

**East Midlands - Nottingham 1 Research Ethics
Committee**

Annual Report

01 April 2015 - 31 March 2016



Part 1 – Committee Membership and Training

Name of REC:	East Midlands - Nottingham 1 Research Ethics Committee
Type of REC:	Authorised REC
Type of Flag:	Research Involving Adults Lacking Capacity (until February/March 2016 when the flag was removed) Research Involving Children
Chair:	Dr Carl Edwards
Vice-Chair:	Reverend Keith Lackenby
Alternate Vice-Chair:	Professor Cris Constantinescu
REC Manager:	Ms Rachel Nelson
REC Assistant:	Ms Teagan Allen
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Chair's overview of the past year:

This has been another year of changes for the committee. We have had an influx of new members whose enthusiasm and knowledge has been a great boost to the committee and brought us back up to a normal level of membership. The committee has also seen some of our most experienced members leaving and particular mention must go to Keith Lackenby my very capable Vice-Chair who has been a great source of support and friendship during my time as Chair.

This year has seen the launch of the on-line portal and a step towards all electronic review of applications; the committee members and REC Managers have made valuable contributions in feeding back on the new systems. The use of electronic review has been successfully embraced through a very well managed process starting with Sub-Committee papers and culminating in Full Meeting reviews. Whilst the systems are still being developed I think the fact that the HRA, Managers and the committees have worked collaboratively so far will ensure the system will evolve into something we will all be proud of. Again this year I cannot thank my REC Managers enough for supporting me and the committee in our work, showing a level of expertise and patience that I always admire.

East Midlands - Nottingham 1 Research Ethics Committee Membership

Name	Profession	Expert or Lay	Dates	
			Appointed	Left
Dr Glenys Caswell	Research Fellow	Expert	01/12/2010	
Professor Cris Constantinescu	Professor of Clinical Neurology	Expert	19/07/2008	
Dr Carl Edwards	Investment Advisor	Lay	01/05/2014	
Dr Sarah Forster	Respiratory Registrar	Expert	30/09/2015	
Dr Ursula Holdsworth	Retired Staff Grade Community Paediatrician	Expert	01/10/2011	
Reverend Keith Lackenby	Reverend	Lay Plus	10/10/2006	
Mrs Sarah Lennon	Ex-Surgical Registrar	Expert	01/09/2011	
Ms Ellen Milazzo	Development and Change Management Consultant	Lay Plus	28/07/2014	
Mr Robert Oldroyd	Chartered Librarian	Lay Plus	10/10/2006	01/06/2015
Mrs Rita Patel	Contracts and Innovation Manager	Lay	22/09/2015	
Dr James Rathbone	Clinical Psychologist	Expert	13/10/2015	
Ms Stephanie Sampson	PhD Student	Lay Plus	18/02/2016	
Mr Ian Thompson	Retired Deputy Head Teacher	Lay Plus	19/10/2006	
Mrs Norma Thompson	Clinical Research Nurse	Expert	10/11/2015	

East Midlands - Nottingham 1 Research Ethics Committee: Deputy Members

Name	Profession	Status	Meeting date attended
None	None	None	None

East Midlands - Nottingham 1 Research Ethics Committee: Co-opted Members

Name	Profession	Status	Meeting date attended
Mr John Baker	Lay Member	Lay	08/09/2015
Mr Alan Caswell	Retired Nurse	Lay	11/08/2015
Mrs Jeanne-Anne Charly	Staff Nurse	Expert	08/09/2015
Mr Paul Hamilton	Retired Local Government Officer	Lay Plus	08/09/2015
Mrs Anne Walker	Lay Member	Lay Plus	09/06/2015

East Midlands - Nottingham 1 Research Ethics Committee: Members' Declarations of Interest:

