

Research Ethics Service

West Midlands - Black Country Research Ethics Committee

Annual Report

01 April 2015 - 31 March 2016



Part 1 - Committee Membership and Training

Name of REC: West Midlands - Black Country Research Ethics Committee

Type of REC: Authorised REC

Type of Flag: Paediatric Studies

Chair: Dr Hilary Paniagua

Vice-Chair: Dr Joseph Arumainayagam

Alternate Vice-Chair: Mr Nanak Singh Sarhadi

REC Manager: Miss Georgia Copeland

REC Assistant: Miss Lindsey

Committee Address: The Old Chapel

Royal Standard Place

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Chair's overview of the past year:

This report has to start with the committee's achievement in obtaining full accreditation status, we have had brilliant audit results as well as pleasing KPI timelines and the quality of work this year has been outstanding. This is all credit to our members and of course the administration work of the Nottingham REC office and in particular Miss Georgia Copeland (REC Manager) and Miss Lindsey Wallace (REC Assistant) for keeping us resolutely to a timeline and providing excellent and timely support. We are settling down into our new venue in Dudley well and the attendance numbers have not been disrupted as we previously suspected it may have been. This has been helped by the fact that our committee has a new member Aisha Malik and Keith Lackenby has also joined us for six months to help us with our work, in particular chairing our proportionate review meetings. We are also pleased that Nanak Sahardi has been appointed as our new alternate vice chair this year. The committee continues to review and process a large number of substantial amendments and I really appreciate the support of the Vice-Chair in this work. The committee will now endeavour in the coming year to maintain the gold standard it has set itself and we look forward to a further positive year to come.

West Midlands - Black Country Research Ethics Committee Membership

Name	Profession	Expert or	Da	tes
		Lay	Appointed	Left
Dr Joseph Arumainayagam	Consultant and Honorary	Expert	01/04/2007	
	Senior Clinical Lecturer in			
	HIV and GUM			
Mrs Chris Bell	Retired	Lay Plus	01/04/2007	
Dr Nicola Erb	Consultant	Expert	01/01/2009	
	Rheumatologist	-		
Reverend Keith Lackenby	Reverend	Lay Plus	21/03/2016	
Dr Aisha Malik	Part-time Tutor Medical	Expert	23/11/2015	
	Ethics			
Dr Hilary Paniagua	Senior Lecturer	Expert	01/04/2007	
Mr Nanak Singh Sarhadi	Consultant Plastic	Expert	01/06/2009	
_	Surgeon			
Dr Julian Sonksen	Consultant in Anaesthesia	Expert	01/01/2008	
	and Critical Care			
Reverend Mark Stobert	Hospital Chaplain	Lay Plus	01/04/2007	
Dr David Vallance	Clinical Biochemist	Expert	01/04/2007	
Mrs Jennifer Walton	Retired Research Nurse	Lay	01/11/2010	
Dr Tony Zalin	Physician	Expert	01/01/2009	

West Midlands - Black Country Research Ethics Committee: Deputy Members

Name	Profession	Status	Meeting date attended
None			

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

Name	Profession	Status	Meeting date attended
Dr John S Fenlon	Statistical Consultant	Expert	13 April 2015
Reverend Keith Lackenby	Reverend	Lay Plus	13 April 2015
Mr Chris Foy	Medical Statistician	Expert	11 May 2015
Dr Ronald Jubb	Retired Consultant Rheumatologist	Expert	11 May 2015
Mr Paul Hamilton	Retired Local Government	Lay Plus	11 May 2015
	Officer		27 July 2015
Professor Paula McGee	Professor of Nursing	Expert	27 July 2015
			28 September 2015
			30 November 2015
Mrs Bernadette Roberts	Retired Finance Manager	Lay	28 September 2015
			26 October 2015
Mr John Warden	Clinical Trials Data and Information Systems Manager	Lay	21 March 2016
Mrs Lynne Gray	Senior Biomedical Scientist	Expert	30 November 2015

