

**Yorkshire & The Humber - Bradford Leeds
Research Ethics Committee**

Annual Report

01 April 2016 - 31 March 2017



Part 1 – Committee Membership and Training

Name of REC:	Yorkshire & The Humber - Bradford Leeds Research Ethics Committee
Type of REC:	Authorised REC
Type of Flag:	Research Involving Adults Lacking Capacity
Chair:	Dr Janet Holt
Vice-Chair:	Ms Anne Davies
Alternate Vice-Chair:	Dr Christopher Skidmore
REC Manager:	Miss Katy Cassidy
REC Assistant:	Miss Sarah Prothero
Committee Address:	Jarrow Business Centre Rolling Mill Road Jarrow NE32 3DT
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Chair's overview of the past year:

The Bradford Leeds Committee and members continue to work well together across the full committee meetings, in subcommittees and with proportionate review (PR). The revised timelines for PR have been helpful and members have worked extremely hard together with the committee chairs, the REC Manager and assistant to ensure the deadlines were met.

Our membership has been stable this year and we have welcomed two new members to the committee, Dr John Keeler and Dr Douglas Morrison.

As in previous years attendance at full, PR and subcommittees has been good. However due to committee members other commitments ensuring each meeting is quorate continues to be an occasional challenge. I am particularly grateful to Leeds colleagues Dr Rhona Bratt and Dr Sheila Fisher for serving as co-opted members at one meeting.

Most members have attended training events during the year and encouraged to complete Self-Directed Learning to achieve the training requirement if they have been unable to attend events. During the year I have represented the committee at regional and national chair's meetings

Mrs Anne Davies has remained Vice Chair, and Dr Christopher Skidmore Alternate Vice Chair during the year and both have had an opportunity to chair a full committee meeting and Dr Skidmore has deputized for me at a North East and Yorkshire & The Humber Chair's Network Meeting.

The support received from our REC Manager, Katy Cassidy and the REC Assistant Sarah Prothero has been excellent, and we have also benefitted from stability in the management of the committee during the year as well as in the membership.

I would like to express appreciation of the support given to me by the Vice and Alternate Vice Chair, the REC Manager and Assistant in ensuring the smooth running of the committee. But most particularly to the members of the Bradford Leeds Committee who continue to demonstrate strong commitment to promoting the values of ethical research and professionalism towards the researchers we have been privileged to meet throughout the year.

Yorkshire & The Humber - Bradford Leeds Research Ethics Committee Membership

Name	Profession	Expert or Lay	Dates	
			Appointed	Left
Mr Sharif Al-Ghazal	Consultant Plastic Surgeon	Expert	01/04/2013	
Professor Diana Anderson	Professor of Biomedical Sciences	Expert	01/04/2013	
Dr. Nigel Birch	Retired Engineer	Lay Plus	01/11/2015	
Ms Anne Davies	Clinical Research Consultant	Lay	17/06/2013	
Dr Stan Dobrzanski	Pharmacist	Expert	18/06/2013	
Mrs Jenny Foggin	Senior Governance & Corporate Affairs Officer	Lay Plus	18/02/2014	
Mr Simon Gelsthorpe	BDCFT Head of Psychological Therapies	Expert	01/04/2013	
Dr Janet Holt	Senior Lecturer	Expert	01/04/2013	
Dr John Keeler	Consultant Anaesthetist	Expert	03/10/2016	
Dr Kirste Mellish	Research Programme Manager	Expert	01/04/2013	
Dr Douglas Morrison	Senior Law Lecturer	Lay	15/03/2017	
Mr Andrew Scally	Senior Lecturer	Expert	01/04/2013	
Dr Christopher Skidmore	Retired University Lecturer	Lay	02/08/2013	

Yorkshire & The Humber - Bradford Leeds Research Ethics Committee: Deputy Members

Name	Profession	Status	Meeting date attended
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Yorkshire & The Humber - Bradford Leeds Research Ethics Committee: Co-opted Members