Name	Declaration of Interest	Date
Dr Glenys Caswell	Work as research fellow for the University of Nottingham in the School of Health Sciences. Work involves conducting research which sometimes includes NHS patients as participants	19/02/2016
Professor Cris Constantinescu	NIHR CRN Division IV Specialty Group Lead for Neurological Disorders (East Midlands)	19/02/2016
Dr Carl Edwards	Associate of Institute of Mental Health University of Nottingham.	08/12/2015
Dr Sarah Forster	Academic Clinical Fellow at University of Nottingham & Nottingham Respiratory Research Group	16/12/2015
Dr Ursula Holdsworth	None Declared.	07/03/2016
Reverend Keith Lackenby	None Declared	19/02/2016
Mrs Sarah Lennon	None Declared	22/02/2016
Ms Ellen Milazzo	None declared.	22/03/2016
Mrs Rita Patel	Works as 'Contracts and Innovation Manager' in Research and Innovation Department at University Hospitals of Leicester NHS Trust.	24/02/2016
Dr James Rathbone	None declared	13/10/2015
Ms Stephanie Sampson	Works as a 'befriender' for Nottingham charity 'Improving Lives.' Previously worked for the Cochrane Schizophrenia Group at the University of Nottingham for three years. Currently a PhD student studying Ethics and Law of coercive interventions in psychiatry and expects to interview RECs for this but has not yet done so	09/03/2016

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

Month	Date	Number of Members Present at Meeting
May	12/05/2015	8
June	09/06/2015	8
August	11/08/2015	8
September	08/09/2015	8
October	13/10/2015	9
November	10/11/2015	9
December	08/12/2015	10
January	12/01/2016	10
February	09/02/2016	10
March	08/03/2016	10

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	24/04/2015	3
May	29/05/2015	3
June	26/06/2015	3
July	17/07/2015	3
August	11/08/2015	3
September	08/09/2015	3
October	13/10/2015	3
November	10/11/2015	7
December	08/12/2015	3
January	12/01/2016	3
February	09/02/2016	3
March	08/03/2016	4

12 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	14/04/2015	2
April	28/04/2015	2
May	12/05/2015	2
May	26/05/2015	2
June	09/06/2015	2
June	23/06/2015	2
July	07/07/2015	2
August	05/08/2015	2
August	11/08/2015	2

August	25/08/2015	2
September	08/09/2015	2
September	29/09/2015	2
October	13/10/2015	2
October	27/10/2015	2
November	10/11/2015	2
November	24/11/2015	2
December	08/12/2015	2
December	22/12/2015	2
January	12/01/2016	2
January	26/01/2016	2
February	09/02/2016	2
February	23/02/2016	2
March	08/03/2016	2
March	22/03/2016	2

24 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	None	None

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

Name	Number of Meetings Attended
Dr Glenys Caswell	6
Professor Cris Constantinescu	8
Dr Carl Edwards	9
Dr Sarah Forster	3
Dr Ursula Holdsworth	10
Reverend Keith Lackenby	10
Mrs Sarah Lennon	10
Ms Ellen Milazzo	7
Mr Robert Oldroyd	1
Mrs Rita Patel	6
Dr James Rathbone	4
Mrs Norma Thompson	2
Mr Ian Thompson	9

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

Name	Number of Meetings Attended
Dr Glenys Caswell	3
Professor Cris Constantinescu	4
Dr Carl Edwards	7
Dr Ursula Holdsworth	4
Reverend Keith Lackenby	10
Mrs Sarah Lennon	4
Ms Ellen Milazzo	3
Mr Robert Oldroyd	1
Dr James Rathbone	1
Mr Ian Thompson	4

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

Name	Number of Meetings Attended
Dr Glenys Caswell	4
Professor Cris Constantinescu	6
Dr Carl Edwards	14
Dr Ursula Holdsworth	5
Reverend Keith Lackenby	12
Mrs Sarah Lennon	6
Mr Ian Thompson	1

