

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

Annual Report

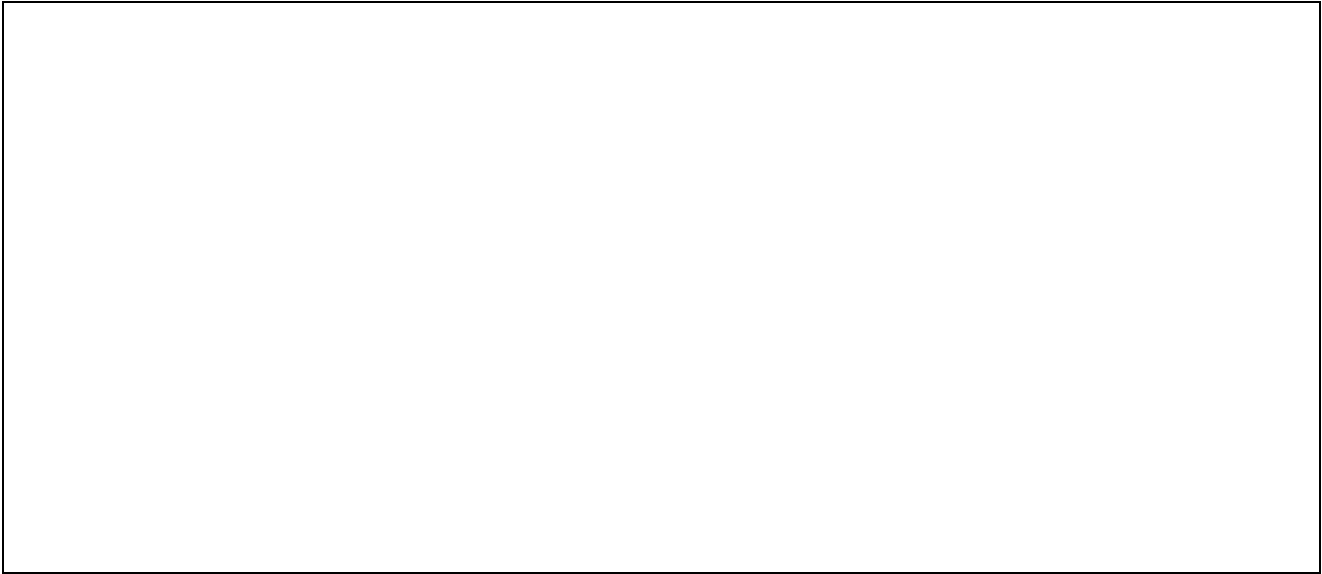
01 April 2016 - 31 March 2017



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 Research Involving Children
Chair:	Mr John Aldridge
Vice-Chair:	Professor Cris Constantinescu
Alternate Vice-Chair:	Ms Ellen Milazzo
REC Manager:	Miss Rebecca Morledge
REC Assistant:	Mr George R. Martin
Committee Address:	The Old Chapel Royal Standard Place Nottingham NG1 6FS
Telephone:	0207 104 8104
Email:	NRESCcommittee.EastMidlands-Nottingham1@nhs.net

Chair's overview of the past year:



East Midlands - Nottingham 1 Research Ethics Committee Membership

Name	Profession	Expert or Lay	Dates	
			Appointed	Left
Mr John Aldridge	Retired Senior Lecturer in Nursing	Lay	01/01/2017	
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	14/02/2017
Dr Sarah Forster	Respiratory Registrar	Expert	30/09/2015	
Dr Ursula Holdsworth	Retired Staff Grade Community Paediatrician	Expert	01/10/2011	
Dr Blerina Kellezi	Lecturer in Psychology	Lay	01/12/2016	
Reverend Keith Lackenby	Reverend	Lay Plus	10/10/2006	10/10/2016
Mrs Sarah Lennon	Ex-Surgical Registrar (GMC registration maintained)	Expert	01/09/2011	
Mr Oliver Matias	Clinical Trials Researcher	Expert	13/12/2016	
Ms Ellen Milazzo	Development and Change Management Consultant	Lay Plus	28/07/2014	
Mrs Rita Patel	Contracts and Innovation Manager	Lay	22/09/2015	14/12/2016
Dr James Rathbone	Clinical Psychologist	Expert	13/10/2015	11/10/2016
Ms Stephanie Sampson	PhD Student	Lay Plus	18/02/2016	
Mr Ian Thompson	Retired Deputy Head Teacher	Lay Plus	19/10/2006	12/10/2016
Mrs Norma Thompson	Clinical Research Nurse	Expert	10/11/2015	

