

**North West - Greater Manchester East Research
Ethics Committee**

Annual Report

01 April 2017 - 31 March 2018



Part 1 – Committee Membership and Training

Name of REC:	North West - Greater Manchester East Research Ethics Committee
Type of REC:	Authorised
Type of Flag:	Qualitative
Chair:	Mr Simon Jones
Vice-Chair:	Professor Janet Marsden
Alternate Vice-Chair:	Dr Philip Lewis
REC Manager:	Mrs Rinat Jibli 01/10/2016 to 01/02/2018 Miss Amber Ecclestone from 01/02/2018
REC Assistant:	Damilola Odunlami – from 01/05/2017 until 28/02/2018 Nina Bakhshayesh – from 01/05/2017 until 28/02/2018
Committee Address:	3rd Floor, Barlow House 4 Minshull Street Manchester M1 3DZ
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Chair's overview of the past year:

I have enjoyed this year as Chair of the committee. It has been a challenging year with members reducing in numbers which puts added pressure on existing members and some changes in support, however, despite this the committee have performed in exemplary fashion and as detailed in the reports the timelines and expected performance has been well within the governance framework.

The committee would appreciate new members and we are actively looking for those- await this space.

I would like to thank the members and the support staff for their incredible hard and much appreciated work.

North West - Greater Manchester East Research Ethics Committee Membership

Name	Profession	Expert or Lay	Dates	
			Appointed	Left
Mr David Asher	Retired Pharmacist	Lay	07/07/2010	
Mr Ian Beaumont	Retired Pharmacist	Lay	06/07/2015	
Mr R Trevor Benn	Retired Statistician	Lay Plus	24/05/2013	
Mr James Burns	Retired	Lay	14/07/2010	
Dr Mary Dolan	Nurse Lecturer	Expert	11/10/2009	
Dr Michael Hollingsworth	Retired Senior Lecturer in Pharmacology	Lay	05/10/2009	
Mr Christopher Houston	Retired	Lay Plus	03/10/2009	
Mr Simon Jones	Podiatrist	Expert	01/09/2009	
Dr Philip Lewis	Consultant Cardiologist	Expert	01/01/2010	
Professor Janet Marsden	Professor of Ophthalmology and Emergency Care	Expert	01/09/2009	
Dr Ashok Patnaik	Policy Analyst	Lay Plus	01/01/2015	20/06/2017
Mrs Mary Speake	Workforce Development Lead and Nurse Manager	Expert	08/10/2009	
Dr Gary Whittle	Consultant in Dental Public Health (retired)	Expert	10/04/2017	

North West - Greater Manchester East Research Ethics Committee: Co-opted Members

Name	Profession	Status	Meeting date attended
Dr Joel Sanderson	Medical Expert	Expert	20/02/2018
Dr Tim S Sprosen	Epidemiologist	Expert	20/02/2018
Mr J Addison	Retired Librarian	Lay Plus	20/02/2018

North West - Greater Manchester East Research Ethics Committee: Members' Declarations of Interest:

Name	Declaration of Interest	Date
Mr David Asher	Shares held in Unit Trusts, etc., including companies involved in healthcare.	06/02/2018
Mr Ian Beaumont	None	19/02/2018
Mr R Trevor Benn	None	13/03/2018
Mr James Burns	Member of the Royal Marsden Hospital.	19/03/2018
Dr Mary Dolan	None	13/03/2018
Dr Michael Hollingsworth	PPI representative and a patient representative on a trial steering group for a study called REFLECT that is being run by Professor Tickle, Manchester Uni	08/02/2018
Mr Christopher Houston	None	06/02/2018
Mr Simon Jones	None	13/03/2018
Professor Janet Marsden	Programme committee of ORBIS Trustee of AHPO Trustee of world Sight Foundation Member and Fellow of royal college of nursing Professor at MMU	19/02/2018
Mrs Mary Speake	None	13/03/2018
Dr Gary Whittle	None	13/03/2018

Meetings for Full Ethical Review 01 April 2017 - 31 March 2018:

Month	Date	Number of Members Present at Meeting
April	18/04/2017	13
June	20/06/2017	9
July	18/07/2017	9
September	19/09/2017	8
October	17/10/2017	10
December	19/12/2017	12
February	20/02/2018	9
March	20/03/2018	10

8 full committee meetings were held during the reporting period.