Training 01 April 2015 - 31 March 2016

Name of Member	Date	Event(s) attended
Professor Cris Constantinescu	01/04/2015	Equality and Diversity Slides
Professor Cris Constantinescu	01/04/2015	Attended Ethics Lecture
Professor Cris Constantinescu	08/12/2015	Buddy / Mentor to new member Sarah Forster
Dr Carl Edwards	25/09/2015	Members Regional Training Day
Dr Ursula Holdsworth	25/09/2015	Members Regional Training Day
Dr Ursula Holdsworth	13/10/2015	Buddy / Mentor to new member James Rathbone
Reverend Keith Lackenby	15/05/2015	NREAP Meeting
Reverend Keith Lackenby	28/05/2015	Research Involving Adults 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
Mrs Sarah Lennon	06/10/2015	Quantitative Research Methods and Statistics
Mrs Sarah Lennon	18/02/2016	Mentor / Buddy to new member Stephanie Sampson
Ms Ellen Milazzo	22/04/2015	Equality and Diversity
Ms Ellen Milazzo	28/05/2015	Research Involving Adults Lacking Capacity
Dr James Rathbone	10/03/2016	Member's Induction
Mr Ian Thompson	16/03/2016	National Members 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:

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	48	100.00
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	3
Number of applications withdrawn prior to the meeting	0
Number of student applications reviewed	29
Number of paediatric applications reviewed	7
Number of device applications reviewed	3
Number of prisoner applications reviewed	0
Number of applications involving adults unable consent reviewed	14
Number of applications reviewed that are funded by the US DHHS	0
Number of qualitative applications reviewed	11

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	6	12.50
Unfavourable Opinion	0	0.00
Provisional Opinion	42	87.50
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 Conditions	40	83.33
Further Information Favourable Opinion with Additional Conditions	2	4.17
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	0	0.00
Favourable Opinion with Additional Conditions	6	12.50
Unfavourable Opinion	0	0.00
Provisional Opinion	0	0.00
Provisional Opinion Pending Consultation with Referee	0	0.00
Further Information response not complete	0	0.00
No decision entered on system	0	0.00
Number of studies withdrawn after the meeting	0	0.00
Total	48	100

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

Total Applications Reviewed	36
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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	4
Number of studies withdrawn prior to the meeting	1
Number of student applications reviewed	22
Number of paediatric applications reviewed	3
Number of device applications reviewed	0
Number of qualitative applications reviewed	6

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	10	27.78
Favourable Opinion with Additional Conditions	9	25.00
No Opinion transfer to full committee for review	0	0.00
Provisional Opinion	16	44.44
Unfavourable Opinion	1	2.78
Total	36	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	48
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	4
Number of completed applications over 40 days as a % of total	8.33%
Number of days taken to final decision – average (mean)	33
Number of completed proportionate review applications for ethical review	36
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	2
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	89
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	4
Number of completed substantial amendments over 28 days as a % of total substantial amendments	4.49%
Number of modified amendments reviewed	2
Number of completed modified amendments over 14 days	0
Number of completed modified amendments over 14 days as a % of total modified amendments	0.00%
Number of minor amendments received	83
Number of substantial amendments received for information	0
Number of substantial amendments received for new sites/PIs	0
Number of annual progress reports received	82

Number of safety reports received	0
Number of Serious Adverse Events received	0
Number of final reports received	14