East Midlands - Nottingham 1 Research Ethics Committee: Deputy Members

None

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

Name	Profession	Status	Meeting date attended
Mrs Jeanne-Anne Charly	Staff Nurse	Expert	14 February 2017
Mr Alan Caswell	Retired Nurse	Lay	10 January 2017

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

Name	Declaration of Interest	Date
Mr John Aldridge	None declared	20/02/2017
Dr Glenys Caswell	Employed as Senior Research Fellow at University of Nottingham in the School of Health Sciences	06/01/2017
Professor Cris Constantinescu	NIHR CRN Division IV Specialty Group Lead for Neurological Disorders (East Midlands)	14/02/2017
Dr Carl Edwards	None declared	10/05/2016
Dr Sarah Forster	Academic Clinical Fellow at University of Nottingham & Nottingham Respiratory Research Group	14/02/2017
Dr Ursula Holdsworth	None declared	10/01/2017
Dr Blerina Kellezi	Senior Lecturer, Nottingham Trent University Associate: Oxford & Nottingham University Associate: International consortium of health and human rights, UK	20/02/2017
Mrs Sarah Lennon	none declared	02/12/2016
Mr Oliver Matias	Clinical Trials Researcher employed by the University of Nottingham Honourary contract with Nottingham University NHS Trust as a clinical trials researcher (to recruit stroke patients from the hospital into clinical trials)	20/02/2017
Ms Ellen Milazzo	None declared.	06/01/2017
Ms Stephanie Sampson	Currently holds a volunteer role with 'Improving Lives', a Nottingham-based charity that provides support to vulnerable people living in the community. Also going to commence paid employment with the same charity in 2017 as a volunteer coordinator. This charity does actively engage in research. Currently part-time PhD student, investigating legal and ethical aspects of psychiatric research into coercion. This will involve research with NHS RECs, and is in the process of being prepared with the HRA.	06/01/2017
Mrs Norma Thompson	Research Nurse in Respiratory Medicine at City Hospital Nottingham. The department often submit project applications to local REC committees for review.	06/01/2017

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

Month	Date	Number of Members Present at Meeting
May	10/05/2016	11
June	14/06/2016	10
August	09/08/2016	12
September	13/09/2016	12
October	11/10/2016	10
December	13/12/2016	10
January	10/01/2017	7
February	14/02/2017	8
March	14/03/2017	11

9 full committee meetings were held during the reporting period.

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

Month	Date	Number of Members Present at Meeting
April	05/04/2016	3
May	10/05/2016	3
June	14/06/2016	3
August	09/08/2016	3
September	13/09/2016	3
October	11/10/2016	4
November	08/11/2016	4
December	13/12/2016	3
January	10/01/2017	3
February	14/02/2017	3
March	14/03/2017	3

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

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

Month	Date	Number of Members Present at Meeting
April	12/04/2016	2
April	19/04/2016	2
April	29/04/2016	2
May	10/05/2016	2
May	23/05/2016	2
June	03/06/2016	2
June	14/06/2016	2
June	30/06/2016	2
July	11/07/2016	2

July	26/07/2016	2
August	09/08/2016	2
August	23/08/2016	2
September	13/09/2016	2
September	27/09/2016	2
October	11/10/2016	2
October	25/10/2016	2
November	08/11/2016	2
November	22/11/2016	2
December	13/12/2016	2
December	28/12/2016	2
January	09/01/2017	2
January	26/01/2017	2
March	14/03/2017	2
March	30/03/2017	2

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

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

None

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

Name	Number of Meetings Attended
Mr John Aldridge	3
Dr Glenys Caswell	7
Professor Cris Constantinescu	7
Dr Carl Edwards	6
Dr Sarah Forster	7
Dr Ursula Holdsworth	9
Dr Blerina Kellezi	2
Reverend Keith Lackenby	4
Mrs Sarah Lennon	8
Mr Oliver Matias	2
Ms Ellen Milazzo	9
Mrs Rita Patel	5
Dr James Rathbone	2
Ms Stephanie Sampson	7
Mrs Norma Thompson	7
Mr Ian Thompson	4

