

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

Annual Report

01 April 2015 - 31 March 2016



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 – August 2015 - ongoing Ms Gillian Mayer – April 2015 – August 2015
REC Assistant:	Miss Sarah Prothero – August 2015 - ongoing Miss Jade Robinson - April 2015 – August 2015
Committee Address:	HRA Jarrow 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 and in subcommittees. Despite the continued challenges of Proportionate Review (PR), members have worked extremely hard together with the PR committee chairs, the REC Manager and assistant to ensure the deadlines were met.

We were very sorry to lose Dr David Dawson from the committee this year. This loss of yet another clinical colleague due to difficulties in balancing this work with clinical commitments is regrettable. In his capacity as an expert member and consultant anaesthetist, Dr Dawson made an invaluable contribution to the work of the committee work generously sharing his clinical and research ethics expertise. Due to work commitments, Ms Rebecca Forster also resigned and Mr Robert Thompson also did not return to the committee following leave of absence. I would like to thank them all for the contributions they have made to the work of the committee, but particularly Dr Dawson who joined the merged committee following a number of years' service on the former Bradford committee. Mrs Jenny Foggin also took a short leave of absence, but we are pleased to have now welcomed her back to the committee.

As in previous years attendance at full, PR and sub committees has been good although meeting the requirement of having a lay plus member at the meetings has been challenging. I am particularly grateful to Dr Rhona Bratt for agreeing to serve as a member of this committee in a lay plus capacity in addition to her work as Chair of the Leeds East Committee. As a very experienced REC member, we have been very fortunate to be able to draw on Dr Bratt's expertise.

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.

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 deputise for me at a the North East and Yorkshire & The Humber NREAP/Chairs' Network Meeting.

We have also had a change of REC Manager during the year due to changed work schedules in the Regional Office. Our new manager, Miss Katy Cassidy, has worked very effectively with the committee since her appointment.

I would like to express appreciation of the support given to me by the Vice and Alternate Vice Chair, the REC Managers (both Gillian Mayer and Katy Cassidy) and Sarah Prothero the REC Assistant in ensuring the smooth running of the committee. But most particularly to the members of the Bradford Leeds Committee who demonstrate such a clear 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	Lay Plus Member	Lay	01/11/2015	
Dr Rhona Bratt	Retired Multi-media Project Manager	Lay Plus	01/07/2015	31/03/2016
Ms Anne Davies	Clinical Research Consultant	Lay	17/06/2013	
Mr David Dawson	Anaesthetist Consultant	Expert	01/04/2013	03/12/2015
Dr Stan Dobrzanski	Clinical Services Manager Pharmacy	Expert	18/06/2013	
Mrs Jenny Foggin	Senior Governance & Corporate Affairs Officer	Lay Plus	18/02/2014	
Ms Rebecca Forster	Project Specialist / Project Operations & Start-Up/ Clinical Development	Lay	01/10/2013	31/12/2015
Mr Simon Gelsthorpe	BDCFT Head of Psychological Therapies	Expert	01/04/2013	
Dr Janet Holt	Senior Lecturer	Expert	01/04/2013	
Dr Kirste Mellish	Research Programme Manager	Expert	01/04/2013	
Mr Andrew Scally	Senior Lecturer	Expert	01/04/2013	
Dr Christopher Skidmore	Retired University Lecturer	Lay	02/08/2013	
Mr Robert Thompson	Director, RTB Tribal Consulting	Lay	08/07/2013	01/10/2015

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

None

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

Name	Profession	Status	Meeting date attended
Jennifer Blaikie	Research Administrator	Lay	19/05/2015
Professor Ken Brodlie	Retired Professor of Visualization	Lay Plus	16/06/2015
Mr Paddy Stevenson	Research Operations Manager	Expert	29/03/2016 (PR)