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
15/EM/0184	The MKD for the treatment of pharmaco-resistant epilepsy in adults	39
15/EM/0189	Exploration of the roles of nurses in type 2 diabetes care	32
15/EM/0213	Empathic and Moral Processing in Personality Disordered Patients - V.1	27
15/EM/0214	IRIDICA BAC BSI Assay Clinical Study	28
15/EM/0218	Long term care in forensic psychiatric settings: carers views	28
15/EM/0233	Living with Obsessive Compulsive Disorder: A Child's Perspective.	41
15/EM/0234	Compassion in the Ward Setting	37
15/EM/0250	BRAVE study	35
15/EM/0253	Individual Placement and Support for patients with offending histories	23
15/EM/0258	FEIBA-GO	43
15/EM/0259	GO for IT	39
15/EM/0296	Effect of exercise intervention on oxidative stress. Version 2.1	37
15/EM/0314	Improving the management of BPSD in care homes	40
15/EM/0329	Rupture of Membranes: women's expectations and experience v1	39
15/EM/0377	Decision making and future planning for children with complex illness	34
15/EM/0384	Nottingham/Leeds Significant Ankle Ligament Injury (SALI) cohort	38
15/EM/0410	Mechanisms underpinning depression in Multiple Sclerosis	41
15/EM/0446	Computed Tomography assessment of Regional Ventilation (CURVE)	38
15/EM/0453	Psychoeducation for TIA and Minor Stroke (OPTIMISM)	42
15/EM/0485	Cerebral Haemodynamics in Stroke Thrombolysis Study Version 0.2	37
15/EM/0495	Standing frames for children with Cerebral Palsy_v1	30
15/EM/0499	Identification of Prostate Cancer Biomarkers in Black Patients	24
15/EM/0529	Knee synovial changes detected by ultrasound in the general population	34
15/EM/0531	Mindfulness for Osteoarthritis-related knee pain	28
15/EM/0538	The Ambulance-Hypo Study	32
15/EM/0544	Mechanism of action of tranexamic acid in isolated TBI v1.1	35
16/EM/0003	Return to Work Following Major Trauma	33
16/EM/0004	Compassion in end of life care: A patient perspective	39
16/EM/0011	Emotional dysregulation and the experience of relationships in groups	28
16/EM/0012	Effect of apple heat modification in Oral Allergy Syndrome	27
16/EM/0035	The INDURMAN Ventilation Study	35
16/EM/0036	HIPHOP pilot study	40

16/EM/0039	Virtual Reality Software for Therapy V1	34
16/EM/0041	Antenatal anxiety intervention: feasibility and acceptability	25
16/EM/0044	PRIDE Intervention Development and Feasibility	36
16/EM/0046	Investigating nociceptin release from immune cells in sepsis V1.0	25
16/EM/0086	SoundZap	23
16/EM/0097	Developing an intervention to improve diagnostic delivery of dementia	28
16/EM/0100	Mindfulness for adults with BPD, a feasibility study (version 1)	21
16/EM/0102	Patient experience in pregnancy research Version 1	23

Further Information Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
15/EM/0395	Vancomycin in Epithelial Lining Fluid, an observational study	35
16/EM/0010	The GA Stimulation Ventilation Study	39

Further Information Unfavourable Opinion

REC Reference	Title	Number of Days on Clock
None	None	None

Favourable Opinion with Standard Conditions

REC Reference	Title	Number of Days on Clock
None	None	None

Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
15/EM/0220	Experiences of peer support workers' journey and role (version 1)	33
15/EM/0325	Model-based versus traditional warfarin dosing in children	29
15/EM/0345	Change in free vitamin D after high dose cholecalciferol	29
15/EM/0378	An extension of the Arnold Lodge Admissions Cohort Outcome Study.	28
15/EM/0442	Working together in Long Term Condition management	24
15/EM/0452	Urinary micronutrient profile as AKI biomarker in the ICU	28

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

Provisional Opinion		
REC Reference	Title	Number of Days on Clock
None	None	None

Provisional Opinion Pending Consultation with Referee		
REC Reference	Title	Number of Days on Clock
None	None	None

Further information response not complete		
REC Reference	Title	Number of Days on Clock
None	None	None

Withdrawn after the meeting		
REC Reference	Title	Number of Days on Clock
None	None	None

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/EM/0191	Decision-making in the management of recurrent tonsillitis	8
15/EM/0193	Vitamin D Level in Nasal Polyposis: A pilot study Version 1.0	11
15/EM/0194	Children's experiences of the diabetic transition from MDIs to CSII	11
15/EM/0301	Parental perceptions of unilateral hearing loss in children Version 1	14
15/EM/0423	Detection of diabetes in people with stroke using HbA1c.	9

