

**Yorkshire & The Humber - South Yorkshire
Research Ethics Committee**

Annual Report

01 April 2015 - 31 March 2016



Part 1 – Committee Membership and Training

Name of REC:	Yorkshire & The Humber - South Yorkshire Research Ethics Committee
Type of REC:	Authorised
Type of Flag:	Paediatrics
Chair:	Dr Ian Woollands
Vice-Chair:	Dr Duane Mellor (until 31/12/2015) Dr Max Huxham (from 15/03/2016)
Alternate Vice-Chair:	Dr Max Huxham (10/04/15 – 10/03/2016)
REC Manager:	Mrs Helen Wilson (01/04/2015 - 03/08/2015) Mrs Gillian Mayer (04/08/2015 – 31/01/2016) Mrs Helen Wilson (01/02/2016 – to date)
REC Assistant:	Miss Kerry Dunbar (01/04/2015 - 03/08/2015) Miss Donna Bennett (04/08/2015 – 31/01/2016) No REC Assistant from 01/02/2016
Committee Address:	HRA Jarrow Jarrow Business Centre Rolling Mill Road Jarrow NE32 3DT
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Chair's overview of the past year:

On behalf of the South Yorkshire Research Ethics Committee, I have once more had the pleasure and privilege of writing the "Chairs Overview of the Past Year".

As Chair of the Committee, I have been ably assisted and supported by the REC Managers Mrs Helen Wilson and Mrs Gillian Mayer along with Miss Kerry Dunbar REC Assistant and wish to acknowledge their hard work which has ensured the smooth running of the Committee to provide an efficient service for researchers.

Unfortunately during the year a number of members had to resign from the Committee due to increased demands from their employment.

On behalf of the Committee, I wish to record our thanks for their contributions and support in the work of the Committee.

Finally, I wish to again record the commitment and support from all the new and continuing REC members who have given freely of their time and expertise to ensure the Committee meets its duties to safeguard the rights, safety, dignity and well-being of people participating in research in the National Health Service.

Yorkshire & The Humber - South Yorkshire Research Ethics Committee Membership

Name	Profession	Expert or Lay	Dates	
			Appointed	Left
Dr Ahmed H Abdelhafiz	Consultant Physician, Elderly Medicine	Expert	07/03/2007	
Dr Parveen Ali	Lecturer	Expert	01/06/2015	
Dr Peter Allmark	Principal Nursing Lecturer	Expert	01/10/2013	
Reverend Joan Ashton	Co-ordinator of Chaplaincy Services	Lay Plus	30/01/2007	18/05/2015
Ms Helen Barlow	Knowledge Service Manager	Lay Plus	30/01/2007	
Professor Nigel Beail	Consultant Clinical Psychologist & Professor of Psychology	Expert	30/01/2007	
Mr David Broomhead	Therapy Consultant	Expert	08/05/2014	
Mr Ian Cawthorne	Pharmacist	Expert	30/01/2007	
Mr Michael Davidson	Retired Senior Personnel Manager	Lay Plus	01/01/2015	
Mr Martin Edmunds	Editor	Lay Plus	10/04/2015	
Dr Max Huxham	Retired Scientist	Lay	15/05/2014	
Dr Duane Mellor	Assistant Professor in Dietetics	Expert	26/09/2013	31/12/2015
Reverend Clive Smith	Trust Chaplaincy Manager (Retired)	Lay	01/06/2015	
Mrs Carole Taylor	Deputy Chief Pharmacist	Expert	01/03/2015	
Dr Ian Woollands	Retired Clinical Director, Occupational Health	Expert	17/02/2014	

Yorkshire & The Humber - South Yorkshire Research Ethics Committee: Deputy Members

Name	Profession	Status	Meeting date attended
None			

Yorkshire & The Humber - South Yorkshire Research Ethics Committee: Co-opted

Name	Profession	Status	Meeting date attended
Dr Rhona Bratt	Retired MultiMedia Project Manager	Lay Plus	PR 12/08/2015
Mr Paddy Stevenson	Clinical Operations Manager	Expert	PR 07/03/2016
Mr Richard Tomlin	Consultant in Research Management (Retired)	Lay Plus	01/10/2015 (teleconference) *