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

Name	Declaration of Interest	Date
Mr Sharif Al-Ghazal	No interests declared.	05/05/2015
Professor Diana Anderson	Positions held: "I am Scientific Advisor to a company called Oncascan. The University of Bradford, has been working with consultants in Bradford Royal Infirmary to try to develop a blood test for detecting susceptibility to cancer. This research has been led by me and it has been shown that cancer patients have greater DNA damage than do healthy individuals and other disease states have intermediate values. Two entrepreneurs are trying to take this to market in conjunction with the Research and Knowledge Transfer Department at the University and UK Government Funding.	18/09/2015
Dr. Nigel Birch	No interests declared.	12/02/2016
Dr Rhona Bratt	No interests declared	14/09/2015
Ms Anne Davies	Anne is a Project Manager for Patients Association	18/02/2016
Mr David Dawson	Paid medical adviser to Philips Respiroics in the UK. Managing Director of OSA Risk Management Ltd. Shareholder: Glaxo Smith Kline, Astra Zeneca. Discussing with Royal College of Anaesthetists establishment of national database to monitor the incidence of death and near misses in patients with sleep apnoea who also have an anaesthetic.	06/10/2015
Dr Stan Dobrzanski	Other activities:"In the last 12 months I have drafted a research paper linked to work partly supported by Bayer Pharmaceuticals related to anticoagulants".	26/06/2015
Mr Simon Gelsthorpe	No declarations noted	01/07/2015
Dr Janet Holt	Janet is Chair of the Faculty of Medicine and Health Research Ethics Committee at the University of Leeds. She is also a member of the University of Leeds Research Ethics Committee and an external member of the Faculty of Business and Law REC at Leeds Beckett University.	24/02/2016
Mr Andrew Scally	Activities: Member of Bradford Leeds REC	01/07/2015
Dr Christopher Skidmore	No interests declared.	28/08/2015
Dr Kirste Mellish	Kirste is employed as the Director of Operations at Leeds Musculoskeletal Biomedical Research Unit, which conducts clinical studies in musculoskeletal research.	10/02/2016

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

Month	Date	Number of Members Present at Meeting
April	21/04/2015	11
May	19/05/2015	9
June	16/06/2015	11
July	21/07/2015	11
August	18/08/2015	11
October	20/10/2015	9
November	17/11/2015	11
December	15/12/2015	9
February	16/02/2016	11
March	15/03/2016	9

10 full committee meetings were held during the reporting period.

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

Month	Date	Number of Members Present at Meeting
April	01/04/2015	3
May	08/05/2015	3
May	19/05/2015	3
June	04/06/2015	3
July	02/07/2015	3
August	06/08/2015	3
September	02/09/2015	3
October	08/10/2015	3
November	04/11/2015	3
December	04/12/2015	3
February	04/02/2016	3
March	02/03/2016	3
March	29/03/2016	3

13 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	09/04/2015	2
April	21/04/2015	2
May	07/05/2015	2
June	18/06/2015	2
July	02/07/2015	2
July	16/07/2015	2
July	30/07/2015	2
August	13/08/2015	2
August	17/08/2015	2

August	27/08/2015	2
September	10/09/2015	2
October	08/10/2015	2
October	22/10/2015	2
November	05/11/2015	2
November	19/11/2015	2
December	03/12/2015	2
December	17/12/2015	2
January	06/01/2016	2
January	21/01/2016	2
February	04/02/2016	2
February	18/02/2016	2
March	03/03/2016	2
March	17/03/2016	2
March	30/03/2016	2

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

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

None

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

Name	Number of Meetings Attended
Mr Sharif Al-Ghazal	9
Professor Diana Anderson	6
Dr. Nigel Birch	3
Dr Rhona Bratt	8
Ms Anne Davies	9
Mr David Dawson	5
Dr Stan Dobrzanski	9
Mrs Jenny Foggin	3
Ms Rebecca Forster	6
Mr Simon Gelsthorpe	10
Dr Janet Holt	8
Dr Kirste Mellish	7
Mr Andrew Scally	9
Dr Christopher Skidmore	8

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

Name	Number of Meetings Attended
Mr Sharif Al-Ghazal	1
Professor Diana Anderson	2
Dr. Nigel Birch	2
Dr Rhona Bratt	1
Ms Anne Davies	6
Mr David Dawson	2
Dr Stan Dobrzanski	4
Mrs Jenny Foggin	2
Mr Simon Gelsthorpe	3
Dr Janet Holt	5
Dr Kirste Mellish	2
Mr Andrew Scally	3
Dr Christopher Skidmore	5

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

Name	Number of Meetings Attended
Mr Sharif Al-Ghazal	1
Professor Diana Anderson	2
Dr Rhona Bratt	3
Ms Anne Davies	2

Mr David Dawson	1
Dr Stan Dobrzanski	3
Mrs Jenny Foggin	3
Mr Simon Gelsthorpe	3
Dr Janet Holt	22
Dr Kirste Mellish	2
Mr Andrew Scally	2
Dr Christopher Skidmore	4

