden of aluminium	29.09.16	29/09/2016	26
14/WM/1220/AM03	Exercise and vitamin D supplementation in older adults (EXVITD)	2.0	26/07/2016	7
14/WM/1220/AM04	Exercise and vitamin D supplementation in older adults (EXVITD)	3	06/10/2016	14
14/WM/1220/AM05	Exercise and vitamin D supplementation in older adults (EXVITD)	Substantial Amendment 4.0_1002	10/02/2017	16
14/WM/1222/AM04	Home based high intensity interval training	4	16/05/2016	8
15/WM/0010/AM04	Study to Observe Disease Progression In Alport Syndrome Patients	3	02/05/2016	10
15/WM/0128/AM01	Nutrition, exercise and muscle metabolism in obesity	1	03/06/2016	14
15/WM/0165/AM06	CHESS Feasibility V1.0	4	17/05/2016	8
15/WM/0165/AM07	CHESS Feasibility V1.0	5	03/08/2016	15
15/WM/0165/AM08	CHESS Feasibility V1.0	Substantial Amendment 6	08/03/2017	9
15/WM/0209/AM03	The role of hippocampal pathology in post-stroke cognitive impairment	Substantial Amendment 2	18/02/2017	7
15/WM/0254/AM02	MERMAIDS - ARI	Protocol amendment 3.0	15/03/2016	24
15/WM/0254/AM03	MERMAIDS - ARI	Protocol version 4.0	11/05/2016	20
15/WM/0258/AM03	Priorities and Preferences for Whole Genome Sequencing	1	29/11/2016	16
15/WM/0340/AM02	AIR: Ankle Injury Rehabilitation	2	22/03/2016	14
15/WM/0340/AM03	AIR: Ankle Injury Rehabilitation	3	25/08/2016	21
15/WM/0341/AM02	The CEMS study	2	05/04/2016	12
15/WM/0341/AM03	The CEMS study	3	27/05/2016	20
15/WM/0341/AM04	The CEMS study	4	20/12/2016	16
15/WM/0343/AM01	The RSV-SAM study	1	26/07/2016	19
15/WM/0343/AM02	The RSV-SAM study	2	17/11/2016	20

15/WM/0359/AM02	Achilles Tendinopathy Management	2	29/03/2016	10
15/WM/0359/AM03	Achilles Tendinopathy Management	3	26/08/2016	12
15/WM/0359/AM04	Achilles Tendinopathy Management	4	21/11/2016	18
15/WM/0380/AM01	Sexual dimorphism in the effects of overfeeding on insulin sensitivity	Substantial Amendment 1	06/03/2017	6
15/WM/0437/AM01	Effects of inflammation on behaviour and the autonomic nervous system	1	15/04/2016	18
15/WM/0445/AM01	Feasibility of a routine postnatal weight management intervention	1	13/04/2016	16
15/WM/0445/AM03	Feasibility of a routine postnatal weight management intervention	Substantial Amendment 2	09/02/2017	14
16/WM/0005/AM01	Protein distribution in older adults	1	01/07/2016	7
16/WM/0005/AM03	Protein distribution in older adults	2	18/10/2016	11
16/WM/0018/AM01	Plenadren versus Hydrocortisone in Primary Hypoadrenalism - Version 1	1	27/06/2016	13
16/WM/0103/AM01	Memory of Skeletal Muscle Growth	1	07/09/2016	11
16/WM/0105/AM02	The acute effects of e-cigarettes on lung function	1	01/09/2016	22
16/WM/0147/AM01	Improving the Assessment of Fatigue in Axial Spondyloarthritis	1	05/08/2016	23
16/WM/0148/AM01	Are We Performing Cataract Surgery Too Early? An Evaluation of PROs	1	04/11/2016	1
16/WM/0152/AM01	PREdiCCt	1	06/06/2016	18
16/WM/0243/AM01	Enhancing the capture and use of patient experience data	1	16/08/2016	6
16/WM/0243/AM03	Enhancing the capture and use of patient experience data	2	09/02/2017	5
16/WM/0250/AM01	PGL14-001 (PREMIUM) - non-interventional study, safety of Esmya	1	12/07/2016	7
16/WM/0250/AM05	PGL14-001 (PREMIUM) - non-interventional study, safety of Esmya	Substantial Amendment 2	15/02/2017	15
16/WM/0289/AM04	NSMM-5001, the INSIGHT-MM study	2	12/10/2016	20
16/WM/0303/AM01	Gellan Contact Study (Gellan sheet and fluid gel)	1	12/10/2016	4
16/WM/0320/AM01	Comparison of RO with standard dressings for treatment of ulcers	1	19/12/2016	16

16/WM/0327/AM02	Evaluation of Practical Body Image therapy for Anorexia Nervosa V2	3	16/01/2017	13
16/WM/0371/AM03	Sedentary behaviour and physical activity in RA and OA	1	20/12/2016	7
16/WM/0500/AM01	Emergency Laparotomy and Frailty (ELF)	1	06/02/2017	11

<b>Unfavourable opinion</b>				
<b>Amendment REC Reference</b>	<b>Title</b>	<b>Version</b>	<b>Date</b>	<b>Number of Days on Clock</b>

**Table 10.2: Breakdown of current status of all modified amendments reviewed within the reporting period**

<b>Favourable opinion timeline</b>				
<b>Amendment REC Reference</b>	<b>Title</b>	<b>Version</b>	<b>Date</b>	<b>Number of Days on Clock</b>

<b>Unfavourable opinion timeline</b>				
<b>Amendment REC Reference</b>	<b>Title</b>	<b>Version</b>	<b>Date</b>	<b>Number of Days on Clock</b>

**Table 11: Items exceeding timelines**

**Full applications for ethical review over 60 day timeline**

REC Reference	Title	Number of Days on Clock
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**Proportionate review applications for ethical review over 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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