Yorkshire & The Humber - South Yorkshire Research Ethics Committee: Members

Name	Declaration of Interest	Date
Dr Ahmed H Abdelhafiz	None.	01/03/2016
Dr Parveen Ali	I am a lecturer at the School of Nursing and Midwifery, University of Sheffield and therefore, I	22/06/2015

	am likely to be involved in health and social care research. However, I am not involved with any other organisation. I am an active researcher and am also a chair of the research ethics committee in School of Nursing and Midwifery, University of Sheffield. I am also a peer reviewer of various peer reviewed academic journals in the field of nursing and domestic violence.	
Dr Peter Allmark	Chair of Sheffield Hallam University Faculty (HWB) Research Ethics Committee Lay Member of Sheffield University REC Member Labour Party	01/03/2016
Ms Helen Barlow	Works as Library and Knowledge Service Manager for the Rotherham NHS Foundation Trust.	01/03/2016
Professor Nigel Beail	Member of the Institute for Learning Disabilities. Ad-hoc peer review for funding bodies.	01/03/2016
Mr David Broomhead	Act as an advisor, reviewing potential research projects prior to submission for approval within Northern Lincolnshire and Goole NHS Foundation Trust; this supports the Trust's R+D function.	31/03/2016
Mr Ian Cawthorne	None.	01/03/2016
Mr Michael Davidson	None.	01/03/2016
Mr Martin Edmunds	None.	01/03/2016
Dr Max Huxham	Member of SMA UK, Member of SMA Europe.	01/03/2016
Reverend Clive Smith	Sessional (part time and temporary) chaplain at HM Prison Moorland, South Yorkshire. One of sons is an Emergency Department Consultant at Aintree Hospital in Liverpool.	04/06/2015
Mrs Carole Taylor	None.	01/03/2016
Dr Ian Woollands	None.	01/03/2016

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

Month	Date	Number of Members Present at Meeting
April	30/04/2015	10
June	25/06/2015	12
July	30/07/2015	10
August	27/08/2015	10
September	24/09/2015	6
October	01/10/2015 *	7
October	29/10/2015	9
November	26/11/2015	11
January	28/01/2016	10
February	25/02/2016	10
March	31/03/2016	10

11 full committee meetings were held during the reporting period.

*discussion and decisions from the inquorate meeting held on 24/09/2015 were ratified on 01/10/15 in a full meeting held by telephone.

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

Month	Date	Number of Members Present at Meeting
June	10/06/2015	3
July	08/07/2015	3
August	12/08/2015	3
September	09/09/2015	3
October	15/10/2015	3
November	11/11/2015	3
December	09/12/2015	3
January	15/01/2016	3
February	08/02/2016	3
March	07/03/2016	3

10 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	01/04/2015	2
April	09/04/2015	2
April	22/04/2015	2
April	23/04/2015 (Humber Bridge REC)*	2
May	07/05/2015 (Humber Bridge REC)*	2
May	07/05/2015	2

May	21/05/2015	2
June	04/06/2015	2
June	19/06/2015	2
July	09/07/2015	2
July	22/07/2015	2
August	06/08/2015	2
August	20/08/2015	2
August	21/08/2015	2
September	03/09/2015	2
September	14/09/2015	2
September	17/09/2015	2
September	24/09/2015	6**
October	15/10/2015	2
November	12/11/2015	2
November	25/11/2015	2
December	10/12/2015	2
December	22/12/2015	2
January	12/01/2016	2
January	26/01/2016	2
February	10/02/2016	2
February	24/02/2016	2
March	08/03/2016	2
March	22/03/2016	2

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

*Sub-Committee comprised of Humber Bridge amendments prior to merger.