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

Name	Number of Meetings Attended
Mr John Aldridge	2
Dr Glenys Caswell	4
Professor Cris Constantinescu	5
Dr Carl Edwards	6
Dr Sarah Forster	1
Dr Ursula Holdsworth	2
Reverend Keith Lackenby	3
Mrs Sarah Lennon	3
Ms Ellen Milazzo	3
Mrs Rita Patel	2
Ms Stephanie Sampson	2
Mrs Norma Thompson	1
Mr Ian Thompson	1

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

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

Training 01 April 2016 - 31 March 2017

Name of Member	Date	Event(s) attended
Mr John Aldridge	18/11/2016	Regional Chairs Meeting
Mr John Aldridge	01/12/2016	National Training Day for Committee Chairs
Mr John Aldridge	21/02/2017	Equality & Diversity
Dr Glenys Caswell	15/09/2016	Planned and chaired an interactive ethics seminar
Dr Glenys Caswell	30/09/2016	Supervised PhD student in development of participant documents and completion of application forms to apply for ethical approval
Dr Glenys Caswell	12/12/2016	Equality and Diversity
Dr Glenys Caswell	30/12/2016	Supervised second PhD student in developing documentation and completing application forms to submit to Faculty ethics committee
Dr Glenys Caswell	14/02/2017	Buddy / Mentor to new member
Dr Carl Edwards	06/05/2016	NREAP Meeting
Dr Carl Edwards	17/09/2016	Equality and Diversity
Dr Carl Edwards	23/09/2016	Local Training Day
Dr Sarah Forster	30/11/2016	Members Induction
Dr Ursula Holdsworth	23/09/2016	Local Training Day Leicester
Reverend Keith Lackenby	08/06/2016	Equality and Diversity Slides
Reverend Keith Lackenby	23/09/2016	Local Training Day Leicester
Mr Oliver Matias	29/03/2017	Equality and Diversity
Ms Ellen Milazzo	23/09/2016	Local Training Day Leicester
Ms Ellen Milazzo	14/02/2017	Buddy / Mentor to new member
Mrs Rita Patel	23/09/2016	Local Training Day Leicester
Mrs Rita Patel	19/10/2016	HARP Member's Portal Webinar
Ms Stephanie Sampson	08/06/2016	Training Committee Members Induction
Ms Stephanie Sampson	09/09/2016	Equality and Diversity
Ms Stephanie Sampson	23/09/2016	Local Training Day Leicester
Ms Stephanie Sampson	19/10/2016	Webinar HARP Members Portal
Mrs Norma Thompson	08/06/2016	Training Committee Members Induction
Mrs Norma Thompson	23/09/2016	Local Training Day Leicester
Mrs Norma Thompson	18/10/2016	Equality and Diversity
Mrs Norma Thompson	01/12/2016	When should Placebo surgery as a control in clinical trials be carried out?
Mrs Norma Thompson	01/12/2016	Are patients with amyotrophic lateral sclerosis at risk of a therapeutic misconception?
Mrs Norma Thompson	02/12/2016	Must research benefit human subjects if it is to be

		permissible?
Mrs Norma Thompson	02/12/2016	Understanding the 'therapeutic misconception from the research participant's perspective'
Mrs Norma Thompson	05/12/2016	Sense and readability; participant information sheets for research studies
Mrs Norma Thompson	05/12/2016	Genetic risk statements regarding ionising radiation for MPE and CRE statements in the IRAS application form and PIS

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	40	100.00
Total Applications Reviewed	40	100

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

Number of applications made invalid by the REC Manager	0
Number of applications withdrawn prior to the meeting	0
Number of student applications reviewed	20
Number of paediatric applications reviewed	4
Number of device applications reviewed	1
Number of prisoner applications reviewed	1
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

Decisions taken at meetings following review of applications	Number	%
Favourable Opinion with Standard Conditions	0	0.00
Favourable Opinion with Additional Conditions	7	17.50
Unfavourable Opinion	1	2.50
Provisional Opinion	32	80.00
Provisional Opinion Pending Consultation with Referee	0	0.00
Total	40	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	29	72.50
Further Information Favourable Opinion with Additional Conditions	3	7.50
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	0	0.00
Favourable Opinion with Additional Conditions	7	17.50
Unfavourable Opinion	1	2.50
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	40	100