Dr Brendan Laverty	Retired Head of Research	Lay	26 October 2015
	Governance		

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

Name	Declaration of Interest	Date
Dr Joseph Arumainayagam	None Declared	04/01/2016
Dr Nicola Erb	None Declared	31/12/2015
Dr Aisha Malik	Part time teaching at Warwick Medical School and	01/02/2016
	Department for continuing education University of Oxford.	
Dr Hilary Paniagua	Reviewer for the NIHR. Chair for the	29/02/2016
	Wolverhampton University Ethics committee	
Mr Nanak Singh Sarhadi	None Declared	29/02/2016
Reverend Mark Stobert	Dudley Group R&D reviewer	29/02/2016
Dr David Vallance	Small number of shareholdings in GSK plc and	28/01/2016
	Astra-Zeneca plc. Total value less than £5000.	
Mrs Jennifer Walton	None Declared	31/12/2015
Dr Tony Zalin	None Declared	29/02/2016
Reverend Keith Lackenby	None Declared	31/03/2016
Mrs Chris Bell	None Declared	31/03/2016
Dr Julian Sonksen	Clinical researcher, and responsible for managing	30/03/2016
	some NIHR studies locally, but do not sit on any	
	peer review bodies	

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

Month	Date	Number of Members Present at Meeting
April	13/04/2015	8
May	11/05/2015	8
June	29/06/2015	8
July	27/07/2015	8
September	28/09/2015	8
October	26/10/2015	7
November	30/11/2015	7
December	17/12/2015	8
January	25/01/2016	9
February	29/02/2016	9
March	21/03/2016	8

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
May	11/05/2015	8
June	29/06/2015	3
July	31/07/2015	3
August	28/08/2015	3
October	26/10/2015	3
November	30/11/2015	3
December	14/12/2015	3
February	29/02/2016	3
March	21/03/2016	3

⁹ 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	02/04/2015	2
April	15/04/2015	2
April	29/04/2015	2
May	15/05/2015	2
May	29/05/2015	2
June	26/06/2015	2
July	10/07/2015	2
July	24/07/2015	2
August	21/08/2015	2
September	04/09/2015	2
September	18/09/2015	2

October	01/10/2015	2
October	30/10/2015	2
November	23/11/2015	2
December	21/12/2015	2
January	08/01/2016	2
January	22/01/2016	2
February	05/02/2016	2
February	18/02/2016	2
March	04/03/2016	2
March	16/03/2016	2

²¹ sub-committee meetings were held during the reporting period.

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

Date	Reason	Action taken
None		

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

Name	Number of Meetings Attended
Dr Joseph Arumainayagam	5
Mrs Chris Bell	5
Dr Nicola Erb	5
Reverend Keith Lackenby	2
Dr Aisha Malik	3
Dr Hilary Paniagua	10
Mr Nanak Singh Sarhadi	7
Dr Julian Sonksen	5
Reverend Mark Stobert	9
Dr David Vallance	7
Mrs Jennifer Walton	6
Dr Tony Zalin	1

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

Name	Number of Meetings
	Attended
Dr Joseph Arumainayagam	2
Mrs Chris Bell	3
Reverend Keith Lackenby	2
Dr Hilary Paniagua	8
Mr Nanak Singh Sarhadi	2
Dr Julian Sonksen	3
Reverend Mark Stobert	2
Dr David Vallance	1
Mrs Jennifer Walton	3
Dr Tony Zalin	1

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

Name	Number of
	Meetings
	Attended
Dr Joseph Arumainayagam	22
Dr Nicola Erb	1
Dr Hilary Paniagua	22
Mr Nanak Singh Sarhadi	1
Dr Julian Sonksen	1
Reverend Mark Stobert	1
Dr David Vallance	1
Mrs Jennifer Walton	1