** One study was referred to a Sub Committee comprised of 6 members for consideration.

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

Date	Reason	Action taken
24/09/2015	Only 6 members attended due to late apologies being submitted	A full meeting (with 7 members) was arranged for the following week (01/10/2015) via teleconference to ratify decisions

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

Name	Number of Meetings Attended
Dr Ahmed H Abdelhafiz	8
Dr Parveen Ali	5
Dr Peter Allmark	7
Reverend Joan Ashton	1
Ms Helen Barlow	10
Professor Nigel Beail	7
Mr David Broomhead	8
Mr Ian Cawthorne	5
Mr Michael Davidson	7
Mr Martin Edmunds	10
Dr Max Huxham	8
Dr Duane Mellor	4
Reverend Clive Smith	7
Mrs Carole Taylor	6
Mr Richard Tomlin	1
Dr Ian Woollands	11

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

Name	Number of Meetings Attended
Dr Ahmed H Abdelhafiz	2
Dr Peter Allmark	2
Ms Helen Barlow	3
Professor Nigel Beail	2
Dr Rhona Bratt	1
Mr David Broomhead	2
Mr Ian Cawthorne	2
Mr Michael Davidson	2
Mr Martin Edmunds	1
Dr Max Huxham	4
Dr Duane Mellor	4
Mr Paddy Stevenson	1
Dr Ian Woollands	4

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

Name	Number of Meetings Attended
Dr Ahmed H Abdelhafiz	4
Dr Peter Allmark	3
Reverend Joan Ashton	2
Ms Helen Barlow	6
Professor Nigel Beail	2
Mr David Broomhead	3
Mr Ian Cawthorne	4
Mr Michael Davidson	1
Mr Martin Edmunds	2
Dr Max Huxham	7
Dr Duane Mellor	11
Mrs Carole Taylor	1
Dr Ian Woollands	16

Training 01 April 2015 - 31 March 2016

Name of Member	Date	Event(s) attended
Dr Ahmed H Abdelhafiz	04/06/2015	Regional Members Training Day
Dr Parveen Ali	28/07/2015	Equality and Diversity
Dr Peter Allmark	04/06/2015	Regional Members Training Day
Professor Nigel Beail	04/06/2015	Regional Members Training Day
Mr David Broomhead	04/06/2015	Regional Members Training Day
Mr Ian Cawthorne	04/06/2015	Regional REC Member Training Event
Mr Michael Davidson	17/04/2015	The 2015 Allam Lecture
Mr Martin Edmunds	23/04/2015	Equality and Diversity
Mr Martin Edmunds	15/06/2015	Members Induction Day
Mr Martin Edmunds	16/03/2016	National Members Training Day
Dr Max Huxham	04/06/2015	Regional Members Training Day
Dr Duane Mellor	04/06/2015	Regional Members Training Day
Dr Duane Mellor	04/07/2015	Equality and Diversity
Reverend Clive Smith	04/11/2015	Members Induction Day
Mrs Carole Taylor	25/06/2015	Equality and Diversity
Mrs Carole Taylor	16/03/2016	Regional Members Training Day
Dr Ian Woollands	04/06/2015	Regional 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	46	100.00
Total Applications Reviewed	46	100

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

Number of applications made invalid by the REC Manager	1
Number of applications withdrawn prior to the meeting	1
Number of student applications reviewed	17
Number of paediatric applications reviewed	10
Number of device applications reviewed	7
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	8

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	1	2.17
Favourable Opinion with Additional Conditions	0	0.00
Unfavourable Opinion	4	8.70
Provisional Opinion	41	89.13
Provisional Opinion Pending Consultation with Referee	0	0.00
Total	46	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	28	60.87
Further Information Favourable Opinion with Additional Conditions	5	10.87
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	1	2.17
Favourable Opinion with Additional Conditions	0	0.00
Unfavourable Opinion	4	8.70
Provisional Opinion	6	13.04
Provisional Opinion Pending Consultation with Referee	0	0.00
Further Information response not complete	2	4.35
No decision entered on system	0	0.00
Number of studies withdrawn after the meeting	0	0.00
Total	46	100