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

Total Applications Reviewed	35
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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	1
Number of studies withdrawn prior to the meeting	0
Number of student applications reviewed	18
Number of paediatric applications reviewed	4
Number of device applications reviewed	1
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	3	8.57
Favourable Opinion with Additional Conditions	8	22.86
No Opinion transfer to full committee for review	1	2.86
Provisional Opinion	23	65.71
Unfavourable Opinion	0	0.00
Total	35	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	4.44
Number of completed applications for full ethical review	40
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	2
Number of completed applications over 40 days as a % of total	5.00%
Number of days taken to final decision – average (mean)	29
Number of completed proportionate review applications for ethical review	34
Number of completed proportionate review applications for ethical review over 14 days (Please note, the timeline for the review of PR applications was extended from 14 to 21 calendar days in December 2016)	6
Number of completed proportionate review applications for ethical review over 21 days'	0
Number of completed proportionate review applications over 14 days as a % of total	17.65%
Number of SSAs (non-Phase 1) reviewed	6
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	59
Number of completed substantial amendments over 35 days	0
Number of completed substantial amendments over 35 days as a % of total substantial amendments	0.00%
Number of completed substantial amendments over 28 days	0
Number of completed substantial amendments over 28 days as a % of total substantial amendments	0.00%
Number of modified amendments reviewed	3
Number of completed modified amendments over 14 days	0
Number of completed modified amendments over 14 days as a % of total modified amendments	0.00%

Number of non substantial amendments received	82
Number of substantial amendments received for information	0
Number of substantial amendments received for new sites/PIs	0
Number of annual progress reports received	63
Number of safety reports received	0
Number of Serious Adverse Events received	0
Number of final reports received	12

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

Further Information Favourable Opinion with Standard Conditions		
REC Reference	Title	Number of Days on Clock
16/EM/0183	Validation of the Nottingham Gender and Body Dysphoria Scale	34
16/EM/0192	COPD and Cognitive Impairment Pilot Study	32
16/EM/0204	RCT of the Effectiveness of BWW compared to Other Online Support	30
16/EM/0218	The Role of the Pulvinar in Perceived Threat in Mental Simulations	30
16/EM/0235	People with learning disabilities identifying psychotic symptoms	28
16/EM/0244	Long term effect of ovarian surgery on ovarian reserve and fertility	30
16/EM/0246	Nottingham Foot Arthritis and Pain Study	25
16/EM/0323	B-SMaRT study	35
16/EM/0339	Using Hepcidin to predict recovery from anaemia after ICU discharge	24
16/EM/0344	MPP VARR	32
16/EM/0399	The Athlete's Heart Study 2	33
16/EM/0401	Neurobiology of the social environment	21
16/EM/0410	The reliability of Satisfaction with CIRCUITS measures	28
16/EM/0429	ACT for distress in head and neck cancer v1.0	30
16/EM/0461	Improving identification of FH in primary care (FAMCAT)	43
16/EM/0484	RECOLLECT	34
16/EM/0489	Post-mortem redistribution	37
16/EM/0505	Mental health needs of older forensic psychiatric patients	42
17/EM/0009	Different ways men and women live through infertility treatment	39
17/EM/0023	Air pollution and children with cystic fibrosis	32
17/EM/0032	Reclassifying constipation using MRI and high resolution manometry	33
17/EM/0061	Occult bone disease in sudden childhood death: A post-mortem study	25
17/EM/0062	LSEC Version 1	17
17/EM/0070	The impact of formulation on working alliance	22
17/EM/0074	Proteomic comparison of two zoonotic infections causing AKI.v.1	16
17/EM/0089	BREAKOUT	24
17/EM/0106	Thermal imaging to assess BAT function in overweight men (BATmen)	24
17/EM/0107	The relationship between symptoms and lung function in asthma	24
17/EM/0114	The Feasibility of a Novel Intervention for At Risk Mental State	27

Further Information Favourable Opinion with Additional Conditions		
REC Reference	Title	Number of Days on Clock
16/EM/0313	An interview study exploring transgender people' social interactions	31
16/EM/0364	Self-Harm and Suicide in females with complex mental health needs	34
16/EM/0423	Stroke Follow up study	39