Training 01 April 2015 - 31 March 2016

Name of Member	Date	Event(s) attended
Mr Sharif Al-Ghazal	29/07/2015	Equality & Diversity
Professor Diana Anderson	04/06/2015	Regional Members' Training Day
Dr. Nigel Birch	16/03/2016	National Members' Training Day
Ms Anne Davies	13/04/2015	Equality & Diversity
Ms Anne Davies	16/03/2016	National Members' Training Day
Mr David Dawson	10/07/2015	Equality & Diversity
Ms Rebecca Forster	08/06/2015	Equality & Diversity (Appreciating Differences)
Mr Simon Gelsthorpe	11/08/2015	Equality & Diversity
Dr Janet Holt	04/06/2015	Regional Members' Training Day
Dr Janet Holt	11/03/2016	Genetic and Genomic Research
Mr Andrew Scally	25/06/2015	Equality & Diversity
Dr Christopher Skidmore	04/09/2015	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	50	100.00
Total Applications Reviewed	50	100

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

Number of applications made invalid by the REC Manager	2
Number of applications withdrawn prior to the meeting	0
Number of student applications reviewed	20
Number of paediatric applications reviewed	7
Number of device applications reviewed	6
Number of prisoner applications reviewed	1
Number of applications involving adults unable consent reviewed	14
Number of applications reviewed that are funded by the US DHHS	0
Number of qualitative applications reviewed	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	2	4.00
Favourable Opinion with Additional Conditions	5	10.00
Unfavourable Opinion	3	6.00
Provisional Opinion	40	80.00
Provisional Opinion Pending Consultation with Referee	0	0.00
Total	50	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	33	66.00
Further Information Favourable Opinion with Additional Conditions	5	10.00
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	2	4.00
Favourable Opinion with Additional Conditions	5	10.00
Unfavourable Opinion	3	6.00
Provisional Opinion	0	0.00
Provisional Opinion Pending Consultation with Referee	0	0.00
Further Information response not complete	1	2.00
No decision entered on system	0	0.00
Number of studies withdrawn after the meeting	1	2.00
Total	50	100

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

Total Applications Reviewed	37
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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	4
Number of student applications reviewed	13
Number of paediatric applications reviewed	6
Number of device applications reviewed	1
Number of qualitative applications reviewed	9

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	25	67.57
Favourable Opinion with Additional Conditions	4	10.81
No Opinion transfer to full committee for review	3	8.11
Provisional Opinion	5	13.51
Unfavourable Opinion	0	0.00
Total	37	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	5.00
Number of completed applications for full ethical review	49
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	2.00%
Number of days taken to final decision – average (mean)	29
Number of completed proportionate review applications for ethical review	31
Number of completed proportionate review applications for ethical review over 14 days	1
Number of completed proportionate review applications over 14 days as a % of total	3.23%
Number of SSAs (non-Phase 1) reviewed	3
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	51
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	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 minor amendments received	30
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	1
Number of Serious Adverse Events received	4
Number of final reports received	53

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/0184	Communication and Dementia Version 1.0	32
15/YH/0203	The development of a pilot outcome measure for group analysis	35
15/YH/0245	Evaluation of factors affecting ostomy products	33
15/YH/0247	Clients' Experiences of an ACT Group for Anxiety and Depression	17
15/YH/0269	MRI cardiopulmonary metrics in pulmonary arterial hypertension	31
15/YH/0270	COGNITION study	30
15/YH/0300	AIMS MS SMART	31
15/YH/0314	How Far Does Motivation Impact Outcome on the VOTP?	33
15/YH/0319	Advanced proton and phosphorous spectroscopy in multiple sclerosis	23
15/YH/0328	Resourcefulness in Later Life	31
15/YH/0363	OT's value in preparation for work: Forensic patients perspectives	25
15/YH/0365	The RP Genome Project	39
15/YH/0369	COPD Breathing Record Study	30
15/YH/0440	Pertrochanteric Endovis Trial (PET) 1.0	51
15/YH/0457	Developing a weight-related co-morbidities screening tool	37
15/YH/0468	Evaluation of the Mental Capacity Assessment Support Tool (MCAST)	38
15/YH/0508	Investigating abnormal babies using DNA sequencing - a new approach	32
15/YH/0509	Post-operative Recovery Exercise Programme using Yoga (PREPY)	25
15/YH/0511	Parents' knowledge about periodontal disease	35
15/YH/0513	FAST: Prevalence and Impact of frailty in Colorectal Surgical patients	19
15/YH/0531	"INVEST in Parkinsonian Dementias"	30
15/YH/0542	LaCeS feasibility	34
15/YH/0550	I-CARE - IBD Cancer and Serious Infections in Europe	33
15/YH/0558	RCT of a web based adherence intervention in cystic fibrosis (V 1)	27
15/YH/0559	PHARLAP, protocol version 8uk	31
16/YH/0040	Promoting Activity, Independence and Stability in Early Dementia	30
16/YH/0047	Linking oral health data of Bradford 5 year olds with their birth data	23
16/YH/0048	BDCFT - study number 192329 - GA data linkage	23
16/YH/0055	TIGA-CUB	32
16/YH/0062	Born in Bradford: The Primary School Years	22
16/YH/0098	CALSITE study	26
16/YH/0105	Men's experiences of CBT in IAPT services in North East Lincolnshire	25