15/EM/0426	Evaluating the Canadian Occupational Performance Measure	13
15/EM/0428	Development of a new nonverbal memory test (v 1.0)	8
15/EM/0476	The effect of hand washing and sanitizers on human skin	13
15/EM/0478	A cognitive interviewing study exploring respiratory questionnaires	14
15/EM/0479	Comparative Study of Shear Wave Elastography in Liver Disease	10
15/EM/0515	Desirability and feasibility of physical activity as medicine	9
15/EM/0569	EncoreAnywhere use in motor neurone disease	7
16/EM/0027	Older People's Rehabilitative Exercise Engagement: OPREE	7
16/EM/0072	Arsenic exposure, pilot study, version 1	14
16/EM/0122	Cancer, Fertility and Me.	13

Further Information Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
16/EM/0070	ThyVoice	12

Further Information Unfavourable Opinion

REC Reference	Title	Number of Days on Clock
None	None	None

Favourable Opinion with Standard Conditions

REC Reference	Title	Number of Days on Clock
15/EM/0190	Describing the management of back pain by community pain clinics	8
15/EM/0303	Non-interventional study of time to relapse of iron deficiency anaemia after Monofer	7
15/EM/0336	Nasal profile changes after maxillary osteotomy procedures	10
15/EM/0368	Peri-haematoma oedema in ICH study	12
15/EM/0383	CAM-PLEX follow-up	7
15/EM/0516	Choroidal Thickness in Hereditary Retinal Disease	7
15/EM/0564	A Retrospective Review of the Hydrus Implant	8
16/EM/0019	Cardiac Sarcomas	9
16/EM/0071	MDT management of pregnant women with cardiac disease	9
16/EM/0120	Develop and evaluate an oral hygiene screening tool	9

Favourable Opinion with Additional Conditions		
REC Reference	Title	Number of Days on Clock
15/EM/0255	RCRT: Recovery after lung cancer radiotherapy	7
15/EM/0257	Transition to High School in Young People with Cleft Lip/Palate	7
15/EM/0386	A breast support intervention for women with breast pain	7
15/EM/0477	Global assays for haemophilia	10
15/EM/0514	Thermographic analysis of laparotomy wounds	8
15/EM/0565	Core outcome sets for gynaecological conditions (COGS)	9
15/EM/0566	Is pacemaker-related cardiac remodelling progressive?	9
16/EM/0069	Knowledge of Risk Factors for Diabetes	7
16/EM/0115	What are the experiences of major trauma patients post discharge? (V1)	9

Unfavourable Opinion		
REC Reference	Title	Number of Days on Clock
15/EM/0335	Mechanisms underpinning depression in Multiple Sclerosis	10

Provisional Opinion		
REC Reference	Title	Number of Days on Clock
None	None	None

Further information response not complete		
REC Reference	Title	Number of Days on Clock
None	None	None

Withdrawn after the meeting		
REC Reference	Title	Number of Days on Clock
None	None	None

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
06/Q2402/57/AM20	Volitional Control of Action in Young people with Tourette Syndrome	Substantial amendment 19	30/01/2015	20
06/Q2402/77/AM06	Localisation of commensal bacteria in skin	Substantial Amendment Version	08/09/2015	19
06/Q2403/137/AM17	Studies of Blood Cell Function	Substantial Amendment 5.0	19/11/2015	28
08/H0403/37/AM08	Derivation of new biomarkers for hepatobiliary and GI disease	Substantial Amendment 2	13/11/2015	21
08/H0403/80/AM11	Population based prospective cohort study of pneumococcal pneumonia	Substantial Amendment 8	08/01/2016	13
08/H0407/1/AM08	Obtaining lung tissue samples for laboratory research	SA5	05/06/2015	20
08/H0407/1/AM09	Obtaining lung tissue samples for laboratory research	Substantial Amendment 6	13/10/2015	12
09/H0403/12/AM11	Quality of life in older women in primary breast cancer	Substantial Amendment 5	14/08/2015	18
10/H0403/10/AM12	Compensated Cirrhosis Cohort Study: Nottingham version 1.0	Substantial Amendment 12 21.12	12/12/2015	8
10/H0403/10/AM13	Compensated Cirrhosis Cohort Study: Nottingham version 1.0	Substantial Amendment 13	10/02/2016	13
10/H0403/10/AM14	Compensated Cirrhosis Cohort Study: Nottingham version 1.0	Substantial Amendment 14	07/03/2016	13
11/EM/0442/AM23	ENCEPH UK - Prospective Cohort Study	Substantial Amendment 24	07/10/2015	18
12/EM/0044/AM12	Arthritis Research UK Gout Treatment Trial - Phase 2	Substantial Amendment 8	21/05/2015	25
12/EM/0044/AM13	Arthritis Research UK Gout Treatment Trial - Phase 2	Substantial Amendment 9	26/11/2015	12
12/EM/0324/AM10	Remembrin Study	Substantial Amendment	15/09/2015	14

