

**North West - Lancaster Research Ethics
Committee**

Annual Report

01 April 2016 - 31 March 2017



Part 1 – Committee Membership and Training

Name of REC:	North West - Lancaster Research Ethics Committee
Type of REC:	Authorised
Type of Flag:	Paediatrics
Chair:	Dr Lisa Booth
Vice-Chair:	Professor Jois Stansfield
Alternate Vice-Chair:	Dr Anas Olabi
REC Manager:	Mrs Carol Ebenezer
REC Assistant:	Ms Zainab Ahmed
Committee Address:	Barlow House 3rd Floor 4 Minshull Street Manchester M1 3DZ
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Chair's overview of the past year:

The Committee closed in January 2017

North West - Lancaster Research Ethics Committee Membership

Name	Profession	Expert or Lay	Dates	
			Appointed	Left
Dr Brenda Ashcroft	Retired Lecturer	Expert	09/09/2009	
Mr David Barber	Pharmacist	Expert	01/10/2005	
Dr Lisa Booth	Senior Lecturer / Chair	Expert	01/09/2006	
Ms Debbie Foord	Retired community psychiatric nurse	Lay	01/10/2015	
Dr Grace Hurford	Senior Lecturer, public services leadership	Lay Plus	01/02/2016	
Dr Brenda Leese	Retired Health Researcher	Lay	10/03/2010	
Dr Laura Machin	Lecturer in Medical Ethics	Lay Plus	02/06/2014	
Dr Anas Olabi	Consultant Paediatrician	Expert	01/01/2007	
Mrs Susan Page	Senior Clinical Tutor	Expert	13/10/2011	
Mrs Gillian Rimington	Paralegal	Lay	23/03/2015	
Mrs Valerie Skinner	Nurse (Retired)	Lay	01/10/2005	21/09/2016
Professor Jois Stansfield	Professor of Speech Pathology	Expert	11/09/2009	
Dr Gary Whittle	Consultant in Dental Public Health (retired)	Expert	01/10/2005	

North West - Lancaster Research Ethics Committee: Co-opted Members

Name	Profession	Status	Meeting date attended
Mr Jimmy Burns	Retired	Lay Plus	13/10/2016
Mr Frank Killen	Retired engineer	Lay	14/07/2016
Dr Peter Owen	Retired Mathematics Lecturer	Lay Plus	14/07/2016, 10/11/2016
Ms Hannah Chambers	Retired	Lay	PRSC 14/04/2016

North West - Lancaster Research Ethics Committee: Members' Declarations of Interest:

Name	Declaration of Interest	Date
Dr Brenda Ashcroft	None	08/12/2016
Mr David Barber	Employed by Lancashire Teaching Hospitals NHS Trust, a large organisation that means a lot of research trials	08/12/2016
Dr Lisa Booth	Senior Lecturer University of Cumbria	08/12/2016
Ms Debbie Foord	None	08/12/2016
Dr Grace Hurford	Senior lecturer at the University of Cumbria Supervision of under and post graduate student dissertations/ PhDs at the University of Cumbria.	08/12/2016
Dr Brenda Leese	Holds shares in Angels PLC	08/12/2016
Dr Laura Machin	Trustee of Institute of Medical Ethics. Associate of Research Ethics. Deputy Chair, FHM REC, Lancaster University. Member of Uni REC. Lancaster Medical School REC Member.	08/12/2016
Dr Anas Olabi	None	08/12/2016
Mrs Susan Page	Employed by University of Central Lancashire although not directly involved in research	08/12/2016
Mrs Gillian Rimington	None	08/12/2016
Professor Jois Stansfield	Trustee: Borough Care (Stockport Care Honary Social Enterprise). Trustee: Total Communication (Learning Disability Social Enterprise). Professor of Speech Pathology MMU.	08/12/2016
Dr Gary Whittle	None	08/12/2016