Name	Profession	Status	Meeting date attended
Dr Sheila E. Fisher	Retired Maxillofacial Surgeon/Clinical Research Fellow	Expert	19/07/2016
Dr Rhona Bratt	Retired Multimedia Project Manager	Lay Plus	19/07/2016

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

Name	Declaration of Interest	Date
Mr Sharif Al-Ghazal	None declared	31/03/2017
Professor Diana Anderson	Taken on role of Designated Individual for the HTA at the University of Bradford again in the last year.	31/03/2017
Dr Stan Dobrzanski	Attended and spoken at Conferences/Meetings sponsored by Bayer, Boehringer Ingelheim and by Pfizer. Lead researcher in 2 multinational clinical trials sponsored by Convatec. Although I retired last year, I still work part time as a pharmacist and am up to date with registration and continuing professional development required by the General Pharmaceutical Council – and am still involved in research	31/03/2017
Mrs Jenny Foggin	None declared	31/03/2017
Dr Janet Holt	Chair of the Faculty of Medicine and Health Research Ethics Committee, University of Leeds Member of the University of Leeds Research Ethics Committee	31/03/2017
Mr Andrew Scally	I am an expert reviewer for several NIHR funding streams I am actively involved in several aspects of the University of Bradford's research ethics governance processes.	31/03/2017
Dr Christopher Skidmore	None declared	31/03/2017
Dr John Keeler	None declared	10/10/2016
Dr. Nigel Birch	Holder of shares in GlaxoSmithKline	31/03/2017
Mr Simon Gelsthorpe	Treasurer of the Division of Clinical Psychology which is part of the British Psychological Society, Holds Honorary Research Fellow status with Bradford University	31/03/2017
Dr Kirste Mellish	Kirste is employed as the Director of Operations at Leeds Musculoskeletal Biomedical Research Unit, which conducts clinical studies in musculoskeletal research.	30/03/2017

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

Month	Date	Number of Members Present at Meeting
April	19/04/2016	10
July	19/07/2016	8
August	16/08/2016	8
October	18/10/2016	9
November	15/11/2016	9
December	13/12/2016	10
January	17/01/2017	7
February	21/02/2017	7
March	21/03/2017	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
April	28/04/2016	3
May	31/05/2016	3
July	04/07/2016	3
August	04/08/2016	3
August	30/08/2016	3
October	03/10/2016	3
October	31/10/2016	3
December	08/12/2016	3
February	21/02/2017	3

9 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	14/04/2016	2
April	28/04/2016	2
May	04/05/2016	2
May	12/05/2016	2
May	26/05/2016	2
June	09/06/2016	2
June	23/06/2016	2
July	07/07/2016	2
July	21/07/2016	2
August	04/08/2016	2
August	18/08/2016	2
September	01/09/2016	2
September	15/09/2016	2

September	29/09/2016	2
October	13/10/2016	2
October	27/10/2016	2
November	10/11/2016	2
November	24/11/2016	2
December	08/12/2016	2
December	22/12/2016	2
January	05/01/2017	2
January	19/01/2017	2
February	02/02/2017	2
February	16/02/2017	2
March	02/03/2017	2
March	16/03/2017	2
March	30/03/2017	2

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

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

Date	Reason	Action taken
21/02/2017	Two apologies received on the day of the meeting and one apology given in advance had not been noted	A Committee member was contacted by telephone and a teleconference was held during the meeting to ratify the decisions.

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

Name	Number of Meetings Attended
Mr Sharif Al-Ghazal	6
Professor Diana Anderson	5
Dr. Nigel Birch	8
Ms Anne Davies	6
Dr Stan Dobrzanski	8
Mrs Jenny Foggin	5
Mr Simon Gelsthorpe	5
Dr Janet Holt	8
Dr John Keeler	1
Dr Kirste Mellish	7
Mr Andrew Scally	7
Dr Christopher Skidmore	8

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

Name	Number of Meetings Attended
Mr Sharif Al-Ghazal	1
Professor Diana Anderson	2
Dr. Nigel Birch	3
Ms Anne Davies	3
Dr Stan Dobrzanski	2
Mr Simon Gelsthorpe	3
Dr Janet Holt	5
Dr Kirste Mellish	1
Dr Kirste Mellish	1
Mr. Andy Scally	2
Dr Christopher Skidmore	3