		15/09/20		
12/EM/0324/AM12	Remembrin Study	Substantial Amendment 07 22.01	22/01/2016	13
12/EM/0350/AM02	GATA1 Expression levels in peripheral blood of patients with ET	Substantial Amendment 04.11.20	04/11/2015	8
13/EM/0160/AM02	Diagnostic potential of low frequency cardiac & skeletal muscle sound	Substantial Amendment 2	26/11/2015	33
13/EM/0214/AM02	Pre-operative Nutrition In Neck of femur Trial (POINT)	Substantial Amendment 2	31/03/2015	14
13/EM/0222/AM01	Myosteatosi s and muscle wasting in pancreatic cancer	Substantial Amendment 1	02/11/2015	19
13/EM/0362/AM01	Pilot randomised, controlled trial of hysteroscopic septal resection	Substantial Amendment 1	22/06/2015	19
13/EM/0416/AM02	LADA	Substantial Amendment 2	24/03/2015	22
14/EM/0013/AM02	Nottingham Osteoarthritis Biomarker Follow Up Study	Substantial Amendment 2	13/04/2015	21
14/EM/0045/AM04	Osteoarthritis Risk in Professional Footballers	Substantial Amendment 4	21/05/2015	25
14/EM/0056/AM02	Epidemiology, management, outcomes and pathophysiology of SCAD	Substantial Amendment SA2	27/08/2015	16
14/EM/0056/AM03	Epidemiology, management, outcomes and pathophysiology of SCAD	Substantial Amendment 3	05/11/2015	11
14/EM/0056/AM04	Epidemiology, management, outcomes and pathophysiology of SCAD	Substantial Amendment 4	01/02/2016	9
14/EM/0061/AM05	Parkinson MR Imaging Repository: Part 1 - Multicentre MRI study in PD	Substantial Amendment 1	15/12/2014	17
14/EM/0061/AM07	Parkinson MR Imaging Repository: Part 1 - Multicentre MRI study in PD	Substantial Amendment 7	18/02/2016	15
14/EM/0081/AM04	Long term evaluation of the management of prostate cancer patients.	Substantial Amendment 2	22/10/2015	11
14/EM/0081/AM05	Long term evaluation of the management of prostate cancer patients.	Substantial Amendment 3	02/11/2015	10
14/EM/0083/AM05	Leg oedema In Multiple Sclerosis (LIMS) Version 1.0	Substantial	05/05/2015	17