Training 01 April 2015 - 31 March 2016

Name of Member	Date	Event(s) attended
Dr Joseph Arumainayagam	09/07/2015	E&D
Dr Joseph Arumainayagam	17/02/2016	Self-directed learning log
Reverend Keith Lackenby	15/05/2015	NREAP Meeting
Reverend Keith Lackenby	28/05/2015	Research Involving Adults
Developed Keith Leekenhy	25/00/2045	Lacking Capacity
Reverend Keith Lackenby	25/09/2015	Members Regional Training Day
Reverend Keith Lackenby	10/11/2015	Buddy / Mentor to new member Norma Thompson
Reverend Keith Lackenby	09/12/2015	National Training Day for Committee Chairs
Dr Aisha Malik	29/02/2016	E&D
Dr Hilary Paniagua	12/11/2015	Diversity in the Workplace E&D
Mr Nanak Singh Sarhadi	02/11/2015	
Mr Nanak Singh Sarhadi	14/02/2016	Training for new REC Chairs
Dr David Vallance	29/02/2016	E&D
Mrs Jennifer Walton	07/02/2016	E&D
Mrs Jennifer Walton	10/02/2016	Self-directed learning log
Dr Tony Zalin	22/07/2015	Equality and Diversity
Dr David Vallance	19/02/2016	HRA Resource: Participants who do not understand English
Dr David Vallance	24/02/2016	The Death of Sidaway; BMJ
Dr David Vallance	25/02/2016	New rules of consent; BMJ
Dr David Vallance	18/02/2016	The impossibility of informed consent; JME
Dr David Vallance	19/02/2016	Using informed consent to save trust; JME
Dr David Vallance	28/01/2016	Study resource QRA Mental Capacity Act
Dr David Vallance	15/02/2016	Some limits of informed consent; JMedEthics

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	2.08
Others	47	97.92
Total Applications Reviewed	48	100

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

Number of applications made invalid by the REC Manager	2
Number of applications withdrawn prior to the meeting	1
Number of student applications reviewed	20
Number of paediatric applications reviewed	6
Number of device applications reviewed	2
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	4	8.33
Favourable Opinion with Additional Conditions	10	20.83
Unfavourable Opinion	2	4.17
Provisional Opinion	32	66.67
Provisional Opinion Pending Consultation with Referee	0	0.00
Total	48	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	29	60.42
Conditions		
Further Information Favourable Opinion with Additional	1	2.08
Conditions		
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	4	8.33
Favourable Opinion with Additional Conditions	10	20.83
Unfavourable Opinion	2	4.17
Provisional Opinion	1	2.08
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	2.08
Total	48	100

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

Total Applications Reviewed	24

Table 6: Breakdown of PRS applications and other activity during reporting period:

Number of applications made invalid by the REC Manager	5
Number of studies withdrawn prior to the meeting	0
Number of student applications reviewed	13
Number of paediatric applications reviewed	4
Number of device applications reviewed	0
Number of qualitative applications reviewed	5

Table 7: Decisions given at proportionate review sub-committee meetings held within the reporting period

Decisions taken at proportionate review sub-	Number	%
committee meetings		
Favourable Opinion with Standard Conditions	7	29.17
Favourable Opinion with Additional Conditions	5	20.83
No Opinion transfer to full committee for review	3	12.50
Provisional Opinion	8	33.33
Unfavourable Opinion	1	4.17
Total	24	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	4.80
Number of completed applications for full ethical review	47
Number of completed applications for full ethical review over	0
60 days	
Number of completed applications over 60 days as a % of	0.00%
total	
Number of completed applications for full ethical review over	0
40 days	
Number of completed applications over 40 days as a % of	0.00%
total	
Number of days taken to final decision – average (mean)	29
Number of completed proportionate review applications for	21
ethical review	
Number of completed proportionate review applications for	0
ethical review over 14 days	
Number of completed proportionate review applications over	0.00%
14 days as a % of total	
Number of SSAs (non-Phase 1) reviewed	0
Number of completed applications for SSA review over 25	0
days	
Number of completed applications for SSA review over 25	0.00%
days as % of all non- Phase 1 SSAs	
Number of SSAs (Phase 1) reviewed	0
Number of completed applications for SSA review over 14	0
days	
Number of completed applications for SSA review over 14	0.00%
days as % of all Phase 1 SSAs	
Number of substantial amendments reviewed	51
Number of completed substantial amendments over 35 days	0
Number of completed substantial amendments over 35 days	0.00%
as a % of total substantial amendments	
Number of completed substantial amendments over 28 days	1
Number of completed substantial amendments over 28 days	1.96%
as a % of total substantial amendments	
Number of modified amendments reviewed	0
Number of completed modified amendments over 14 days	0
Number of completed modified amendments over 14 days as	0.00%
a % of total modified amendments	
Number of minor amendments received	26
Number of substantial amendments received for information	0
Number of substantial amendments received for new	0
sites/PIs	
Number of annual progress reports received	55