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

Total Applications Reviewed	25
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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	2
Number of student applications reviewed	10
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	23	92.00
Favourable Opinion with Additional Conditions	0	0.00
No Opinion transfer to full committee for review	1	4.00
Provisional Opinion	1	4.00
Unfavourable Opinion	0	0.00
Total	25	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	4.60
Number of completed applications for full ethical review	46
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	4.35%
Number of days taken to final decision – average (mean)	29
Number of completed proportionate review applications for ethical review	24
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	10
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	68
Number of completed substantial amendments over 35 days	0
Number of completed substantial amendments over 35 days as a % of total substantial amendments	0.00%
Number of completed substantial amendments over 28 days	1
Number of completed substantial amendments over 28 days as a % of total substantial amendments	1.47%
Number of modified amendments reviewed	0
Number of completed modified amendments over 14 days	0
Number of completed modified amendments over 14 days as a % of total modified amendments	0.00%
Number of minor amendments received	56
Number of substantial amendments received for information	0
Number of substantial amendments received for new sites/Pis	0
Number of annual progress reports received	70
Number of safety reports received	0
Number of Serious Adverse Events received	0
Number of final reports received	45

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/YH/0196	Autism in patients with Osteogenesis Imperfecta	29
15/YH/0198	The relationship between psychosocial characteristics and weight loss	26
15/YH/0213	Prevention of morbidity in sickle cell disease: phase II (POMS 2b)	33
15/YH/0272	Assessment and characterization of microvascular function by DOT	33
15/YH/0290	The Impact of Specialist Seating on Quality of Life and Function	38
15/YH/0291	Bleeding disorders in women undergoing surgery for menorrhagia	25
15/YH/0315	Tele monitoring Study	26
15/YH/0318	Spatial evaluation of patient interval factors in GOC	40
15/YH/0330	BME experiences of language and cultural barriers when accessing IAPT	38
15/YH/0332	ACtiF - Adherence to treatment in adults with Cystic Fibrosis 2.2B	38
15/YH/0336	Cognitive Analytic Consultancy: A small N case series v.1	28
15/YH/0362	Identifying Novel Causes of Childhood Bone Fragility	43
15/YH/0377	Expectations of psychological therapy in Huntington's disease	26
15/YH/0382	Understanding Change in Mentalisation-Based Therapy	26
15/YH/0396	Natural History of Memory Complaints	24
15/YH/0398	MERIDIAN 2-3 year follow up study	30
15/YH/0426	CATCH-uS: Children with ADHD in transition to adult services	28
15/YH/0441	HITT for People with Mild Multiple Sclerosis	28
15/YH/0453	Children's Diabetes and Bone Study (C-DaB). Version 1	28
15/YH/0503	MRI-MVR (pilot)	25
15/YH/0523	Rapid dEtectioN Of carbapenem reslstant oRganisms (RENOIR)	17
15/YH/0540	MRI of the fetal lungs	19
15/YH/0569	Stress and affordability of assisted reproductive treatments	30
16/YH/0009	Does antenatal vitamin D alter bone's later response to vibration?	34
16/YH/0037	Digital disease phenotyping in inherited bone fragility	25
16/YH/0063	COMMANDS-02 : An e-consult NAFLD Integrated Care Pathway	31
16/YH/0135	The expectations of parents of children undergoing rehabilitation	28
16/YH/0142	Improving diagnosis in idiopathic cytopenia using gene sequencing	28

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

15/YH/0297	Evaluation of the "Breatheasy" in pre-hospital care	42
15/YH/0392	Supply chain evaluation for foot orthotic provision in the NHS	23
15/YH/0425	Systemic Consultations in ID Services: Experiences of Care Staff	28
15/YH/0429	Next Generation Sequencing in Suspected Infection: SePSI V1.0	26
15/YH/0458	SMART COPD Feasibility Study v1.0	26

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/YH/0028	Therapist Effects & Professional Practice Variability in IAPT	22

Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
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Unfavourable Opinion

REC Reference	Title	Number of Days on Clock
15/YH/0195	BME experiences of language and cultural barriers when accessing IAPT	26
15/YH/0215	Disordered Eating in South Asian Women	27
16/YH/0082	Participant experiences of changing research practices. Version 1	21
16/YH/0143	LACE	32