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

Month	Date	Number of Members Present at Meeting
June	09/06/2016	10
July	14/07/2016	8
September	08/09/2016	10
October	13/10/2016	7
November	10/11/2016	7
January	11/01/2017 Business Meeting only	6

5 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	21/04/2016	3
May	20/05/2016	4
June	27/06/2016	4
July	26/07/2016	3
September	22/09/2016	3
October	20/10/2016	3
November	21/11/2016	3
January	12/01/2017	3

8 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	01/04/2016	2
April	08/04/2016	2
April	15/04/2016	2
April	29/04/2016	3
May	13/05/2016	2
May	20/05/2016	2
June	10/06/2016	3
June	17/06/2016	2
July	08/07/2016	2
July	15/07/2016	2
July	22/07/2016	2
July	29/07/2016	3
August	05/08/2016	2
August	19/08/2016	2
August	26/08/2016	2
September	02/09/2016	3

September	23/09/2016	2
October	07/10/2016	2
October	28/10/2016	2
November	25/11/2016	2
December	02/12/2016	2
December	23/12/2016	2
January	13/01/2017	2
January	31/01/2017	2
March	31/03/2017	2

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

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

0

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

Name	Number of Meetings Attended
Dr Brenda Ashcroft	5
Mr David Barber	4
Dr Lisa Booth	4
Ms Debbie Foord	3
Dr Grace Hurford	4
Dr Brenda Leese	6
Dr Laura Machin	3
Dr Anas Olabi	1
Mrs Susan Page	4
Mrs Gillian Rimington	3
Professor Jois Stansfield	4
Dr Gary Whittle	3

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

Name	Number of Meetings Attended
Dr Lisa Booth	7
Ms Debbie Foord	1
Dr Brenda Leese	4
Mrs Susan Page	1
Mrs Gillian Rimington	6
Professor Jois Stansfield	6

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

Name	Number of Meetings Attended
Dr Lisa Booth	23
Ms Debbie Foord	1
Professor Carol Haigh (post Lancaster closure – Preston Vice-Chair)	1
Dr Brenda Leese	8
Dr Rob Monks (post Lancaster closure – Preston Chair)	1
Professor Jois Stansfield	20

Training 01 April 2016 - 31 March 2017

Name of Member	Date	Event(s) attended
Mr David Barber	09/06/2016	Self directed learning log - Equality and Diversity, Mental Capacity Act Good Clinical Practice training
Dr Lisa Booth	06/07/2016	Local Training Day - York Regional Day
Dr Lisa Booth	06/07/2016	Local Training Day - North East and Yorkshire Regional Training
Ms Debbie Foord	30/06/2016	Self Directed learning log - NRES document defining research, RES language and exclusion, Confidentiality and Research, from Social Scientist, MRC Human Tissue legislation, summary of consent, licensing, Access to health records act
Dr Grace Hurford	08/06/2016	Member Induction
Dr Anas Olabi	21/04/2016	Equality and Diversity
Mrs Gillian Rimington	29/06/2016	Handling Health-Related Findings in Research (Joint MRC/HRA)
Professor Jois Stansfield	12/07/2016	Adults lacking capacity
Professor Jois Stansfield	14/10/2016	Genetics and genomic research

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	19	100.00
Total Applications Reviewed	19	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	9
Number of paediatric applications reviewed	3
Number of device applications reviewed	1
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	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	1	5.26
Favourable Opinion with Additional Conditions	8	42.11
Unfavourable Opinion	1	5.26
Provisional Opinion	9	47.37
Provisional Opinion Pending Consultation with Referee	0	0.00
Total	19	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	9	47.37
Further Information Favourable Opinion with Additional Conditions	0	0.00
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	1	5.26
Favourable Opinion with Additional Conditions	8	42.11
Unfavourable Opinion	1	5.26
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	19	100

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

Total Applications Reviewed	22
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Table 6: Breakdown of PRS applications and other activity during reporting period:

Number of applications made invalid by the REC Manager	1
Number of studies withdrawn prior to the meeting	3
Number of student applications reviewed	12
Number of paediatric applications reviewed	0
Number of device applications reviewed	0
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	4	18.18
Favourable Opinion with Additional Conditions	7	31.82
No Opinion transfer to full committee for review	0	0.00
Provisional Opinion	11	50.00
Unfavourable Opinion	0	0.00
Total	22	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	3.8
Number of completed applications for full ethical review	19
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	0
Number of completed applications over 40 days as a % of total	0.00%
Number of days taken to final decision – average (mean)	22
Number of completed proportionate review applications for ethical review	22
Number of completed proportionate review applications for ethical review over 14 days (please note the timeline for reviewing 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 14 days as a % of total	4.55%
Number of SSAs (non-Phase 1) reviewed	1
Number of completed applications for SSA review over 25 days	0
Number of completed applications for SSA review over 25 days as % of all non- Phase 1 SSAs	0.00%
Number of SSAs (Phase 1) reviewed	0
Number of completed applications for SSA review over 14 days	0
Number of completed applications for SSA review over 14 days as % of all Phase 1 SSAs	0.00%
Number of substantial amendments reviewed	59
Number of completed substantial amendments over 35 days	0
Number of completed substantial amendments over 35 days as a % of total substantial amendments	0.00%
Number of completed substantial amendments over 28 days	1
Number of completed substantial amendments over 28 days as a % of total substantial amendments	1.69%
Number of modified amendments reviewed	2
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	39

Number of substantial amendments received for information	0
Number of substantial amendments received for new sites/PIs	0
Number of annual progress reports received	53
Number of safety reports received	0
Number of Serious Adverse Events received	0
Number of final reports received	37

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/NW/0446	Voices Impact Scale (VIS): Evaluation	26
16/NW/0456	Understanding Sensory Perception in Early Development.	29
16/NW/0472	Patients and relatives recognising changes in patient wellness	20
16/NW/0543	Lived experience of severe and enduring eating disorder	30
16/NW/0631	Experiences of short-term VAD	23
16/NW/0756	Empowerment & Learning Disabilities - The Therapeutic Relationship	33
16/NW/0757	Caring For Caregivers: Pilot RCT	28
16/NW/0804	Evaluating Cottage Hospice: A new model of care	28
16/NW/0818	ENTEROSGEL IN TREATMENT OF ACUTE DIARRHOEA IN ADULTS	31

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
16/NW/0751	Effect of fat and sugar on liver fat	14

Favourable Opinion with Additional Conditions		
REC Reference	Title	Number of Days on Clock
16/NW/0544	SkyCeiling	13
16/NW/0550	Estimating blood concentrations of anaesthetics during OLV	14
16/NW/0551	Breathing Face Mask and Mouthpiece User Research Study V 1.0	14
16/NW/0632	Making Every Contact Count: Mental Health	20
16/NW/0645	T-cell regulation in HPV+ve OPSCC and normal tonsil	23
16/NW/0657	OSCARSS Cluster RCT & Process Evaluation	20

16/NW/0666	Trial recruitment for an imaging study of bone and joint health	14
16/NW/0750	ZestiVits	14

Unfavourable Opinion

REC Reference	Title	Number of Days on Clock
16/NW/0410	Prenatal testing for high-risk women	29

Provisional Opinion

REC Reference	Title	Number of Days on Clock
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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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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/NW/0312	Womens' experience of being offered influenza vaccination in pregnancy	11
16/NW/0316	Observations of multidisciplinary care planning meetings	14
16/NW/0329	Perceptions of Pulmonary Rehab in ILD	13
16/NW/0419	Monitoring / quantification of exercise dose in cardiac rehabilitation	7
16/NW/0425	HORIZONS: Understanding the impact of cancer diagnosis and treatment	9

16/NW/0582	Developing a patient-centred outcome measure for PA patients	10
16/NW/0585	Functional performance measures and readmission in COPD.	12
16/NW/0703	Validation of the use of artificial nose (NeOse)	6
16/NW/0776	Hand Recognition After Stroke	17
16/NW/0841	Developing a tool to measure missed care in mental health nursing	13
16/NW/0843	Development of an objective measurement of diminished expression	9

