

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

Annual Report

01 April 2016 - 31 March 2017



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, Qualitative
Chair:	Dr Ian Woollands
Vice-Chair:	Dr Max Huxham
Alternate Vice-Chair:	Mr David Broomhead
REC Manager:	Mrs Helen Wilson
REC Assistant:	Mrs Amanda Carr (wef 01/01/2017) Ms Kerry Dunbar (until 31/12/16)
Committee Address:	Room 001 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 Mrs Helen Wilson, REC Manager along with REC Assistants Miss Kerry Dunbar and Mrs Amanda Carr and wish to acknowledge their hard work which has ensured the smooth running of the Committee to provide an efficient service for researchers.

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	
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	12/03/2017
Mr Martin Edmunds	Editor	Lay Plus	10/04/2015	
Mrs Nancy Figueroa	Royal Voluntary Service	Lay Plus	09/09/2016	
Dr Max Huxham	Retired Scientist	Lay	15/05/2014	
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

No deputies were appointed.

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

Name	Profession	Status	Meeting date attended
Dr Rhona Bratt	Retired Multimedia Mgr	Lay Plus	June 2016 December 2016
Dr Annette Hames	Consultant Clinical Psychologist and Honorary Clinical Senior Lecturer	Expert	December 2016
Mrs Aitaterini Staikoura-Wilson	Pharmacist	Expert	March 2017
Miss Kate Woodrow	Assistant Chief Pharmacist	Expert	March 2017

Yorkshire & The Humber - South Yorkshire Research Ethics Committee: Members' Declarations of Interest:

Name	Declaration of Interest	Date
Dr Ahmed H Abdelhafiz	None.	15/02/2017
Dr Parveen Ali	Lecturer at university of Sheffield	15/02/2017
Ms Helen Barlow	Work as Library and Knowledge Service Manager, The Rotherham Foundation Trust.	09/03/2017
Professor Nigel Beail	Trustee: British Institute for Learning Disabilities. Occasionally asked to peer review for various funding bodies and also peer reviews D Clin Psy research submissions at the University of Sheffield.	31/03/2017
Dr David Broomhead	Advise NHS staff/ students on potential research projects that are under development within Northern Lincolnshire and Goole NHS Foundation Trust as part of an advisory committee. Any link to this research would be declared should the South Yorkshire REC be asked for opinion.	15/02/2017
Mr Ian Cawthorne	Nil - other than activities as an NHS hospital pharmacist involved in the dispensing of clinical trials.	14/02/2017
Mr Michael Davidson	None.	22/02/2017
Mr Martin Edmunds	None	15/02/2017
Mrs Sindy Nancy Figueroa Merino	None.	01/10/2016
Dr Max Huxham	Involved with Spinal Muscular Atrophy Support UK and SMA Europe	21/03/2017
Reverend Clive Smith	None to my knowledge. I own some portfolios of investment bonds which are managed by a financial advisor, just possible that I may have a rather indirect and distant relationship with such an organisation. But I am currently unaware of any.	27/03/2017
Mrs Carole Taylor	Dispensing of medicines for clinical trials at the Rotherham NHS Foundation Trust.	01/03/2017
Dr Ian Woollands	None.	31/03/2017

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

Month	Date	Number of Members Present at Meeting
May	26/05/2016	12
June	30/06/2016	9
July	28/07/2016	9
August	25/08/2016	8
September	29/09/2016	9
November	24/11/2016	9
December	20/12/2016	8
January	26/01/2017	12
March	23/03/2017	8

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
May	09/05/2016	3
June	07/06/2016	3
July	14/07/2016	3
August	11/08/2016	3
September	07/09/2016	3
October	12/10/2016	3
November	09/11/2016	3
December	23/12/2016	3
January	12/01/2017	3
February	08/02/2017	3
March	06/03/2017	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	05/04/2016	2
April	18/04/2016	2
May	03/05/2016	2
May	17/05/2016	2
May	31/05/2016	2
May	31/05/2016	3
June	14/06/2016	2
June	29/06/2016	2
July	14/07/2016	2
July	27/07/2016	2
August	10/08/2016	2

August	24/08/2016	2
September	07/09/2016	2
September	20/09/2016	2
September	26/09/2016	3
October	05/10/2016	2
October	19/10/2016	2
November	01/11/2016	2
November	15/11/2016	2
November	28/11/2016	2
December	13/12/2016	2
December	28/12/2016	2
January	16/01/2017	2
February	02/02/2017	2
February	09/02/2017	2
February	21/02/2017	2
March	03/03/2017	2
March	09/03/2017	2

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

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

No inquorate meetings were held.