16/YH/0111	Falls in Care Homes (FinCH)	27
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Further Information Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
15/YH/0260	Continuous antibiotic prophylaxis in colorectal surgery.	28
15/YH/0271	CARDIOFLOW study	31
15/YH/0317	4AT validation study	35
15/YH/0360	NORM PPCI	29
15/YH/0501	Use of a frailty index in end of life care	32

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
15/YH/0246	CHERNAC	20
15/YH/0451	The excess cardiovascular risk of rheumatoid arthritis: a cohort study	35

Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
15/YH/0268	Using FANI to Explore Non-Epileptic Attack Disorder	24
15/YH/0277	Improving memory services for South Asian families	24
15/YH/0455	Born in Bradford's Better Start (BiBBS) Cohort Study	35
15/YH/0488	What Works? in dementia training and education v1	15
16/YH/0054	Plasma diurnal variation in and absorption of EPA and DHA	24

Unfavourable Opinion

REC Reference	Title	Number of Days on Clock
15/YH/0199	Pathophysiology of ovarian cancer	29
15/YH/0329	EXERCISE CAPACITY IN PRIMARY SJÄ-GREN'S SYNDROME	23
15/YH/0338	The Bradley Measure of Self for People with Dementia	24

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		
REC Reference	Title	Number of Days on Clock
16/YH/0104	The Biochemical and Radiological Evaluation of Bone Health in MPS	n/a

Withdrawn after the meeting		
REC Reference	Title	Number of Days on Clock
15/YH/0202	Effort Testing in Young Onset with Dementia Services	29

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/0169	The relationship between tinnitus, hyperacusis and anxiety in children	8
15/YH/0327	First Consultation for Low Mood in General Practice	12
15/YH/0418	Understanding patients' perspectives about adrenal crises	10
16/YH/0146	Aiding Atrial Fibrillation Detection in Primary Care	14

Further Information Favourable Opinion with Additional Conditions		
REC Reference	Title	Number of Days on Clock
15/YH/0175	Microcirculation in Paediatric Congenital Heart Disease	11

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/0166	Personal Growth with Auditory and Visual Hallucinations - v1.0	9
15/YH/0228	Selecting implants for breast reconstruction	12
15/YH/0230	Human Cell models of genetic risk for Parkinson's disease	13
15/YH/0231	Enjoyable Exercise Games for Older People at Risk of Falls	13
15/YH/0250	Validation of the PsAID - GOPAID	14
15/YH/0251	Analysis of neural progenitor cells in premature infant CSF (v1)	10
15/YH/0273	Global diversity mapping of HLA and KIR genes in anonymous human DNA	14
15/YH/0276	Post authorisation observational study of Lemtrada in MS patients	14
15/YH/0298	Evaluation of a Long Term Conditions Clinic - version 1	13
15/YH/0326	Educating adolescents at Risk of Anaphylaxis and their Future Doctors	47
15/YH/0371	Ex-vivo study of lectins in cervical screening	14
15/YH/0375	Patient's perception of consent in clinical trials	13
15/YH/0376	An exploration of person-centred care in a weight management clinic.	13
15/YH/0381	Investigating dissatisfaction in English general practice.	8
15/YH/0416	Specific respiratory infections as triggers of acute medical events	11
15/YH/0417	Raman and FTIR spectroscopy in melanoma	9
15/YH/0459	Quality of life and palliative care need in MSA and PSP	10
15/YH/0461	Patients' perspectives of compression textiles for venous leg ulcer	11
15/YH/0549	Patient and Public Involvement in Quality Improvement Projects	8
16/YH/0051	EMBalance. A feasibility/proof of concept study	7
16/YH/0052	Evaluation of the Effectiveness of the Orenzia Patient Alert Cards	7
16/YH/0099	Providing better information and support for AMD patients	12
16/YH/0100	Gut microbiota profiling for diseased states	12
16/YH/0102	Investigation of bleeding risk in pre-operative patients	13
16/YH/0103	Music in Pregnancy: Minimising Stress	12