Proportionate Review Sub-Committee Meetings held during 01 April 2017 - 31 March 2018:

Month	Date	Number of Members Present at Meeting
April	25/04/2017	3
June	27/06/2017	3
July	21/07/2017	3
September	15/09/2017	3
October	20/10/2017	3
November	17/11/2017	3
December	27/12/2017	3
January	24/01/2018	3
March	28/03/2018	3

9 proportionate review sub-committee meetings were held during the reporting period.

Sub-Committee Meetings held during 01 April 2017 - 31 March 2018:

Month	Date	Number of Members Present at Meeting
April	13/04/2017	2
May	09/05/2017	2
May	25/05/2017	2
June	09/06/2017	2
June	30/06/2017	2
July	28/07/2017	2
August	15/08/2017	2
September	07/09/2017	2
September	29/09/2017	2
October	20/10/2017	4
November	20/11/2017	4
December	20/12/2017	2
January	20/01/2018	2
February	20/02/2018	2

March	20/03/2018	2
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15 sub-committee meetings were held during the reporting period.

Details of inquorate meeting held: 01 April 2017 - 31 March 2018

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Attendance of Members at full committee meetings:01 April 2017 - 31 March 2018

Name	Number of Meetings Attended
Mr David Asher	7
Mr Ian Beaumont	6
Mr R Trevor Benn	7
Mr James Burns	7
Dr Mary Dolan	8
Dr Michael Hollingsworth	6
Mr Christopher Houston	6
Mr Simon Jones	5
Dr Philip Lewis	5
Professor Janet Marsden	6
Dr Ashok Patnaik	1
Mrs Mary Speake	5
Dr Gary Whittle	8

Attendance of Members at proportionate review sub-committee meetings: 01 April 2017 - 31 March 2018

Name	Number of Meetings Attended
Mr David Asher	2
Mr Ian Beaumont	3
Dr Michael Hollingsworth	4
Mr Christopher Houston	2
Mr Simon Jones	7
Professor Janet Marsden	8

Attendance of Members at sub-committee meetings: 01 April 2017 - 31 March 2018

Name	Number of Meetings Attended
Mr David Asher	2
Mr Ian Beaumont	1
Dr Michael Hollingsworth	1
Mr Simon Jones	15
Professor Janet Marsden	15

Training 01 April 2017 - 31 March 2018

Name of Member	Date	Event(s) attended
Mr David Asher	02/03/2018	Equality and Diversity Training
Mr Ian Beaumont	27/09/2017	Training - Assessing the Consequences (benefits and harms) of Research: a Health Research Authority workshop
Mr R Trevor Benn	07/09/2017	Annual Scientific meeting of Society for Social Medicine at Manchester University
Mr James Burns	14/11/2017	Training - Handling Health-Related Findings in Research (Joint MRC/HRA)
Mr James Burns	02/03/2018	Equality and Diversity
Dr Mary Dolan	20/02/2018	E&D
Dr Mary Dolan	01/03/2018	Regional Training Day
Dr Michael Hollingsworth	31/01/2018	Complex Cases
Dr Michael Hollingsworth	27/03/2018	General Data Protection Regulations" by Dr Rachel Smith, Medical Research Council.
Dr Michael Hollingsworth	28/03/2018	Medical Device training
Mr Christopher Houston	30/11/2017	Training - Genetic and Genomic Research
Mr Simon Jones	24/11/2017	Training - HRA National Chairs' Day and Policy Event
Professor Janet Marsden	06/09/2017	Training Day MODREC
Mrs Mary Speake	01/11/2017	Confidentiality and information governance considerations in research
Dr Gary Whittle	31/01/2018	Complex Cases