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

Name	Number of Meetings Attended
Dr Ahmed H Abdelhafiz	6
Dr Parveen Ali	5
Dr Peter Allmark	1
Ms Helen Barlow	9
Professor Nigel Beail	7
Mr David Broomhead	5
Mr Ian Cawthorne	8
Mr Michael Davidson	6
Mr Martin Edmunds	6
Mrs Nancy Figueroa	1
Dr Max Huxham	7
Reverend Clive Smith	6
Mrs Carole Taylor	5
Dr Ian Woollands	7

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

Name	Number of Meetings Attended
Dr Ahmed H Abdelhafiz	2
Dr Parveen Ali	2
Ms Helen Barlow	2
Professor Nigel Beail	2
Mr David Broomhead	3
Mr Ian Cawthorne	1
Mr Michael Davidson	2
Mr Martin Edmunds	3
Dr Max Huxham	4
Reverend Clive Smith	2
Mrs Carole Taylor	3
Dr Ian Woollands	7

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

Name	Number of
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	Meetings Attended
Dr Ahmed H Abdelhafiz	4
Dr Parveen Ali	2
Dr Peter Allmark	2
Ms Helen Barlow	5
Professor Nigel Beail	2
Mr David Broomhead	7
Mr Ian Cawthorne	3
Mr Michael Davidson	2
Mr Martin Edmunds	3
Dr Max Huxham	8
Reverend Clive Smith	2
Mrs Carole Taylor	3
Dr Ian Woollands	15

Training 01 April 2016 - 31 March 2017

Name of Member	Date	Event(s) attended
Dr Ahmed H Abdelhafiz	06/07/2016	Regional Members Training Day
Dr Parveen Ali	15/09/2016	Members Induction
Ms Helen Barlow	12/07/2016	Research Involving Adults Who Lack Capacity (including research in emergency situations)
Professor Nigel Beail	31/03/2017	SDL 16 – 17 – Private reading on research related topics.
Dr David Broomhead	30/06/2016	Training for New REC Chairs
Mr Michael Davidson	15/04/2016	2016 Allam Lecture, Hull
Mr Michael Davidson	06/07/2016	Regional Members Training Day
Mr Martin Edmunds	06/07/2016	Local Members Training Day
Mr Martin Edmunds	22/03/2017	National Members Training Day
Mrs Sindy Nancy Figueroa Merino	15/10/2016	Members Induction - Online
Mrs Sindy Nancy Figueroa Merino	19/11/2016	Equality and Diversity - online
Mrs Sindy Nancy Figueroa Merino	10/01/2017	Committee Members Induction
Mrs Sindy Nancy Figueroa Merino	01/02/2017	Medical Devices Training Day
Dr Max Huxham	30/06/2016	Training for New REC Chairs
Reverend Clive Smith	13/06/2016	Equality Diversity and Human Rights
Mrs Carole Taylor	22/03/2017	National Training Members Day
Dr Ian Woollands	01/12/2016	National Training Day for Committee Chairs

PART 2: REC WORKLOAD AND ACTIVITY DURING THE REPORTING PERIOD

Table 1: Applications assigned to a full committee meeting held within the reporting period:

Applications for full ethical review – Study Type	Number	%
Clinical Trial of Investigational Medicinal Product	0	0.00
Phase 1	0	0.00
Gene Therapy	0	0.00
Research Tissue Bank (including renewals)	0	0.00
Research Database (including renewals)	1	2.70
Others	36	97.30
Total Applications Reviewed	37	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	15
Number of paediatric applications reviewed	9
Number of device applications reviewed	3
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	7