Further Information Unfavourable Opinion		
REC Reference	Title	Number of Days on Clock
none		

Favourable Opinion with Standard Conditions		
REC Reference	Title	Number of Days on Clock
none		

Favourable Opinion with Additional Conditions		
REC Reference	Title	Number of Days on Clock
16/EM/0212	MIRROR Trial version 1.0	25
16/EM/0243	Skin autofluorescence as a risk marker in people receiving dialysis	23
16/EM/0257	The STarT MSK Trial version 1.0	23
16/EM/0492	HSH BME Patient Experiences	29
16/EM/0500	Indapamide treatment for heart failure - a pilot study	29
17/EM/0003	PIMPERNEL	23
17/EM/0027	Objective testing of non-adherence to cardiovascular medications	28

Unfavourable Opinion		
REC Reference	Title	Number of Days on Clock
17/EM/0031	ADHEAR Hearing System: evaluation on experienced patients	22

Provisional Opinion		
REC Reference	Title	Number of Days on Clock
none		

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

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

Withdrawn after the meeting		
REC Reference	Title	Number of Days on Clock
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
16/EM/0155	CIPHER Phase A: Understanding surgical practice and developing a PROM	14
16/EM/0157	Development of a physical activity referral scheme	12
16/EM/0162	CHAMPIONS Study v1.0	14
16/EM/0208	Non-pharmacological interventions for Delirium in Critical illness	14
16/EM/0209	Serum concentrations of amoxicillin, metronidazole and gentamicin	14
16/EM/0409	Correlation between dental erosion and Salivary Pepsin.	12
16/EM/0412	Melatonin in pregnancy (MEL-P)	13
16/EM/0413	Adapting invitation letters to increase breast screening attendance	12
16/EM/0434	Understanding and Measuring Resilience in Older People in the UK	11
16/EM/0435	Exploring perceptions for the consequence of alcohol use in later life	14
16/EM/0438	A comparison of oximetry sensors during the six minute walk test	16
16/EM/0467	Acceptability & Feasibility of GMHAT in Primary Care	8
16/EM/0472	Nurse-led callback service evaluation	9

16/EM/0473	Exploring CBT as part of a parent training for children who stammer	10
16/EM/0517	Client perceptions of unhelpful aspects of CBT within IAPT	10
17/EM/0021	Idiopathic Pulmonary Fibrosis Job Exposures Study (IPF JES)	10
17/EM/0033	Chromoendoscopy in inflammatory bowel disease	8
17/EM/0072	IMRABIOME_v1.0	17
17/EM/0110	Pattern of Use and Safety/Effectiveness Nivolumab in Oncology Practice	16
17/EM/0111	Associative learning in alcohol dependence	19
17/EM/0112	A Safer Ramadan	15

Further Information Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
16/EM/0437	Cognitive CI study	11

Further Information Unfavourable Opinion

REC Reference	Title	Number of Days on Clock
none		

Favourable Opinion with Standard Conditions

REC Reference	Title	Number of Days on Clock
16/EM/0210	Validity of an Actigraph accelerometer following critical illness	14
16/EM/0356	IPF in Intensive Care Unit v.1.2 (08/06/2016)	8
17/EM/0113	Implementation of multiprofessional sepsis training	12

Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
16/EM/0265	Obesity and Acute Abdominal Pain	10
16/EM/0267	Pharmacist consultations with paediatric patients with epilepsy. V7	13
16/EM/0268	Identification of forefoot pain using a novel expert derived protocol	13
16/EM/0355	Rituximab Surveillance Study in Vasculitis (RIVAS)	11
16/EM/0474	CLOTS-QoL Study	6
16/EM/0515	Carbonic Anhydrase Inhibitors as Antithrombotic Agents (CAIATA)	8
16/EM/0516	Assessing a new test of the ear in children	10

17/EM/0071	IL13R \pm 2-targeted therapy for pancreatic cancer	15
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Unfavourable Opinion