Number of safety reports received	3
Number of Serious Adverse Events received	0
Number of final reports received	32



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

REC Reference	on Favourable Opinion with Standard Conditions Title	Number of Days on Clock
15/WM/0120		Number of Days on Clock
	Views of the Borderline Personality Disorder	28
15/WM/0123	Decision-making in paediatric epilepsy surgery	18
15/WM/0128	Nutrition, exercise and muscle metabolism in obesity	27
15/WM/0199	Tubal Catheterisation for Tubal Infertility	28
15/WM/0205	Nerve block versus non-targeted local anaesthesia in breast surgery.	25
15/WM/0209	The role of hippocampal pathology in post-stroke cognitive impairment	39
15/WM/0246	Exploring Patterns of Mentalisation	25
15/WM/0248	Developing a non-invasive stable isotope-based measure of skeletal muscle mass	25
15/WM/0254	MERMAIDS - ARI	40
15/WM/0258	Priorities and Preferences for Whole Genome Sequencing	30
15/WM/0340	AIR: Ankle Injury Rehabilitation	32
15/WM/0341	The CEMS study	24
15/WM/0359	Achilles Tendinopathy Management	26
15/WM/0380	Sexual dimorphism in the effects of overfeeding on insulin sensitivity	37
15/WM/0419	Immune control of EBV-positive DLBCL (ICEPOP) version 1.0	37
15/WM/0437	Effects of inflammation on behaviour and the autonomic nervous system	32
15/WM/0438	Exploring interventions over the watchful waiting period in 'glue ear'	36
15/WM/0445	Feasibility of a routine postnatal weight management intervention	33
16/WM/0003	RENEWAL - A clinical and research database for use in chronic pain	30
16/WM/0005	Protein distribution in older adults	37
16/WM/0018	Plenadren versus Hydrocortisone in Primary Hypoadrenalism - Version 1	36
16/WM/0037	POLYMATH- Pathogenesis Of Lymphoma for Therapy	39
16/WM/0058	Nutrition and post-exercise mitochondrial biogenesis	33
16/WM/0059	Skeletal muscle glycogen manipulation and adaptation to exercise	27
16/WM/0103	Memory of Skeletal Muscle Growth	40
16/WM/0105	The acute effects of e-cigarettes on lung function	40
16/WM/0141	Women's experience of unilateral mastectomy without reconstruction	40
16/WM/0146	NICU and parents experience of building a relationship.	32
16/WM/0147	Improving the Assessment of Fatigue in Axial Spondyloarthropathy	32



REC Reference	Title	Number of Days on Clock
15/WM/0216	Autonomic Dysfunction In ANCA-associated vasculitis	36

Further Informati	on 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/0326	Pain flare in patients undergoing radiotherapy for bone metastases	18
15/WM/0343	The RSV-SAM study	19
15/WM/0385	Wireless Monitoring	25
16/WM/0041	Skin fibroblast cells - version 1	28

Favourable Opinion with Additional Conditions		
REC Reference	Title	Number of Days on Clock
15/WM/0121	Experience of involvement in co-design in mental health services V.1.0	17
15/WM/0125	Shared and individual perspectives in couples' relationships after ABI	17
15/WM/0161	Objective measurement of ADHD and ASD in adults	24
15/WM/0165	CHESS Feasibility V1.0	31
15/WM/0167	Pre- and post-treatment nerve root tractography in the lumbar spine - a pilot study	22
15/WM/0200	Metabolomics in SLE	30
15/WM/0219	Human single neuron recordings in epilepsy patients v1	18
15/WM/0382	An evaluation of a coagulation system (Xprecia Stride)	25
15/WM/0387	Group-based Compassion Focussed Psychotherapy - version 1	25
15/WM/0428	Glycogen use during habitual running training sessions	28

Unfavourable Opi	nion	
REC Reference	Title	Number of Days on Clock

16/WM/0150	Can vibration therapy increase bone length?	27
16/WM/0151	NGAL 1.0	29

Provisional Opinion		
REC Reference	Title	Number of Days on Clock
15/WM/0358	Defining the clotting defect in children undergoing cardiac surgery	n/a

Provisional Opini	on 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
15/WM/0251	The Ambulance-Hypo Study	24