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	3	8.11
Favourable Opinion with Additional Conditions	1	2.70
Unfavourable Opinion	5	13.51
Provisional Opinion	28	75.68
Provisional Opinion Pending Consultation with Referee	0	0.00
Total	37	100
Number of studies sent back to full committee meeting for final opinion	1	

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	22	59.46
Further Information Favourable Opinion with Additional Conditions	6	16.22
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	3	8.11
Favourable Opinion with Additional Conditions	1	2.70
Unfavourable Opinion	5	13.51
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	37	100

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

Total Applications Reviewed	28
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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	6
Number of studies withdrawn prior to the meeting	2
Number of student applications reviewed	13
Number of paediatric applications reviewed	4
Number of device applications reviewed	1
Number of qualitative applications reviewed	4

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	35.71
Favourable Opinion with Additional Conditions	6	21.43
No Opinion transfer to full committee for review	6	21.43
Provisional Opinion	6	21.43
Unfavourable Opinion	0	0.00
Total	28	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	4.11
Number of completed applications for full ethical review	37
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	1
Number of completed applications over 40 days as a % of total	2.70%
Number of days taken to final decision – average (mean)	28
Number of completed proportionate review applications for ethical review	21
Number of completed proportionate review applications for ethical review over 14 days (Please note, the timeline for review of PR applications was extended from 14 to 21 calendar days in December 2016)	1
Number of completed proportionate review applications for ethical review over 21 days	0
Number of completed proportionate review applications over 21 days as a % of total	0.00%
Number of SSAs (non-Phase 1) reviewed	0
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	57
Number of completed substantial amendments over 35 days	1
Number of completed substantial amendments over 35 days as a % of total substantial amendments	1.75%
Number of completed substantial amendments over 28 days	3
Number of completed substantial amendments over 28 days as a % of total substantial amendments	5.26%
Number of modified amendments reviewed	1
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	80

Number of substantial amendments received for information	0
Number of substantial amendments received for new sites/PIs	0
Number of annual progress reports received	50
Number of safety reports received	0
Number of Serious Adverse Events received	3
Number of final reports received	418

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/YH/0116	Vibration Analysis as a Method for Fracture Screening in Children	26
16/YH/0183	The difference in releasing of EMPs in T2DM	26
16/YH/0185	Effect of HV optimisation in cardiac resynchronisation therapy	26
16/YH/0201	Understanding the carer's experience of palliative care	30
16/YH/0272	use of oxygen in heart failure with preserved ejection fraction	26
16/YH/0278	Partnership in Prostate Cancer Care (the ICARE-P Study)	27
16/YH/0309	Skin barrier function and skin vulnerability	30
16/YH/0317	Barriers to exercise after TIA and NDS	38
16/YH/0325	I-WOTCH V1.0	18
16/YH/0335	ANTELOPE	32
16/YH/0353	Evaluation of Performance & Safety of Lotus Edge Valve	30
16/YH/0383	Clinical utility of multimodal imaging in surgical tumour patients	35
16/YH/0389	Exploring the Experience of Living with Young Onset Dementia [V1]	29
16/YH/0394	Patient Pain experience with Orthodontic Fixed Appliance Treatment	39
16/YH/0410	Microbiological test for latent tuberculosis infection (Micro-LTBI)	27
16/YH/0490	Sheffield Children Sleeping Well Project	20
17/YH/0009	An Ethnographic Study in Community Nursing	34
17/YH/0021	Human endotoxaemia model	28
17/YH/0026	Osteogenesis Imperfecta Phenotype-based Assays	31
17/YH/0101	Mortality, morbidity and cost-effectiveness in radiotherapy	26
17/YH/0102	VIP: Video informed practice/Voices in partnership - Version 1.0	26
17/YH/0105	ThrIVe-B programme for Bipolar Mood Instability: A feasibility study	23