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/NW/0422	Self reported oral disease	1
16/NW/0507	CARRIAGE: Investigating Staphylococcus aureus nasal carriage	10
16/NW/0779	Parents' perceptions of antibiotic use and antibiotic resistance PAUSE	10
17/NW/0037	Format of patient education for different sociodemographic groups	2

Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
16/NW/0318	SleepSure: a study aimed at improving sleep for hospital inpatients	12
16/NW/0509	Intra-operative red cell salvage and postoperative acidosis	3
16/NW/0513	Using patient blogs to measure self-care	3
16/NW/0580	An exploration of students' learning experiences in a Recovery College	8
16/NW/0586	Optimising the care of patients receiving oral SACTs - part three V1.0	8
16/NW/0840	Comparison of MR elastography liver with and without navigator trigger	6
17/NW/0046	Optical Coherence Tomography for Margin identification in BCC	10

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
11/NW/0041/AM01	Studies of Gene Transfer in Human Saphenous Vein	1	23/01/2017	3
12/NW/0132/AM02	Next Generation OCT resources: Version 1.0	2	01/08/2016	25
12/NW/0520/AM08	Focusing on Clozapine Unresponsive Symptoms	7	13/07/2016	13
13/NW/0120/AM07	Use of computer games to test visual fields in children (v1)	3	13/09/2016	8
13/NW/0120/AM08	Use of computer games to test visual fields in children (v1)	5	06/01/2017	8
13/NW/0227/AM02	Pelvic Vein Incompetence Study	2	20/09/2016	1
13/NW/0247/AM05	QulBs - Quantitative Imaging Biomarkers derived from MRI	3	13/10/2016	4
14/NW/0206/AM13	Comprehensive Longitudinal Assessment of Salford Integrated Care	11	27/06/2016	14
14/NW/0206/AM15	Comprehensive Longitudinal Assessment of Salford Integrated Care	12	26/07/2016	3
14/NW/0218/AM07	Finesse vs. Pen for Bolus Insulin in T2 DM, revision C	7	01/06/2016	3
14/NW/0218/AM08	Finesse vs. Pen for Bolus Insulin in T2 DM, revision C	8	10/01/2017	9
14/NW/0242/AM06	CFS/ME in the NHS: outcomes after treatment by NHS specialist services	4	15/04/2016	10
14/NW/0298/AM09	Cortical glutamate/GABA and inflammation in psychosis (CGIP)	8	08/07/2016	7
14/NW/1371/AM03	Long Term Outcomes of Acute Kidney Injury	2	20/01/2017	13
14/NW/1459/AM01	ENDO-EV	2	21/11/2016	9
14/NW/1485/AM02	Clinical Study on POSS-PCU vascular grafts for vascular access v1.0	2	09/01/2017	13
14/NW/1510/AM02	Dry January - Healthy Volunteers 1 month Alcohol Abstention	2	13/10/2016	1
15/NW/0038/AM03	Identification of foreign protein in rheumatological disease Version 1	1	25/05/2016	6
15/NW/0127/AM01	Psychological outcomes following craniotomy	3	13/07/2016	11
15/NW/0267/AM01	Masked FreeStyle Libre Performance Check	1	18/03/2016	6
15/NW/0267/AM05	Masked FreeStyle Libre Performance Check	2	25/07/2016	1
15/NW/0282/AM03	The function of genetic variants in immune cells	3	04/08/2016	13
15/NW/0732/AM05	REACT Trial	1.2	22/03/2016	7
15/NW/0732/AM07	REACT Trial	1.3	05/09/2016	13
15/NW/0732/AM08	REACT Trial	1.4	11/11/2016	3