REC Reference	Title	Number of Days on Clock
none		

Provisional Opinion

REC Reference	Title	Number of Days on Clock
None		

Further information response not complete

REC Reference	Title	Number of Days on Clock
17/EM/0073	Brevera Study	n/a

Withdrawn after the meeting

REC Reference	Title	Number of Days on Clock
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/Q2403/137/AM18	Studies of Blood Cell Function	6.0	19/12/2016	0
08/H0403/80/AM12	Population based prospective cohort study of pneumococcal pneumonia	9	21/06/2016	17
09/H0403/71/AM13	Prevention of decline in cognition after stroke trial. Version 1.0	Substantial Amendment SA/01/16	31/08/2016	19
10/H0403/10/AM15	Compensated Cirrhosis Cohort Study: Nottingham version 1.0	Substantial Amendment No 15	17/03/2016	2
10/H0403/98/AM16	Factors affecting speech processing in complex auditory environments	Substantial Amendment 10	30/06/2016	4
13/EM/0214/AM04	Pre-operative Nutrition In Neck of femur Trial (POINT)	Substantial Amendment 4	06/03/2016	10
13/EM/0343/AM05	Complete v culprit-only revascularisation in PPCI for STEMI - COMPLETE	2	28/02/2017	22
14/EM/0056/AM05	Epidemiology, management, outcomes and pathophysiology of SCAD	5	02/06/2016	13
14/EM/0081/AM08	Long term evaluation of the management of prostate cancer patients.	5	15/11/2016	7
14/EM/0083/AM06	Leg oedema In Multiple Sclerosis (LIMS) Version 1.0	Substantial Amendment 3.0	20/10/2016	14
14/EM/0092/AM03	Clinical correlates and outcomes of treatment for trans people (v1)	4	15/03/2017	18
14/EM/0145/AM05	Methotrexate induced liver fibrosis	5	23/02/2017	12
14/EM/1084/AM03	Depression and Self-harm Study (e-DASH) V1.1	Substantial Amendment 3	25/05/2016	9
14/EM/1285/AM01	Dynamics of pneumolysin in adults with pneumococcal pneumonia.	1	21/06/2016	17
15/EM/0003/AM03	Motility in Crohn's disease	Substantial Amendment 2	12/05/2016	8
15/EM/0005/AM07	Chair Based Exercise (CBE) Feasibility Study Version 1	Substantial	16/03/2016	16

		Amendment 7		
15/EM/0005/AM08	Chair Based Exercise (CBE) Feasibility Study Version 1	8	05/09/2016	11
15/EM/0018/AM01	REALITY Feasibility study	Substantial Amendment 1	16/05/2016	6
15/EM/0109/AM01	Characterising Phenotypes of Mtb Infection (ISIT-TB)	Substantial Amendment 1	12/08/2016	24
15/EM/0114/AM01	A feasibility study of early and enhanced rehabilitation in ICU	1	18/03/2016	12
15/EM/0115/AM02	Obsessive relational intrusion: behaviours, motives and perceptions	Substantial Amendment 4.0	13/05/2016	14
15/EM/0153/AM06	OARS-The Outcomes in Ankle Replacement Study	Substantial Amendment 2	25/10/2016	11
15/EM/0253/AM02	Individual Placement and Support for patients with offending histories	Substantial Amendment 2	05/01/2017	9
15/EM/0259/AM03	GO for IT	3	16/06/2016	4
15/EM/0303/AM15	Non-interventional study of time to relapse of iron deficiency anaemia after Monofer	2	13/02/2017	13
15/EM/0314/AM03	Improving the management of BPSD in care homes	Substantial Amendment MEDREV V	30/03/2016	15
15/EM/0314/AM04	Improving the management of BPSD in care homes	Substantial Amendment MEDREV V	12/10/2016	12
15/EM/0314/AM05	Improving the management of BPSD in care homes	Substantial Amendment MEDREV V	22/11/2016	13
15/EM/0314/AM07	Improving the management of BPSD in care homes	4.0	22/02/2017	21
15/EM/0345/AM04	Change in free vitamin D after high dose cholecalciferol	Substantial Amendment 3	28/09/2016	13
15/EM/0345/AM05	Change in free vitamin D after high dose cholecalciferol	Substantial Amendment 4	21/10/2016	11
15/EM/0377/AM02	Decision making and future planning for children with complex illness	Substantial Amendment 1	16/03/2016	14
15/EM/0384/AM05	Nottingham/Leeds Significant Ankle Ligament Injury (SALI) cohort	Substantial Amendment 3	22/08/2016	27
15/EM/0386/AM04	A breast support intervention for women with breast pain	Substantial Amendment 2	07/04/2016	12