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

15/YH/0505	NHS Diabetes Prevention Programme WP2	13
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15/YH/0510	Identifying a high-risk profile in endometrial cancer	12
15/YH/0551	User Engagement & Involvement in learning disability services	8
16/YH/0147	Validity of adapted GAD-7 and PHQ-9 measures for adults with LD	11

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
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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
04/Q1202/49/AM06	Nitric oxide in haemolytic anaemia including PNH (Version 1)	Substantial Amendment 3, 01/12	01/12/2015	9
08/H1313/17/AM14	Clinical Variation in Psychoses	Substantial Amendment 10 - Cha	25/06/2015	13
08/H1313/36/AM04	Acromegaly and Quality of Life	Substantial Amendment 2, 18/06	06/07/2015	17
09/H1302/44/AM20	(duplicate) Eurotherm3235trial	Substantial Amendment 14, 27/0	02/10/2015	23
10/H1313/37/AM05	Genetics of Schizophrenia in the Pakistani Population of W Yorkshire	Substantial Amendment 3 - Chan	25/06/2015	13
12/YH/0097/AM01	Bowditch revisited: defining the optimum heart rate range in CHF	Substantial Amendment 1.0, 26/	31/03/2015	13
12/YH/0297/AM01	The natural history of diabetic & non-diabetic chronic kidney disease	Substantial Amendment 1, 20/01	26/01/2016	23
12/YH/0534/AM02	Delirium in general hospital as a marker of undiagnosed dementia	Substantial Amendment 2, 11/02	20/04/2015	16
12/YH/0555/AM02	SEMAC	Substantial Amendment 2, 05/05	18/05/2015	17
13/YH/0016/AM09	The DCM EPIC study 1.0	Substantial Amendment 7, 28/09	14/10/2015	8
13/YH/0016/AM10	The DCM EPIC study 1.0	Substantial Amendment 8, 14/01	15/01/2016	15

13/YH/0018/AM03	ANKHD1 as a regulator of JAK/STAT signalling. Version 1	Substantial Amendment 3, 15/04	16/04/2015	5
13/YH/0270/AM01	HeadUp Evaluation	Substantial Amendment 1 - 4/6/	04/06/2015	10
14/YH/0040/AM02	Attune Primary TKA Survivorship	Substantial Amendment 2, 18/03	20/03/2015	20
14/YH/0040/AM03	Attune Primary TKA Survivorship	Substantial Amendment 3, 15/10	31/10/2015	23
14/YH/0116/AM02	(England) CULPRIT-SHOCK	Amendment 1, 09/06/2015	23/07/2015	19
14/YH/0117/AM02	Biomarkers of neuropathic pain	Substantial Amendment 2, 28/05	10/06/2015	8
14/YH/0117/AM03	Biomarkers of neuropathic pain	Substantial Amendment 3, 04/02	16/02/2016	17
14/YH/1068/AM04	Telehealth in Motor Neurone Disease	Substantial Amendment 3, 14/04	15/04/2015	21
14/YH/1117/AM02	Impact of vascular conditions on quality of life	Substantial Amendment 1 - Change of CI, 01/06/15	02/06/2015	21
14/YH/1120/AM03	CARE Study	Substantial Amendment 2, 24/02	09/03/2016	19
14/YH/1225/AM02	Prevalence of OSA in Adults with Type 1 Diabetes Mellitus	Substantial Amendment 1, 27/01	25/03/2015	14
14/YH/1226/AM01	DEFINE - Diabetes Exercise and Fitness Needs	Substantial Amendment 1, 17/04	17/04/2015	18
14/YH/1289/AM01	Plegridy Real World Observational Program (POP)	Substantial Amendment 1 ,	22/07/2015	28