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

Name	Number of Meetings Attended
Mr Sharif Al-Ghazal	2
Professor Diana Anderson	3
Dr. Nigel Birch	4
Ms Anne Davies	4
Dr Stan Dobrzanski	3
Mrs Jenny Foggin	1
Mr Simon Gelsthorpe	3

Dr Janet Holt	25
Dr Kirste Mellish	1
Dr Kirste Mellish	2
Mr Andrew Scally	2
Dr Christopher Skidmore	4

Training 01 April 2016 - 31 March 2017

Name of Member	Date	Event(s) attended
Professor Diana Anderson	27/04/2016	Data Protection, Information Security and Freedom of Information
Professor Diana Anderson	27/04/2016	Unconscious Bias
Professor Diana Anderson	14/05/2016	Diversity in the Workplace
Professor Diana Anderson	20/05/2016	Health and Safety
Professor Diana Anderson	20/05/2016	Recruitment and Selection
Professor Diana Anderson	06/07/2016	Local Training Day - North East and Yorkshire Regional Training
Professor Diana Anderson	16/02/2017	Training - National Members Training Day
Dr. Nigel Birch	06/07/2016	Local Training Day - North East and Yorkshire Regional Training
Dr Stan Dobrzanski	20/10/2016	Quantitative Research Methods and Statistics - A Health Research Authority Workshop
Dr Stan Dobrzanski	16/02/2017	Training - National Members Training Day
Dr Janet Holt	09/11/2016	The Practicalities of Running a REC - a workshop for Chairs and REC Managers
Dr Janet Holt	01/12/2016	National Training for Chairs
Dr Kirste Mellish	16/02/2017	Training - National Members Training Day
Dr Christopher Skidmore	06/07/2016	Local Training Day - North East and Yorkshire Regional Training
Dr Christopher Skidmore	22/03/2017	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)	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	4
Number of applications withdrawn prior to the meeting	1
Number of student applications reviewed	10
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	10
Number of applications reviewed that are funded by the US DHHS	0
Number of qualitative applications reviewed	4

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	2	5.41
Favourable Opinion with Additional Conditions	8	21.62
Unfavourable Opinion	0	0.00
Provisional Opinion	27	72.97
Provisional Opinion Pending Consultation with Referee	0	0.00
Total	37	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	21	56.76
Further Information Favourable Opinion with Additional Conditions	4	10.81
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	2	5.41
Favourable Opinion with Additional Conditions	8	21.62
Unfavourable Opinion	0	0.00
Provisional Opinion	1	2.70
Provisional Opinion Pending Consultation with Referee	0	0.00
Further Information response not complete	1	2.70
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	23
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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	8
Number of studies withdrawn prior to the meeting	2
Number of student applications reviewed	10
Number of paediatric applications reviewed	3
Number of device applications reviewed	1
Number of qualitative applications reviewed	3

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	17	73.91
Favourable Opinion with Additional Conditions	2	8.70
No Opinion transfer to full committee for review	0	0.00
Provisional Opinion	3	13.04
Unfavourable Opinion	1	4.35
Total	23	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	4
Number of completed applications over 40 days as a % of total	10.81%
Number of days taken to final decision – average (mean)	29
Number of completed proportionate review applications for ethical review	23
Number of completed proportionate review applications for ethical review over 14 days (Please note, the timetable for the 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	1
Number of completed proportionate review applications over 21 days as a % of total	4.35%
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	81
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	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 non substantial amendments received	105

Number of substantial amendments received for information	0
Number of substantial amendments received for new sites/PIs	0
Number of annual progress reports received	30
Number of safety reports received	0
Number of Serious Adverse Events received	1
Number of final reports received	1