Provisional Opinion

REC Reference	Title	Number of Days on Clock
15/YH/0446	Investigation of Ametropic amblyopia	n/a
15/YH/0487	scarring outcome (SCOUT)	n/a
15/YH/0539	ILA HEART Lipids	n/a
16/YH/0010	Recovery of braking response after right ACL surgery V0.1	n/a
16/YH/0011	Clinical study to test photonic chips as non-invasive glucose sensors	n/a
16/YH/0140	Metabolic diseases identified from measurement of serum ferritin	n/a

Provisional Opinion 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
16/YH/0036	Investigation of Eczema	n/a
16/YH/0141	Therapeutic relationships and attitudes	n/a

Withdrawn after the meeting		
REC Reference	Title	Number of Days on Clock

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/YH/0519	Prevalence of Hypertension in Patients with Osteoarthritis	12

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

Further Information Unfavourable Opinion		
REC Reference	Title	Number of Days on Clock

Favourable Opinion with Standard Conditions		
REC Reference	Title	Number of Days on Clock
15/YH/0283	The RISE test in heart failure	8
15/YH/0284	Eye Check: A proof-of-concept study	8

15/YH/0285	DOLORisk Dundee	8
15/YH/0331	Oral Corticosteroids: the Incidence of Glaucoma and Cataracts in COPD	9
15/YH/0333	Pre-operative Pocket Echocardiography Trial	10
15/YH/0334	Rebuilding the human thymus to create a tolerising system	10
15/YH/0383	Wheelchair Skills Programme for Young People	13
15/YH/0394	Immunogenicity of the influenza vaccine post RIC allograft	9
15/YH/0395	Estimating the burden of complications of gastrointestinal infections	9
15/YH/0421	Sarcopenia and outcomes in patients diagnosed with penile cancer	12
15/YH/0423	Postoperative morbidity and CPET in oesophagectomy	12
15/YH/0469	Tayside Brushing Study - Adult Follow Up	13
15/YH/0475	Clinical and radiological characteristics of VKA and NOAC ICH	9
15/YH/0476	RETROSPECTIVE CHOLANGIOCARCINOMA STUDY (FGFR)	11
15/YH/0563	Patients' experience of recovery following knee replacement surgery	13
15/YH/0565	GLOWING Pilot Cluster RCT	14
15/YH/0568	Delivering Digital Drugs	14
16/YH/0012	NOVEMBR study v1.0	9
16/YH/0017	TrUE PROMS ver1.0	9
16/YH/0023	Health Economic Modelling of Blood Donation	10
16/YH/0059	Service user and professionals' views of antipsychotic prescribing	11
16/YH/0106	Sexual Health Attendance and Adverse Childhood Experiences study	10
16/YH/0108	Clinical Interventions as Networks	11

Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
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Unfavourable Opinion

REC Reference	Title	Number of Days on Clock
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Provisional Opinion

REC Reference	Title	Number of Days on Clock
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Further information response not complete

REC Reference	Title	Number of Days on Clock
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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/H1310/69/AM01	The effects of a pragmatic exercise intervention in people with MS - 1	Substantial Amendment 1	01/04/2015	8
09/H1304/45/AM03	Soy and testosterone in men with diabetes	Substantial Amendment 2	07/04/2015	12
10/H1304/13/AM06	Environment chemicals that accumulate in fat	Substantial Amendment 5	16/04/2015	17
10/H1304/5/AM01	Soy and bone turnover markers (Version 1)	Substantial Amendment 1	02/04/2015	15
10/H1304/6/AM02	Microfluidic based Cancer Tissue Biopsy Analysis ver 1	Substantial Amendment 2 - 27/5	27/05/2015	21
10/H1304/7/AM05	Isolation of Treg cells from HNSCC (Version 1)	Substantial Amendment 5 - 27/5	27/05/2015	29
10/H1310/60/AM05	Sheffield Minimally Invasive Autopsy Research Technique (SMART)	Substantial Amendment 1	29/12/2014	21
11/YH/0282/AM02	Cellular regeneration of scaffolds	1	01/07/2015	14
11/YH/0347/AM02	The role of dynamic mechanical loading on bone mineral density (v.1)	SA2	09/12/2015	27
12/YH/0101/AM16	Lifestyle Matters	Substantial Amendment 8	14/05/2015	21
12/YH/0101/AM18	Lifestyle Matters	Substantial Amendment 10, 14.0	17/08/2015	17
12/YH/0344/AM04	Observational study to Predict ReAdmission for HF patients.	Substantial Amendment 3	30/03/2015	9
12/YH/0356/AM03	Ultrafast MRI Imaging In Diagnosis Of Constipation	Substantial Amendment 2	20/03/2015	8
12/YH/0487/AM06	Optimising pacemaker therapy (OPT-PACE)	Substantial Amendment 4	20/05/2015	18
12/YH/0487/AM07	Optimising pacemaker therapy (OPT-PACE)	Substantial Amendment 5 - 20/6	20/06/2015	19