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
15/WM/0241	The Impact of an Emotional Health and Wellbeing Service	14
15/WM/0280	HEAD-US Inter-rater repeatability	14
15/WM/0322	Pilot study - Outlining the immune profile of ovarian cancer	8
15/WM/0400	Type 2 diabetes patients' perceptions on healthy eating advice	10
15/WM/0460	Efficacy of transition for young people with learning disability	12

16/WM/0113	What overweight patients consider a healthy body size and why	10
16/WM/0148	Are We Performing Cataract Surgery Too Early? An Evaluation of PROs	11

Further Informati	on Favourable Opinion with Additional Conditions	
REC Reference	Title	Number of Days on Clock

Further Informati	on 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/0237	A radiomics feature classification defining ovarian tumour aggression	7		
15/WM/0239	Attitudes towards endometrial cancer	8		
15/WM/0281	The effect of UV radiation on the infectivity of VZV clades- version 1	13		
15/WM/0321	Incidence of Nitrofurantoin Drug Induced Liver Injury	3		
15/WM/0474	What is the best way to measure head circumference?	11		
16/WM/0115	Optimising radiotherapy for dental rehabilitation	6		
16/WM/0155	Early mobilisation after ICH	11		

Favourable Opinion with Additional Conditions				
REC Reference	Title	Number of Days on Clock		
15/WM/0172	Gardening as an occupational therapy intervention for adult males	7		
15/WM/0173	Is gastro-oesophageal reflux related to otitis media in cleft palate?	12		
15/WM/0324	Cell Populations from Ligament Tissue - Version 1	11		
16/WM/0114	Self Esteem & Oral Health-Related Quality of Life prior to jaw surgery	5		
16/WM/0152	PREdiCCt	11		

Unfavourable Opinion				
REC Reference	Title	Number of Days on Clock		
15/WM/0401	CKD Patient-Centric Online Community v1	8		

Provisional Opinion				
REC Reference	Title	Number of Days on Clock		
15/WM/0458	Patients' perception of consent for laparoscopic surgery: A survey	n/a		

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

Favourable opinion				
Amendment REC Reference	Title	Version	Date	Number of Days on Clock
08/H1202/131/AM05	Dose response of whey protein ingestion following resistance training	3	14/04/2015	30
08/H1204/174/AM11	BIBF 1120 plus docetaxel in patients with non small cell lung cancer	12.01.16	12/01/2016	7
09/H1203/69/AM08	Genetic biomarkers and postnatal depression	5	12/02/2016	3
09/H1204/62/AM15	MRC patient cohorts: childhood type 2 diabetes Version 1	Amendment 11	30/03/2015	18
10/H1202/58/AM02	Chest wall motion analysis in disease, version 1	3	09/02/2016	8
10/H1202/81/AM07	TREC	6	27/08/2015	12
11/WM/0037/AM01	Evaluation of Scoliosis Using Dynamic Surface Topography	09.02.16	09/02/2016	8
11/WM/0127/AM07	EURO-WABB	7	21/08/2015	15
11/WM/0127/AM08	EURO-WABB	8	11/01/2016	12
11/WM/0227/AM01	Determining factors causing weight change in psychiatric inpatients	Amendment 1	20/02/2015	20
12/WM/0049/AM01	Asthma, Obesity and Obstructive Sleep Apnoea Study	1	03/11/2015	20
12/WM/0089/AM06	Chronic Disease Research Centre - Diabetes Division Ver: 1.0212	7	21/10/2015	26
12/WM/0258/AM04	Outcomes in patients with inflammatory arthritis	4	10/04/2015	27
12/WM/0269/AM05	Community Monitoring in Chronic Liver Disease (d-LIVER)	4	17/05/2015	16
12/WM/0320/AM05	The metabolic effects of DNA epimutations in Growth Disorders V1.1	SA04	14/01/2016	11
13/WM/0213/AM05	Autism and Psychosis	Amendment 6	30/03/2015	17
13/WM/0464/AM01	Identifying a Core Outcome Set for Cardiac Arrest Clinical Trials	1	25/06/2015	23
13/WM/0470/AM02	glycaemic abnormalities in sleep apnoea	Substantial Amendment 1	19/03/2015	15
14/WM/0010/AM04	LiverMultiscan with MRI – replacing liver biopsy	3	10/08/2015	26
14/WM/0010/AM05	LiverMultiscan with MRI – replacing liver biopsy	4	09/09/2015	10