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/0134	14022 - Clinical Evaluation of the Cementless ATTUNE TKA System	28
16/YH/0153	RegeniTherix CS2	26
16/YH/0155	The "Model-AD" study	34
16/YH/0304	The PREeMPT study	25
16/YH/0320	Born in Bradford Growing Up	28
16/YH/0344	Pilot trial of Intensive Language Action Therapy	43
16/YH/0347	Accelerometry in children and young people with arthritis	42
16/YH/0351	MRI assessment of cystic fibrosis and primary ciliary dyskinesia	32
16/YH/0433	Force Limiting Obstetric Forceps for Instrumental vagina Delivery.	29
16/YH/0442	POSY-TEICO OBS13842	27
16/YH/0448	Opioid Analgesic Dependence Study (OAD)	30
16/YH/0451	Implementation and evaluation of a ward patient experience toolkit	29
16/YH/0466	Psychosocial outcomes and readiness for transition in JIA	31
16/YH/0478	DISTRESSED - A feasibility study of a novel distress recognition tool.	27
16/YH/0487	TRUCE - TRreatment in Urgent dental Care: an Ethnographic study. v.4	23
16/YH/0498	Volunteerism in Acute Hospital Wards	43
17/YH/0006	HIP ATTACK	44
17/YH/0013	The RE-ENERGIZE Study	34
17/YH/0019	Screening for depression in cystic fibrosis	30
17/YH/0055	MIDFUT	36
17/YH/0084	Lung inflammation and cystic fibrosis related arthropathy	31

Further Information Favourable Opinion with Additional Conditions		
REC Reference	Title	Number of Days on Clock
16/YH/0283	The Bradford Tooth Fairy Project. Human dentine - a unique biomarker	35
16/YH/0463	CAD/CAM vs chairside bonded retainer: A multicenter RCT	25
17/YH/0005	Validation of translational biomarkers of neuropathic pain	26
17/YH/0048	Inequalities in access to sexual health services among young people	28

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/0298	GP Reminders for Bowel Scope Screening non-participants	25
17/YH/0082	TRECA Phase 2: multimedia information for assisting trial recruitment	27

Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
16/YH/0156	Cancer, Dementia and Information needs (Can-DO) v1	22
16/YH/0157	PLATO - Personalising Anal cancer radioTherapy dose	22
16/YH/0284	Ekso Bone Mineral Density Study Version 1.0	21
16/YH/0357	Microbial and host interactions in diabetic periodontal disease.	28
16/YH/0426	Remote vital signs monitoring in surgical patients	22
16/YH/0493	Repetitive Vocalisation in the Hospital (Patients and Carers)	20
17/YH/0001	Leeds Paediatric Cystic Fibrosis Unit: Annual Psychosocial Review	24
17/YH/0050	MBSR in adolescents with IBD	17

Unfavourable Opinion

REC Reference	Title	Number of Days on Clock
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Provisional Opinion

REC Reference	Title	Number of Days on Clock
17/YH/0003	SCOPE Trial	n/a

Provisional Opinion Pending Consultation with Referee

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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17/YH/0097	HERO - Home-based Extended Rehabilitation for Older People	n/a
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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
17/YH/0059	Emotions and eating disorders	12
17/YH/0066	Integrating mental, physical and social care in long term conditions	14
17/YH/0067	VASO - Vitamin D and Arthroplasty Surgery Outcomes (v.1)	12

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/0177	What are the predicting factors for kneeling after TKR/PKR?	8
16/YH/0179	APACHE	10
16/YH/0180	Use of pulse oximetry in the prediction of ICU mortality	10
16/YH/0244	The RISK Study : Risk prediction for AKI in acute medical admissions	9
16/YH/0288	Trial of a transanal irrigation system in spinal cord injured patients	11
16/YH/0336	TERRA - Treat and Extend Ranibizumab Regimen for AMD	13
16/YH/0337	Infrared thermal imaging in transplantation	13
16/YH/0343	Worry, rumination, depression and chronic pain v1	13

16/YH/0385	i-c-TNBC	11
16/YH/0386	Identifying DNA profiles of sputum in patients with stage I NSCLC	14
16/YH/0387	TRECA (Phase 1 - user testing study)	10
16/YH/0437	Care Planning in the Frail Elderly: GPPS data analysis	8
16/YH/0438	Prebiotics in Immunity and Inflammation V1	8
16/YH/0439	Donor Preference Survey	8
16/YH/0468	Enhanced Medication Summaries to reduce high-risk prescribing 01	13
16/YH/0471	Experiences of incidentally identified haemoglobinopathy carriers V1.0	10
16/YH/0513	tolerability and adverse drug reactions of antiepileptic drugs	14

Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
16/YH/0338	Evaluating effect of music on women undergoing Outpatient hysteroscopy	26
16/YH/0515	Why do some women with breast cancer choose not to exercise?	13

Unfavourable Opinion

REC Reference	Title	Number of Days on Clock
16/YH/0289	Development & validation of the craving automated scale for substance	11

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
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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
07/H1302/112/AM22	Born in Bradford Version 2	Substantial Amendment 23, 04/0	04/04/2016	10
08/H1302/21/AM05	The Born in Bradford Infection and Allergy Study (Version 1)	Substantial Amendment 6, 07/02	07/02/2017	9
12/YH/0010/AM02	Simultaneous kissing stenting for the left main stem	Substantial Amendment 1, 18/05	23/05/2016	8
12/YH/0097/AM02	Bowditch revisited: defining the optimum heart rate range in CHF	Substantial Amendment 2, 31/05	02/06/2016	23
12/YH/0394/AM03	The impact of medication prescribed for trigeminal neuralgia	Substantial Amendment 2, 01/03	05/04/2016	10
13/YH/0016/AM11	The DCM EPIC study 1.0	Substantial Amendment 9, 23/03	23/03/2016	23
13/YH/0016/AM12	The DCM EPIC study 1.0	Substantial Amendment 10, 06/0	07/07/2016	17
13/YH/0241/AM05	Single-port versus conventional laparoscopic colorectal surgery	Substantial Amendment 2, 28/12	12/01/2017	21
13/YH/0265/AM01	Quantitative Coronary Angiography in Coronary Heart Disease	Substantial Amendment 1, 01/03	22/03/2016	11
13/YH/0268/AM02	Circadian glucose in gestational diabetes	Substantial Amendment 2, 20/04	05/05/2016	8
13/YH/0310/AM05	Genotype and Phenotype in Inherited Neurodegenerative Disease	Substantial Amendment 4,	02/08/2016	10

		08/08		
13/YH/0310/AM06	Genotype and Phenotype in Inherited Neurodegenerative Disease	Substantial Amendment 5, 14/11	17/11/2016	8
14/YH/0076/AM06	BALANCED	Substantial Amendment 4, 01/09	01/09/2016	14
14/YH/0079/AM03	Do people pass on ESBL infections to others in their household?	Substantial Amendment 1, 15/11	05/12/2016	15
14/YH/0117/AM04	Biomarkers of neuropathic pain	Substantial Amendment 4, 12/10	18/10/2016	9
14/YH/0155/AM02	Experiencing transplant with stories from survivors	Substantial Amendment 3, 19/03	01/06/2016	14
14/YH/1117/AM03	Impact of vascular conditions on quality of life	Substantial Amendment 2 - Chan	01/06/2016	26
14/YH/1120/AM07	CARE Study	Substantial Amendment 3, 16/11	17/11/2016	10
14/YH/1254/AM01	PANTHER	Substantial Amendment 1, 03/02	06/05/2016	22
14/YH/1267/AM02	RCT - Epidural vs. wound catheter following liver resection	Substantial Amendment 2, 31/03	12/04/2016	10
14/YH/1289/AM04	Plegridy Real World Observational Program (POP)	Substantial Amendment 3, 15/04	22/04/2016	21
14/YH/1289/AM05	Plegridy Real World Observational Program (POP)	Substantial Amendment 4, 02/02	02/08/2016	14
15/YH/0021/AM01	Holistic Assessment and Care Planning in Prostate Cancer	Substantial Amendment 1, 08/04	06/06/2016	22