Further Information Favourable Opinion with Additional Conditions		
REC Reference	Title	Number of Days on Clock
16/YH/0218	Peer support for carers	43
16/YH/0268	BRAVO Feasibility Study	29
16/YH/0355	Video guided exercise after stroke	37
16/YH/0428	Experiences of equipment provision in occupational therapy: version 1	36
16/YH/0494	Predictive value of colonic manometry for intractable constipation	17
17/YH/0027	Needs after CaP treatment for Black men and their partners ver1	24

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
16/YH/0207	Thermal Imaging Compared to Skeletal Survey in Children Below 2 Years	25
16/YH/0491	Invasive Listeria Infection in babies	20
17/YH/0095	Life and Bladder Cancer Patient Reported Outcomes Survey	21

Favourable Opinion with Additional Conditions		
REC Reference	Title	Number of Days on Clock
16/YH/0262	How reliable are respiratory rate measurements in children	26

Unfavourable Opinion		
REC Reference	Title	Number of Days on Clock
16/YH/0280	Treatment Alternatives in Rare Disease; Assessment of Options in iSGS	24
16/YH/0322	Does the the PneuX tube prevent VAE/C/Ps in heart and lung transplants	21
16/YH/0362	Combining information from the senses	27
16/YH/0429	Diabetes treatment observation study (Project Greyjoy)	33
17/YH/0054	The use of Subcostal port in Laparoscopic cholecystectomy	21

Provisional Opinion		
REC Reference	Title	Number of Days on Clock

Provisional Opinion Pending Consultation with Referee		
REC Reference	Title	Number of Days on Clock

Further information response not complete		
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REC Reference	Title	Number of Days on Clock
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Withdrawn after the meeting

REC Reference	Title	Number of Days on Clock
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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/YH/0444	A pilot study to investigate iron and RBC damage in type 2 diabetes	12
16/YH/0446	Service users' experiences of a MDT in a specialist airways service	12
16/YH/0523	MacMillan Objective Physical Activity Assessment Project. Version 1	10
16/YH/0524	South Asian Asthma Self-Management	10
17/YH/0014	Baby oxygen saturation study	10

Further Information Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
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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/0202	Implementation of the 'Caring for Someone with Cancer' booklet	9
16/YH/0248	Maternal Anxiety and Depression and Filial Educational Outcomes	8
16/YH/0249	Pervasive prehabilitation programme	7
16/YH/0358	Lung health in HIV	14
16/YH/0360	Understanding Dyspnoea in Patients with Heart Failure in the Community	13
16/YH/0482	CYP2C19 variants in predicting clopidogrel efficacy	13

17/YH/0010	Assessing human brain slices as 'benchtop' injury models	9
17/YH/0036	Anonymous HIV testing in patients with mononucleosis-like illness	15
17/YH/0037	Impact of Weather on GP Home Visiting	14
17/YH/0039	Psychological Predictors of Alcohol Use and Weight Loss After WLS	12

Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
16/YH/0199	Metacognition, social functioning and early mental health difficulties	11
16/YH/0306	Investigating the development of Bregs in healthy humans	9
16/YH/0308	Descriptive study of occupational asthma caused by acrylic compounds	9
16/YH/0356	Bladder Cancer UK Biomarker NIS	14
17/YH/0075	Effect of time taken to refer to CCOT for patients with a high NEWS v1	10
17/YH/0077	Development of an RT-qPCR-based method for HIV viral load testing	13

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
16/YH/0391	Pilot survey of mothers and babies	22