4.4/\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\	IIH:WT	Ι	20/07/2015	24
14/WM/0011/AM05		4	29/07/2015	24
14/WM/0011/AM08	IIH:WT	5	05/02/2016	14
14/WM/0066/AM03	The LYNC study version 1	2	18/06/2015	4
14/WM/0134/AM01	Diffusion-weighted MR imaging assessment of mesothelioma	1	21/05/2015	11
14/WM/1047/AM03	Music therapy for children with autism (Version 1.0)	1	14/10/2015	14
14/WM/1080/AM01	PROSEC 2014	1	16/12/2015	25
14/WM/1114/AM01	Infant feeding and the body burden of aluminium	1	09/12/2015	22
14/WM/1128/AM01	STOP-HCV Cirrhosis Study	18.06.15	18/06/2015	20
14/WM/1132/AM04	DISCHARGE Pilot Study	1.0	09/11/2015	8
14/WM/1220/AM01	Exercise and vitamin D supplementation in older adults (EXVITD)	1	25/01/2016	12
14/WM/1222/AM01	Home based high intensity interval training	1	28/09/2015	1
14/WM/1222/AM03	Home based high intensity interval training	3	10/12/2015	10
15/WM/0005/AM01	CFMATTERS Study	1	07/01/2016	19
15/WM/0006/AM01	INfluence of Successful Periodontal Intervention on REnal Disease	2	09/09/2015	11
15/WM/0006/AM03	INfluence of Successful Periodontal Intervention on REnal Disease	3	07/03/2016	9
15/WM/0007/AM01	GETSET for CFS/ME: an interview study	1	23/04/2015	11
15/WM/0010/AM01	Study to Observe Disease Progession In Alport Syndrome Patients	07.05.15	07/05/2015	26
15/WM/0010/AM02	Study to Observe Disease Progession In Alport Syndrome Patients	2	14/08/2015	23
15/WM/0010/AM03	Study to Observe Disease Progession In Alport Syndrome Patients	2	04/12/2015	25
15/WM/0120/AM01	Views of the Borderline Personality Disorder	1	15/10/2015	14
15/WM/0123/AM01	Decision-making in paediatric epilepsy surgery	1	29/04/2015	25
15/WM/0165/AM01	CHESS Feasibility V1.0	1	10/08/2015	28
15/WM/0165/AM02	CHESS Feasibility V1.0	2	12/11/2015	26
15/WM/0165/AM05	CHESS Feasibility V1.0	3	23/02/2016	20
15/WM/0209/AM01	The role of hippocampal pathology in post-stroke cognitive	1	10/11/2015	14
	impairment	_		·

15/WM/0340/AM01	AIR: Ankle Injury Rehabilitation	1	25/11/2015	12
15/WM/0341/AM01	The CEMS study	1	03/02/2016	15
15/WM/0359/AM01	Achilles Tendinopathy Management	1	11/01/2016	27
15/WM/0382/AM02	An evaluation of a coagulation system (Xprecia Stride)	2	19/01/2016	22
818/AM03	Serological evaluation of endogenous virus HERV-K10 in renal	3	01/12/2015	12
	lupus			
985/AM07	The detection and quantification of HERVs	3	01/12/2015	12

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

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

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

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

Table 11: Items exceeding timelines						
Full applications for	r ethical review over 60 day timeline					
				Number of Days on Clock		
Proportionate revie	w applications for ethical review over 14 day	timeline				
REC Reference	REC Reference Title			Number of Days on Clock		
SSAs (non Phase 1	over 25 day timeline					
REC Reference	<u> Fitle</u>		Number of Days on Clock			
SSAs (Phase 1) ove	SSAs (Phase 1) over 14 day timeline					
REC Reference Title			Number of Days on Clock			
	ments over 35 day timeline					
Amendment REC	Title	Version	Date	Number of Days on Clock		
Reference				CIOCK		
	nts over 14 day timeline			N		
Amendment REC Reference	Title	Version	Date	Number of Days on Clock		