15/YH/0056/AM02	Assessing non-standard applications for a solid state gamma camera	Substantial Amendment 2, 09/02	15/02/2017	13
15/YH/0073/AM02	An exploration of the experiences of carers of stroke survivors	Substantial Amendment 1, 07/04	12/04/2016	10
15/YH/0246/AM01	CHERNAC	Substantial Amendment 1, 03/08	18/08/2016	18
15/YH/0260/AM04	Continuous antibiotic prophylaxis in colorectal surgery.	Substantial Amendment 3, 03/11	07/11/2016	12
15/YH/0269/AM04	MRI cardiopulmonary metrics in pulmonary arterial hypertension	Substantial Amendment 4, 23/05	23/05/2016	17
15/YH/0269/AM05	MRI cardiopulmonary metrics in pulmonary arterial hypertension	Substantial Amendment 5, 10/10	27/10/2016	14
15/YH/0276/AM03	Post authorisation observational study of Lemtrada in MS patients	Substantial Amendment 1, 29/06	29/06/2016	8
15/YH/0276/AM08	Post authorisation observational study of Lemtrada in MS patients	Substantial Amendment 2, 20/01	13/01/2017	7
15/YH/0317/AM02	4AT validation study	Substantial Amendment 2, 28/07	05/08/2016	13
15/YH/0326/AM02	Educating adolescents at Risk of Anaphylaxis and their Future Doctors	Substantial Amendment 2, 25/01	25/01/2017	13
15/YH/0365/AM02	The RP Genome Project	Substantial Amendment 3, 21/06	22/06/2016	13
15/YH/0376/AM01	An exploration of person-centred care in a weight management clinic.	Substantial Amendment 1, 16/01	07/03/2017	23
15/YH/0455/AM03	Born in Bradford's Better Start (BiBBS) Cohort Study	Substantial	19/07/2016	16

		Amendment 2, 18/07		
15/YH/0457/AM01	Developing a weight-related co-morbidities screening tool	Substantial Amendment 1, 01 08	11/08/2016	13
15/YH/0488/AM03	What Works? in dementia training and education v1	Substantial Amendment 1, 02/03	07/03/2017	24
15/YH/0513/AM01	FAST: Prevalence and Impact of frailty in Colorectal Surgical patients	Substantial Amendment 1, 15/09	04/11/2016	11
15/YH/0531/AM02	"INVEST in Parkinsonian Dementias"	Substantial Amendment 2, 06/04	03/05/2016	10
15/YH/0531/AM03	"INVEST in Parkinsonian Dementias"	Substantial Amendment 3, 18/05	19/05/2016	12
15/YH/0531/AM05	"INVEST in Parkinsonian Dementias"	Substantial Amendment 4, 11/08	11/08/2016	17
15/YH/0531/AM08	"INVEST in Parkinsonian Dementias"	Substantial Amendment 5, 11/11	11/11/2016	17
15/YH/0549/AM01	Patient and Public Involvement in Quality Improvement Projects	Substantial Amendment 1, 06/02	09/02/2017	17
15/YH/0550/AM01	I-CARE - IBD Cancer and Serious Infections in Europe	Substantial Amendment 1, 17/06	27/06/2016	15
15/YH/0550/AM05	I-CARE - IBD Cancer and Serious Infections in Europe	Substantial Amendment 2, 15/11	16/11/2016	12
16/YH/0040/AM01	Promoting Activity, Independence and Stability in Early Dementia	Substantial Amendment 1, 01/06	15/06/2016	14
16/YH/0040/AM04	Promoting Activity, Independence and Stability in Early Dementia	Substantial Amendment 2,	31/10/2016	6