		22.7		
14/YH/1289/AM03	Plegridy Real World Observational Program (POP)	Substantial Amendment 2, 10/12	09/12/2015	4
14/YH/1306/AM01	Longer-term support for stroke survivors and their carers	Substantial Amendment 1 - 17/6	17/06/2015	14
14/YH/1306/AM02	Longer-term support for stroke survivors and their carers	Substantial Amendment 2, 11/08	12/08/2015	20
14/YH/1306/AM04	Longer-term support for stroke survivors and their carers	Substantial Amendment 2, 12/01	11/01/2016	7
14/YH/1306/AM05	Longer-term support for stroke survivors and their carers	Substantial Amendment 4, 02/03	10/03/2016	27
14/YH/1315/AM01	CoMFFort-Q in CIEDs - clinical outcomes study	Substantial Amendment 1, 28/07	07/08/2015	15
14/YH/1315/AM02	CoMFFort-Q in CIEDs - clinical outcomes study	Substantial Amendment 2 - 23/0	22/09/2015	14
15/YH/0024/AM01	Parkinson's-related dementia iCST (Focus Groups & Manual Development)	Substantial Amendment 1, 28/08	30/08/2015	14
15/YH/0059/AM02	Becker MD Natural History Study	Substantial Amendment 1, 29/01	05/02/2016	9
15/YH/0184/AM01	Communication and Dementia Version 1.0	Substantial Amendment 1, 03/08	03/08/2015	18
15/YH/0231/AM01	Enjoyable Exercise Games for Older People at Risk of Falls	Substantial Amendment 1, 14/08	14/08/2015	15
15/YH/0260/AM01	Continuous antibiotic prophylaxis in colorectal surgery.	Substantial Amendment 1.1, 15/	30/10/2015	18

15/YH/0260/AM02	Continuous antibiotic prophylaxis in colorectal surgery.	Substantial Amendment 2.1, 05/	25/11/2015	7
15/YH/0269/AM01	MRI cardiopulmonary metrics in pulmonary arterial hypertension	Substantial Amendment 1, 08/12	10/12/2015	6
15/YH/0269/AM02	MRI cardiopulmonary metrics in pulmonary arterial hypertension	Substantial Amendment 2, 14/01	26/01/2016	8
15/YH/0269/AM03	MRI cardiopulmonary metrics in pulmonary arterial hypertension	Substantial Amendment 3, 03/03	11/03/2016	24
15/YH/0270/AM01	COGNITION study	Substantial Amendment 1, 17/12	31/12/2015	17
15/YH/0271/AM01	CARDIOFLOW study	Substantial Amendment 1, 21/01	27/01/2016	8
15/YH/0317/AM01	4AT validation study	Substantial Amendment 1, 05/01	02/02/2016	15
15/YH/0326/AM01	Educating adolescents at Risk of Anaphylaxis and their Future Doctors	Substantial Amendment 1, 17/02	26/02/2016	21
15/YH/0328/AM01	Resourcefulness in Later Life	Substantial Amendment 1, 01/03	07/03/2016	14
15/YH/0365/AM01	The RP Genome Project	Substantial Amendment 1, 08/01	06/01/2016	13
15/YH/0455/AM01	Born in Bradford's Better Start (BiBBS) Cohort Study	Substantial Amendment 1, 29/02	02/03/2016	16
15/YH/0459/AM01	Quality of life and palliative care need in MSA and PSP	Substantial Amendment 1, 14/12/15	17/12/2015	1
15/YH/0531/AM01	"INVEST in Parkinsonian Dementias"	Substantial	18/02/2016	15

		Amendment 1, 12/02		
16/YH/0051/AM01	EMBalance. A feasibility/proof of concept study	Substantial Amendment 1, 18/02	19/02/2016	17

Unfavourable opinion				
Amendment REC Reference	Title	Version	Date	Number of Days on Clock
14/YH/0155/AM01	Experiencing transplant with stories from survivors	Substantial Amendment 1, 22/06	22/07/2015	24

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
14/YH/0155/AM01/1	Experiencing transplant with stories from survivors	Substantial Amendment 2 - Modified	29/09/2015	10

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 14 day timeline

REC Reference	Title	Number of Days on Clock
15/YH/0326	Educating adolescents at Risk of Anaphylaxis and their Future Doctors	47

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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