		Amendment 2		
14/EM/0099/AM06	Home Administered Pre-surgical Psychological Intervention for Knee OA	3	27/03/2015	7
14/EM/0136/AM01	Improving glycaemic control with L-carnitine. Version 1.0	1	18/03/2015	28
14/EM/0145/AM02	Methotrexate induced liver fibrosis	Substantial Amendment 1	22/06/2015	1
14/EM/0145/AM03	Methotrexate induced liver fibrosis	Substantial amendment 15.09.15	01/10/2015	14
14/EM/0184/AM02	The AKORDD study of Outreach in Acute Kidney Injury	2	25/03/2015	21
14/EM/0184/AM03	The AKORDD study of Outreach in Acute Kidney Injury	Substantial Amendment 3	05/05/2015	10
14/EM/0184/AM04	The AKORDD study of Outreach in Acute Kidney Injury	Substantial Amendment 05.06.15	18/06/2015	26
14/EM/0211/AM03	GB122 Project	Substantial Amendment 1	11/11/2015	8
14/EM/1031/AM13	AWARE	13	25/03/2015	17
14/EM/1084/AM01	Depression and Self-harm Study (e-DASH) V1.1	Substantial Amendment 1	23/04/2015	22
14/EM/1084/AM02	Depression and Self-harm Study (e-DASH) V1.1	Substantial Amendment 2.	11/02/2016	13
14/EM/1136/AM02	p-MiVAKI 1.0	Substantial Amendment 1	30/03/2015	17
14/EM/1161/AM01	Brain pulsation and head injury (version 1)	Substantial Amendment 1	26/05/2015	21
14/EM/1193/AM01	Visual Impairment after Stroke	substantial amendment 1	20/05/2015	18
14/EM/1193/AM02	Visual Impairment after Stroke	Substantial Amendment 21.08.20	21/08/2015	32
14/EM/1195/AM01	An Assessment of Cognitive function in Chronic Kidney Disease	Amendment 1	20/10/2015	13
14/EM/1224/AM01	The Acceptance - Quality of Life relationship in cancer. Version 1.1	Substantial Amendment 1	06/05/2015	9
14/EM/1225/AM03	A feasibility study evaluating three fragility risk assessment	Substantial	14/12/2015	9

	tools	Amendment 2		
14/EM/1299/AM02	Staphylococcus aureus associated with Atopic eczema - Pilot study	Substantial Amendment 2	01/05/2015	10
15/EM/0003/AM02	Motility in Crohn's disease	Substantial Amendment 1	05/11/2015	8
15/EM/0005/AM02	Chair Based Exercise (CBE) Feasibility Study Version 1	Substantial Amendment 2	25/03/2015	20
15/EM/0005/AM03	Chair Based Exercise (CBE) Feasibility Study Version 1	Substantial Amendment 3	02/06/2015	15
15/EM/0005/AM04	Chair Based Exercise (CBE) Feasibility Study Version 1	Substantial Amendment 4	25/08/2015	24
15/EM/0005/AM05	Chair Based Exercise (CBE) Feasibility Study Version 1	Substantial Amendment 5	24/09/2015	5
15/EM/0005/AM06	Chair Based Exercise (CBE) Feasibility Study Version 1	Substantial Amendment 6.	14/10/2015	15
15/EM/0010/AM01	What is a mental health crisis? Version 1	SA Substantial Amendment 1	02/07/2015	27
15/EM/0010/AM02	What is a mental health crisis? Version 1	Substantial Amendment 2	14/12/2015	23
15/EM/0011/AM01	Comparison of Different Shoulder Scoring Systems V1	Substantial Amendment 1	19/01/2016	9
15/EM/0011/AM02	Comparison of Different Shoulder Scoring Systems V1	Substantial Amendment 1.5	10/02/2016	16
15/EM/0090/AM02	Group vs. one to one dietetic interventions in lipid clinic version2.	Substantial Amendment 2	19/04/2015	21
15/EM/0153/AM02	OARS-The Outcomes in Ankle Replacement Study	Substantial Amendment 21.08.20	21/08/2015	31
15/EM/0184/AM01	The MKD for the treatment of pharmaco-resistant epilepsy in adults	Substantial Amendment 1	18/12/2015	16
15/EM/0190/AM01	Describing the management of back pain by community pain clinics	Substantial Amendment SA01	08/10/2015	25
15/EM/0194/AM02	Children's experiences of the diabetic transition from MDIs to CSII	Substantial Amendment 4.7	27/10/2015	7
15/EM/0233/AM02	Living with Obsessive Compulsive Disorder: A Child's Perspective.	Substantial Amendment	18/12/2015	21