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/H1305/59/AM03	Pancreatectomy and Tissue Factor	Amendment 3, Version 3.0, Augu	20/08/2016	21
08/H1310/49/AM07	Molecular signatures of Temporal Lobe Epilepsy (TLE).	1, 29/04/16	29/04/2016	24
10/H1304/44/AM01	Ultrasound guided cannulation of dialysis fistulas	Amendment 1, 27/09/2016	27/09/2016	15
10/H1304/7/AM06	Isolation of Treg cells from HNSCC (Version 1)	Amendment No 6 (16.6.16)	16/06/2016	16
11/YH/0356/AM02	Regulation of airway inflammation	2	09/08/2016	21
13/YH/0028/AM04	Molecular Genetic Investigations of Amelogenesis Imperfecta	Substantial Amendment 3 - 28/1	28/11/2016	30
13/YH/0114/AM06	A Pilot Study of Biomarkers in Patients with Periodontal Disease	1, (16 February 2016)	21/03/2016	14
13/YH/0145/AM01	Advanced fetal MRI	1, 12 May 2016	12/05/2016	13
13/YH/0145/AM02	Advanced fetal MRI	Number 2, 13 January 2017	17/01/2017	10
13/YH/0238/AM02	Application of microfluidics in Glioblastoma multiforme	Amendment No 2	03/10/2016	18
13/YH/0329/AM04	Perceptions about predictive testing in those at risk	3, 10/03/2016	16/03/2016	25
13/YH/0329/AM05	Perceptions about predictive testing in those at risk	Amendment 4, 02/06/2016	12/06/2016	21
14/YH/0001/AM06	Counselling for Depression: The PRaCTICED Trial	Substantial Amendment No 5 - 1	14/04/2016	20
14/YH/0001/AM07	Counselling for Depression: The PRaCTICED Trial	no 5, 12/04/16	03/05/2016	19
14/YH/0019/AM12	STructured lifestyle Education for People Wlth SchizophrEnia V1.0	No 7, 9 May 2016	10/05/2016	23
14/YH/0019/AM15	STructured lifestyle Education for People Wlth SchizophrEnia V1.0	No. 8, 6 October 2016	07/10/2016	22
14/YH/0086/AM03	RESPOND Protocol Number: TP6461	Amendment 04 - 14 April 2016	14/04/2016	20
15/YH/0084/AM01	Synthetic aperture radar detection of breast tumours	Version 2, 14	29/03/2016	12

		March 2016		
15/YH/0084/AM02	Synthetic aperture radar detection of breast tumours	Version 3, 26 May 2016	06/06/2016	7
15/YH/0093/AM05	Validation of Autism Assessment Instruments for deaf children	Amendment 3, 25/08/16	15/09/2016	26
15/YH/0196/AM02	Autism in patients with Osteogenesis Imperfecta	2, 29/04/2016	03/05/2016	20
15/YH/0213/AM02	Prevention of morbidity in sickle cell disease: phase II (POMS 2b)	Amendment 1, 07/09/2016	08/09/2016	27
15/YH/0285/AM02	DOLORisk Dundee	2.0, 25/3/2016	15/04/2016	16
15/YH/0285/AM03	DOLORisk Dundee	3.0, 11 August 2016	29/08/2016	14
15/YH/0285/AM04	DOLORisk Dundee	4.0, 2/12/2016	17/01/2017	15
15/YH/0291/AM01	Bleeding disorders in women undergoing surgery for menorrhagia	Amendment number 1, 12.4.16	19/04/2016	15
15/YH/0291/AM02	Bleeding disorders in women undergoing surgery for menorrhagia	Substantial Amendment number 2	16/05/2016	17
15/YH/0291/AM03	Bleeding disorders in women undergoing surgery for menorrhagia	3, 10 August 2016	10/08/2016	20
15/YH/0297/AM02	Evaluation of the "Breatheasy" in pre-hospital care	SA1, 09.12.16	09/12/2016	14
15/YH/0382/AM02	Understanding Change in Mentalisation-Based Therapy	Amendment #1, 24.03.16	07/04/2016	7
15/YH/0382/AM03	Understanding Change in Mentalisation-Based Therapy	#2 18.05.16	18/05/2016	19
15/YH/0398/AM06	MERIDIAN 2-3 year follow up study	Amendment 2, 29/09/2016	04/10/2016	17
15/YH/0398/AM07	MERIDIAN 2-3 year follow up study	Amendment 3, 25/01/17	25/01/2017	23
15/YH/0426/AM02	CATCH-uS: Children with ADHD in transition to adult services	Amendment 1 - 17/05/2016	19/05/2016	13
15/YH/0458/AM01	SMART COPD Feasibility Study v1.0	Amendment 1, 20.07.16	21/07/2016	11
15/YH/0469/AM02	Tayside Brushing Study - Adult Follow Up	1 04/01/2016	13/01/2017	9
15/YH/0476/AM01	RETROSPECTIVE CHOLANGIOCARCINOMA STUDY (FGFR)	Amendment 1, 15.3.16	04/05/2016	23
15/YH/0503/AM01	MRI-MVR (pilot)	One. 23/02/2017	27/02/2017	21
15/YH/0563/AM01	Patients' experience of recovery following knee replacement	1.4, 05/09/2016	06/09/2016	13