15/EM/0423/AM01	Detection of diabetes in people with stroke using HbA1c.	01	05/09/2016	18
15/EM/0446/AM01	Computed Tomography assessment of Regional Ventilation (CURVE)	Amendment 1	28/09/2016	9
15/EM/0453/AM01	Psychoeducation for TIA and Minor Stroke (OPTIMISM)	Substantial Amendment 1	20/12/2016	7
15/EM/0478/AM01	A cognitive interviewing study exploring respiratory questionnaires	Substantial Amendment 1	23/08/2016	16
15/EM/0478/AM02	A cognitive interviewing study exploring respiratory questionnaires	Substantial Amendment 2	11/01/2017	12
15/EM/0495/AM02	Standing frames for children with Cerebral Palsy_v1	Substantial Amendment Kisler H	23/05/2016	11
15/EM/0529/AM01	Knee synovial changes detected by ultrasound in the general population	Substantial Amendment 2.0	04/04/2016	13
15/EM/0531/AM01	Mindfulness for Osteoarthritis-related knee pain	Substantial Amendment 2.0	20/04/2016	19
16/EM/0010/AM01	The GA Stimulation Ventilation Study	Substantial Amendment 1	18/07/2016	10
16/EM/0027/AM01	Older People's Rehabilitative Exercise Engagement: OPREE	Substantial Amendment 17.06.20	17/06/2016	10
16/EM/0035/AM01	The INDURMAN Ventilation Study	Substantial Amendment V1.2	14/06/2016	4
16/EM/0041/AM01	Antenatal anxiety intervention: feasibility and acceptability	Substantial Amendment 2.0	19/04/2016	10
16/EM/0044/AM01	PRIDE Intervention Development and Feasibility	Substantial Amendment V2	31/10/2016	7
16/EM/0070/AM02	ThyVoice	Substantial Amendment 01	05/01/2017	3
16/EM/0071/AM01	MDT management of pregnant women with cardiac disease	Substantial Amendment 1	14/04/2016	9
16/EM/0100/AM01	Mindfulness for adults with BPD, a feasibility study (version 1)	Substantial Amendment 1	12/05/2016	13
16/EM/0122/AM02	Cancer, Fertility and Me.	1	01/08/2016	8
16/EM/0162/AM01	CHAMPIONS Study v1.0	Substantial Amendment 1	25/05/2016	13

16/EM/0212/AM01	MIRROR Trial version 1.0	Substantial Amendment 1	21/10/2016	21
16/EM/0364/AM01	Self-Harm and Suicide in females with complex mental health needs	Substantial Amendment 1	21/11/2016	8
16/EM/0401/AM01	Neurobiology of the social environment	Substantial Amendment 1.0	23/11/2016	15
16/EM/0438/AM01	A comparison of oximetry sensors during the six minute walk test	Substantial Amendment 1	05/01/2017	11
Q1020310/AM06	Mucosal cell interactions as determinants of intestinal disease	Substantial Amendment 2	12/04/2016	14

Unfavourable opinion

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
08/H0403/96/AM01	Fibrotic quantification of renal transplant biopsies	Substantial Amendment 3	17/02/2016	7
14/EM/1230/AM01	PI3K signalling in COPD	Substantial Amendment 1	20/07/2016	14

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
08/H0403/96/AM01/1	Fibrotic quantification of renal transplant biopsies	Modified Amendment 03.05.2016	03/05/2017	8
14/EM/0092/AM02/1	Clinical correlates and outcomes of treatment for trans people (v1)	Modified Amendment 3	30/03/2016	1
14/EM/1230/AM01/1	PI3K signalling in COPD	Modified Amendment 2	01/09/2016	13

Unfavourable opinion timeline				
Amendment REC Reference	Title	Version	Date	Number of Days on Clock
none				

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

REC Reference	Title	Number of Days on Clock
none		

Proportionate review applications for ethical review over 14 day timeline

REC Reference	Title	Number of Days on Clock
16/EM/0438	A comparison of oximetry sensors during the six minute walk test	16

SSAs (non Phase 1) over 25 day timeline

REC Reference	Title	Number of Days on Clock
none		

SSAs (Phase 1) over 14 day timeline

REC Reference	Title	Number of Days on Clock
none		

Substantial Amendments over 35 day timeline

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

Modified Amendments over 14 day timeline

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