15/EM/0233/AM04	Living with Obsessive Compulsive Disorder: A Child's Perspective.	Substantial Amendment 3	30/01/2016	9
15/EM/0234/AM01	Compassion in the Ward Setting	Substantial Amendment 08.01.20	08/01/2016	20
15/EM/0250/AM01	BRAVE study	Substantial Amendment 1	05/11/2015	19
15/EM/0253/AM01	Individual Placement and Support for patients with offending histories	Substantial Amendment 1	15/01/2016	16
15/EM/0255/AM01	RCRT: Recovery after lung cancer radiotherapy	Substantial Amendment 1	12/08/2015	13
15/EM/0259/AM01	GO for IT	Substantial Amendment 04.11.20	04/11/2015	20
15/EM/0259/AM02	GO for IT	Substantial Amendment 2	04/02/2016	15
15/EM/0314/AM01	Improving the management of BPSD in care homes	Substantial Amendment 06/11/20	06/11/2015	18
15/EM/0325/AM02	Model-based versus traditional warfarin dosing in children	Substantial Amendment 1	02/10/2015	8
15/EM/0325/AM03	Model-based versus traditional warfarin dosing in children	Substantial Amendment 2	05/02/2016	12
15/EM/0329/AM01	Rupture of Membranes: women's expectations and experience v1	Substantial amendment 1	01/10/2015	14
15/EM/0329/AM03	Rupture of Membranes: women's expectations and experience v1	Substantial Amendment 2	10/11/2015	6
15/EM/0345/AM01	Change in free vitamin D after high dose cholecalciferol	Substantial Amendment 22.09.20	22/09/2015	7
15/EM/0345/AM02	Change in free vitamin D after high dose cholecalciferol	2.0Substantial Amendment 2	02/12/2015	34
15/EM/0384/AM01	Nottingham/Leeds Significant Ankle Ligament Injury (SALI) cohort	Substantial Amendment 2	23/02/2016	13
15/EM/0386/AM01	A breast support intervention for women with breast pain	Substantial Amendment 1	29/10/2015	13

15/EM/0410/AM01	Mechanisms underpinning depression in Multiple Sclerosis	Substantial Amendment 1	08/02/2016	20
15/EM/0452/AM01	Urinary micronutrient profile as AKI biomarker in the ICU	1.0Substantial Amendment 1	05/01/2016	21

Unfavourable opinion

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
11/EM/0442/AM21	ENCEPH UK - Prospective Cohort Study	22	11/05/2015	27
14/EM/0092/AM02	Clinical correlates and outcomes of treatment for trans people (v1)	Substantial Amendment 2	02/02/2016	21
14/EM/0184/AM05	The AKORDD study of Outreach in Acute Kidney Injury	Substantial Amendment 5	15/12/2015	21
15/EM/0090/AM01	Group vs. one to one dietetic interventions in lipid clinic version2.	Substantial Amendment 1	16/04/2015	21

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
11/EM/0442/AM21/1	ENCEPH UK - Prospective Cohort Study	Modified Amendment	30/07/2015	1
14/EM/0184/AM05/1	The AKORDD study of Outreach in Acute Kidney Injury	AKORDD substantial amendment 5	03/02/2016	9

Unfavourable opinion timeline

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
None	None	None	None	None

Table 11: Items exceeding timelines**Full applications for ethical review over 60 day timeline**

REC Reference	Title	Number of Days on Clock
None	None	None

Proportionate review applications for ethical review over 14 day timeline

REC Reference	Title	Number of Days on Clock
None	None	None

SSAs (non Phase 1) over 25 day timeline

REC Reference	Title	Number of Days on Clock
None	None	None

SSAs (Phase 1) over 14 day timeline

REC Reference	Title	Number of Days on Clock
None	None	None

Substantial Amendments over 35 day timeline

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
None	None	None	None	None

Modified Amendments over 14 day timeline

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
None	None	None	None	None