	surgery			
15/YH/0565/AM02	GLOWING Pilot Cluster RCT	Amendment 1, 05/04/2016	09/05/2016	15
16/YH/0009/AM01	Does antenatal vitamin D alter bone's later response to vibration?	1	24/02/2017	19
16/YH/0012/AM05	NOVEMBR study v1.0	Substantial Amendment 2 - 3/10	03/10/2016	34
16/YH/0135/AM01	The expectations of parents of children undergoing rehabilitation	1	27/07/2016	20
16/YH/0207/AM01	Thermal Imaging Compared to Skeletal Survey in Children Below 2 Years	1, 13.07.2016	07/09/2016	13
16/YH/0268/AM01	BRAVO Feasibility Study	Substantial Amendment 1	13/09/2016	27
16/YH/0268/AM03	BRAVO Feasibility Study	Substantial Amendment 2 - 25/1	25/10/2016	8
16/YH/0278/AM01	Partnership in Prostate Cancer Care (the ICARE-P Study)	1	17/08/2016	28
16/YH/0278/AM03	Partnership in Prostate Cancer Care (the ICARE-P Study)	Substantial Amendment 2 - 29/1	29/11/2016	10
16/YH/0325/AM01	I-WOTCH V1.0	Amendment One, 19 Dec 2016	19/12/2016	25
16/YH/0353/AM02	Evaluation of Performance & Safety of Lotus Edge Valve	Substantial Amendment 1 - 31/1	31/10/2016	14
16/YH/0355/AM01	Video guided exercise after stroke	Substantial Amendment 1 - 8/11	08/11/2016	13
16/YH/0358/AM01	Lung health in HIV	1.0, 11 October 2016	17/10/2016	17
16/YH/0389/AM01	Exploring the Experience of Living with Young Onset Dementia [V1]	1 – 27.01.2017	01/02/2017	26
16/YH/0410/AM01	Microbiological test for latent tuberculosis infection (Micro-LTBI)	Amendment #1, date 02 February	02/02/2017	20
16/YH/0490/AM01	Sheffield Children Sleeping Well Project	1, 20th January	20/01/2017	27

		2017		
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Unfavourable opinion				
Amendment REC Reference	Title	Version	Date	Number of Days on Clock
15/YH/0093/AM09	Validation of Autism Assessment Instruments for deaf children	Substantial Amendment 5 - 21/1	21/11/2016	38
16/YH/0141/AM03	Therapeutic relationships and attitudes	Amendment number 1: Date: 27/0	03/02/2017	19

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
16/YH/0141/AM03/1	Therapeutic relationships and attitudes	Modified Amendment 1: 27.01.20	24/02/2017	7

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

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

REC Reference	Title	Number of Days on Clock
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Proportionate review applications for ethical review over 21 day timeline

REC Reference	Title	Number of Days on Clock
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SSAs (non Phase 1) over 25 day timeline

REC Reference	Title	Number of Days on Clock
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SSAs (Phase 1) over 14 day timeline

REC Reference	Title	Number of Days on Clock
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Substantial Amendments over 35 day timeline

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
15/YH/0093/AM09	Validation of Autism Assessment Instruments for deaf children	Substantial Amendment 5 - 21/1	21/11/2016	38

Modified Amendments over 14 day timeline

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
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