13/YH/0028/AM03	Molecular Genetic Investigations of Amelogenesis Imperfecta	Substantial Amendment 2, versi	16/12/2015	28
13/YH/0045/AM01	Psychological determinants of job retention in Multiple Sclerosis	Substantial Amendment 1, 03.09	03/09/2015	14
13/YH/0070/AM02	Virtual Coronary Physiology: An angiogram is all you need	Substantial Amendment 1	30/03/2015	17
13/YH/0186/AM02	Factors affecting cascade genetic screening and counselling	Substantial Amendment 1 - 22/5	22/05/2015	27
13/YH/0194/AM02	Stool sampling in primary care: A feasibility study	Substantial Amendment 2	20/05/2015	18
13/YH/0237/AM04	Vitamin D & Immunity Study. Version 1.1	Substantial Amendment 3, (No./	09/11/2015	13
13/YH/0237/AM05	Vitamin D & Immunity Study. Version 1.1	Substantial Amendment 4, 30.09	09/11/2015	16
13/YH/0238/AM01	Application of microfluidics in Glioblastoma multiforme Version 2.1 04.03.16	Substantial Amendment 1		23
13/YH/0319/AM08	The PACE Study: Physical activity facilitation for older adults v1.0	Substantial Amendment 5 - 04/0	04/08/2015	28
13/YH/0354/AM02	Exercise Training During Chemotherapy in Advanced Lung Cancer Patients	Substantial Amendment 2, (Vers	02/11/2015	9
13/YH/0424/AM01	Inpatient vs outpatient management of hyperemesis	Substantial Amendment 1, Decem	11/12/2015	27
14/YH/0001/AM03	Counselling for Depression: The PRaCTICED Trial	Substantial Amendment 2 - 20/5	20/05/2015	27
14/YH/0001/AM04	Counselling for Depression: The PRaCTICED Trial	Substantial Amendment 3, 03.10	24/11/2015	8
14/YH/0001/AM05	Counselling for Depression: The PRaCTICED Trial	No 4	18/01/2016	16

14/YH/0019/AM08	STructured lifestyle Education for People Wlth SchizophrEnia V1.0	Substantial Amendment 4 - 9/6/1	09/06/2015	15
14/YH/0019/AM10	STructured lifestyle Education for People Wlth SchizophrEnia V1.0	Substantial Amendment 5, 09 No	10/11/2015	15
14/YH/0019/AM11	STructured lifestyle Education for People Wlth SchizophrEnia V1.0	6.0	29/01/2016	23
14/YH/0032/AM01	Renal denervation effects in patients with chronic kidney disease (V3)	Substantial Amendment 1, 06/07	30/09/2015	9
14/YH/0045/AM03	CITADAL: Computerised Treatment for Adolescent Depression and Low Mood	Substantial Amendment 2	27/08/2015	17
14/YH/0064/AM02	IMPAQTS V1	Substantial Amendment 1 - 03/0	12/03/2015	20
14/YH/0086/AM02	RESPOND Protocol Number: TP6461	Substantial Amendment 2 - 15/6	15/06/2015	28
14/YH/0087/AM01	Collection of joint mesenchymal stem cells (MSCs)	Substantial Amendment 1 , 02.0	06/11/2015	15
14/YH/0124/AM01	COMBAT 1	Substantial Amendment 1, 22.10	03/11/2015	9
14/YH/0129/AM08	Evaluation of FeNO for predicting response to inhaled corticosteroids	Substantial Amendment 4	13/05/2015	22
14/YH/0144/AM05	Validation of Medication Nonadherence Model (UK)	Substantial Amendment 3	13/05/2015	9
14/YH/0174/AM01	Fat stem cells: model and potential therapy for Motor Neurone Disease	Substantial Amendment 1, 30.10	31/10/2015	10
14/YH/0179/AM02	PLATE NOX Version 1	1	02/12/2015	12
14/YH/1010/AM02	Gastric capsule examination for iron deficiency anaemia	Substantial Amendment 1, 13.01	15/01/2016	20
14/YH/1043/AM01	Use of mywellness key in patients with COPD: a feasibility	Substantial	25/05/2015	26