		25/10		
16/YH/0040/AM05	Promoting Activity, Independence and Stability in Early Dementia	2.1	12/12/2016	8
16/YH/0047/AM01	Linking oral health data of Bradford 5 year olds with their birth data	Substantial Amendment 1, 05/10	24/10/2016	8
16/YH/0048/AM01	BDCFT - study number 192329 - GA data linkage	Substantial Amendment 1, 05/10	24/10/2016	8
16/YH/0051/AM02	EMBalance. A feasibility/proof of concept study	Substantial Amendment 2, 18/07	19/07/2016	27
16/YH/0054/AM01	Plasma diurnal variation in and absorption of EPA and DHA	Substantial Amendment 1, 29/06	01/07/2016	21
16/YH/0055/AM02	TIGA-CUB	Substantial Amendment 1, 29/06	30/06/2016	11
16/YH/0062/AM01	Born in Bradford: The Primary School Years	Substantial Amendment 1, 15/04	21/04/2016	21
16/YH/0062/AM02	Born in Bradford: The Primary School Years	Substantial Amendment 2, 03/10/2016	03/10/2016	10
16/YH/0098/AM01	CALSITE study	Substantial Amendment 1, 13/06	20/06/2016	9
16/YH/0099/AM01	Providing better information and support for AMD patients	Substantial Amendment 1, 16/10	18/10/2016	13
16/YH/0100/AM01	Gut microbiota profiling for diseased states	Substantial Amendment 1, 20/06	20/06/2016	14
16/YH/0100/AM02	Gut microbiota profiling for diseased states	Substantial Amendment 2, 08/09	28/10/2016	23
16/YH/0111/AM01	Falls in Care Homes (FinCH)	Substantial	08/07/2016	12

		Amendment 1, 08/07		
16/YH/0111/AM05	Falls in Care Homes (FinCH)	Substantial Amendment 2, 08/12	08/12/2016	7
16/YH/0111/AM07	Falls in Care Homes (FinCH)	Substantial Amendment 3, 23/02	06/03/2017	10
16/YH/0153/AM01	RegeniTherix CS2	Substantial Amendment 1, 02/08	08/08/2016	15
16/YH/0157/AM02	PLATO - PersonaLising Anal cancer radioTherapy dOse	Substantial Amendment 1, 06/01	13/01/2017	7
16/YH/0179/AM01	APACHE	Substantial Amendment 1, 17/05	18/05/2016	11
16/YH/0288/AM02	Trial of a transanal irrigation system in spinal cord injured patients	Substantial Amendment 1, 02/02	02/02/2017	13
16/YH/0320/AM01	Born in Bradford Growing Up	Substantial Amendment 1, 16/12	15/12/2016	6
16/YH/0320/AM03	Born in Bradford Growing Up	Substantial Amendment 2, 01/03	02/03/2017	19
16/YH/0336/AM05	TERRA - Treat and Extend Ranibizumab Regimen for AMD	Substantial Amendment 1, 15/11	16/11/2016	12
16/YH/0336/AM07	TERRA - Treat and Extend Ranibizumab Regimen for AMD	Substantial Amendment 2, 30/11	30/11/2016	21
16/YH/0351/AM01	MRI assessment of cystic fibrosis and primary ciliary dyskinesia	Substantial Amendment 1, 08/12	16/12/2016	25
16/YH/0385/AM01	i-c-TNBC	Substantial Amendment 1,	08/12/2016	15

		07/12		
16/YH/0386/AM01	Identifying DNA profiles of sputum in patients with stage I NSCLC	Substantial Amendment 1, 14/11	28/11/2016	17
16/YH/0387/AM01	TRECA (Phase 1 - user testing study)	Substantial Amendment 1, 19/09	22/09/2016	15
16/YH/0387/AM02	TRECA (Phase 1 - user testing study)	Substantial Amendment 2, 07/12	14/12/2016	21
16/YH/0426/AM01	Remote vital signs monitoring in surgical patients	Substantial Amendment 1, 11/11	16/11/2016	13
16/YH/0438/AM01	Prebiotics in Immunity and Inflammation V1	Substantial Amendment 1, 07/03	14/03/2017	14
16/YH/0448/AM01	Opioid Analgesic Dependence Study (OAD)	Substantial Amendment 1, 08/12	12/12/2016	10
16/YH/0466/AM01	Psychosocial outcomes and readiness for transition in JIA	Substantial Amendment 1, 16/03	17/03/2017	19
16/YH/0471/AM01	Experiences of incidentally identified haemoglobinopathy carriers V1.0	Substantial Amendment 1, 06/12	09/01/2017	9

Unfavourable opinion

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
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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
16/YH/0338	Evaluating effect of music on women undergoing Outpatient hysteroscopy	26

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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