15/NW/0732/AM09	REACT Trial	1.5	13/01/2017	5
15/NW/0791/AM01	Using patient experiences to improve recovery after critical illness	1	04/11/2016	27
15/NW/0941/AM01	Measuring Severe Harm	1	25/04/2016	2
15/NW/0941/AM03	Measuring Severe Harm	2	17/10/2016	29
15/NW/0946/AM01	ADHD diagnosis, self-identity and personal relationships: Version 1	1	13/05/2016	4
15/NW/0958/AM01	Cognitive functioning and moderating factors in epilepsy	1	10/03/2016	8
15/NW/0958/AM02	Cognitive functioning and moderating factors in epilepsy	2	14/07/2016	5
15/NW/0967/AM01	Impact of child's co-morbid difficulties on caregivers	1	01/04/2016	1
15/NW/0989/AM01	Preparing to Care for Baby	1	19/04/2016	7
15/NW/0990/AM01	RPE65 Natural History Study	1	27/05/2016	7
16/NW/0094/AM01	S-REF and suicidal ideation ESM	1	22/04/2016	3
16/NW/0116/AM02	Biotec BetaGlycans AS; WOULGAN BIOGEL; WBG-03	1	28/11/2016	6
16/NW/0117/AM01	Vaginal self-sampling for non-attenders v1.1	1	22/08/2016	9
16/NW/0159/AM01	Enhancing patient involvement in undergraduate medical education	One	16/03/2016	12
16/NW/0227/AM01	Developing an app for children and young people self-managing CKD	1	04/04/2016	7
16/NW/0318/AM02	SleepSure: a study aimed at improving sleep for hospital inpatients	1	01/06/2016	1
16/NW/0318/AM04	SleepSure: a study aimed at improving sleep for hospital inpatients	2	18/11/2016	0
16/NW/0425/AM02	HORIZONS: Understanding the impact of cancer diagnosis and treatment	1	19/07/2016	8
16/NW/0425/AM03	HORIZONS: Understanding the impact of cancer diagnosis and treatment	2	23/09/2016	10
16/NW/0425/AM04	HORIZONS: Understanding the impact of cancer diagnosis and treatment	3	21/12/2016	14
16/NW/0425/AM05	HORIZONS: Understanding the impact of cancer diagnosis and treatment	4	27/02/2017	6
16/NW/0446/AM03	Voices Impact Scale (VIS): Evaluation	1	27/02/2017	1
16/NW/0472/AM01	Patients and relatives recognising changes in patient wellness	1	29/06/2016	1
16/NW/0507/AM01	CARRIAGE: Investigating Staphylococcus aureus nasal carriage	1.1	11/08/2016	18
16/NW/0507/AM02	CARRIAGE: Investigating Staphylococcus aureus nasal	2	16/11/2016	18

	carriage			
16/NW/0513/AM01	Using patient blogs to measure self-care	1	29/11/2016	6
16/NW/0543/AM01	Lived experience of severe and enduring eating disorder	1	24/11/2016	0
16/NW/0657/AM01	OSCARSS Cluster RCT & Process Evaluation	1	01/11/2016	12
16/NW/0657/AM02	OSCARSS Cluster RCT & Process Evaluation	2	09/01/2017	6
16/NW/0804/AM01	Evaluating Cottage Hospice: A new model of care	1	07/02/2017	5
16/NW/0818/AM02	ENTEROSGEL IN TREATMENT OF ACUTE DIARRHOEA IN ADULTS	1	09/02/2017	1

Unfavourable opinion

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
15/NW/0733/AM02	Proportion of Endometrial Tumours Associated Lynch Syndrome (PETALS)	2	12/05/2016	4
15/NW/0990/AM02	RPE65 Natural History Study	2	13/12/2016	14
16/NW/0456/AM02	Understanding Sensory Perception in Early Development.	2	09/12/2016	9

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
15/NW/0292/AM01/1	School readiness in children with HIE	1	04/04/2016	2
15/NW/0733/AM02/1	Proportion of Endometrial Tumours Associated Lynch Syndrome (PETALS)	2	01/06/2016	5

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 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
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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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