	study	Amendment 1 - 25/5		
14/YH/1043/AM02	Use of mywellness key in patients with COPD: a feasibility study	2	16/12/2015	14
14/YH/1130/AM01	Delivering CBT tailored to subtypes of voice-hearing. Version 2	Substantial Amendment 1	19/03/2015	17
14/YH/1140/AM01	Adjustment after a mild cognitive impairment (MCI) diagnosis	Substantial Amendment 1 - 05/	05/03/2015	26
14/YH/1152/AM03	Response to one-legged cycling in idiopathic pulmonary fibrosis	Substantial Amendment 3 - 31/3	31/03/2015	17
14/YH/1156/AM04	CT-Based FE Bone Models	Substantial Amendment 3 - 22/5	22/05/2015	12
14/YH/1314/AM02	Optimisation of Circulating Tumour Cell Detection in Bone Sarcomas	Substantial Amendment 1, 22.12	29/12/2015	14
15/YH/0075/AM01	Mindfulness, Psychological Functioning & Coping in a Stroke Population	Substantial Amendment 1 - 22/6	22/06/2015	16
15/YH/0088/AM01	Investing in Happiness: Children with rare diseases	Substantial Amendment 1, 10.08	10/08/2015	16
15/YH/0090/AM01	The impact of social action services on end of life experience v1	Substantial Amendment 1	05/05/2015	25
15/YH/0093/AM01	Validation of Autism Assessment Instruments for deaf children	Substantial Amendment 1	07/05/2015	24
15/YH/0093/AM02	Validation of Autism Assessment Instruments for deaf children	Substantial Amendment 2 - 10/6	10/06/2015	21
15/YH/0121/AM01	Electrical impedance myography of the tongue	Substantial Amendment 1 , 17.0	17/08/2015	18
15/YH/0131/AM01	RIGHT CF Study	1	20/01/2016	21
15/YH/0135/AM03	Alternatives to face to face GP consultations V1	1 01/03/2016	10/03/2016	19
15/YH/0196/AM01	Autism in patients with Osteogenesis Imperfecta	Substantial	27/08/2015	8

		Amendment 1, 26.08		
15/YH/0213/AM01	Prevention of morbidity in sickle cell disease: phase II (POMS 2b)	Substantial amendment 1	24/12/2015	13
15/YH/0285/AM01	DOLORisk Dundee	1	08/01/2016	15
15/YH/0318/AM01	Spatial evaluation of patient interval factors in GOC	Ver3, Feb 2016	19/02/2016	14
15/YH/0332/AM01	ACtiF - Adherence to treatment in adults with Cystic Fibrosis 2.2B	Substantial Amendment 1, 18.11	24/11/2015	7
15/YH/0383/AM01	Wheelchair Skills Programme for Young People	1, 17.12.15	17/12/2015	13
15/YH/0398/AM01	MERIDIAN 2-3 year follow up study	Amendment 1	22/12/2015	13
15/YH/0429/AM01	Next Generation Sequencing in Suspected Infection: SePSI V1.0	Substantial Amendment 1 , Prot	09/12/2015	26
16/YH/0012/AM03	NOVEMBR study v1.0	1.0	03/02/2016	20

Unfavourable opinion

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
11/YH/0006/AM19	MERIDIAN	Substantial Amendment 12 - 12/	12/06/2015	20

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
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Unfavourable opinion timeline

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
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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 14 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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