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	39	100.00
Total Applications Reviewed	39	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	1
Number of student applications reviewed	20
Number of paediatric applications reviewed	1
Number of device applications reviewed	2
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	10

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	0	0.00
Favourable Opinion with Additional Conditions	6	15.38
Unfavourable Opinion	3	7.69
Provisional Opinion	30	76.92
Provisional Opinion Pending Consultation with Referee	0	0.00
Total	39	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	25	64.10
Further Information Favourable Opinion with Additional Conditions	5	12.82
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	0	0.00
Favourable Opinion with Additional Conditions	6	15.38
Unfavourable Opinion	3	7.69
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	39	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	7
Number of studies withdrawn prior to the meeting	1
Number of student applications reviewed	4
Number of paediatric applications reviewed	1
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	7	30.43
Favourable Opinion with Additional Conditions	8	34.78
No Opinion transfer to full committee for review	5	21.74
Provisional Opinion	3	13.04
Unfavourable Opinion	0	0.00
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	4.88
Number of completed applications for full ethical review	39
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 days taken to final decision – average (mean)	35
Number of completed proportionate review applications for ethical review	18
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	72
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 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	69
Number of substantial amendments received for information	0
Number of substantial amendments received for new sites/PIs	0
Number of annual progress reports received	52
Number of safety reports received	0
Number of Serious Adverse Events received	2
Number of final reports received	64

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
17/NW/0229	INVEST	35
17/NW/0233	Buying abortion through the internet	36
17/NW/0235	Treatment of cleft palate speech using modified electropalatography	30
17/NW/0250	CLASP: Renewed Online Feasibility Study	31
17/NW/0251	Sensor validation study - quality assurance	34
17/NW/0253	Managing active and healthy ageing with use of caring service robots	20
17/NW/0357	Obesity-related cardiovascular risk and bariatric surgery	29
17/NW/0368	Assessing measures of physical activity and sleep in schizophrenia v1	30
17/NW/0414	Take up of psychosocial interventions for early stage dementia	34
17/NW/0420	Exploring needs of carers of people with dementia towards end of life	41
17/NW/0424	Microneurography in complex regional pain syndrome	49
17/NW/0501	QOL in couples starting dialysis	36
17/NW/0597	PanDA Pancreatic cancer Dietary Assessment study	36
17/NW/0601	Nurse-Led Rapid Access Chest Pain Clinic. Version 1.0	34
17/NW/0604	PERSUADE	35
17/NW/0605	Experiencing Obsessions and Compulsions in Daily Life	47
17/NW/0688	Connecting People Implementation Study	29
17/NW/0701	The effect of compression on post-ankle injury swelling	40
18/NW/0097	Imaging brain pathology in dementia using PET and MRI Version 2.0	44
18/NW/0102	Dementias Platform UK MR-PET network harmonisation study	45
18/NW/0182	PROVE-DB	32
18/NW/0188	Assertive Outreach following the Manchester Arena attack	36
18/NW/0205	CityVerve COPD project	51
18/NW/0211	The EX-FRAIL CKD Trial	26
18/NW/0219	Changes in Gene Expression of the Decidua in Placental Dysfunction	52

Further Information Favourable Opinion with Additional Conditions		
REC Reference	Title	Number of Days on Clock
17/NW/0547	Study of Rectal Prolapse with AAR parameters and RAIR	37
17/NW/0548	A study of the Effect of Catheters on AAR Parameters in the Anal Canal	37
17/NW/0549	Study of Anal Sphincter Function and RAIR under GA and NMB using AAR	37

18/NW/0123	Early Intervention Participatory Action Research Project	39
18/NW/0209	DEFEND	36

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
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Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
17/NW/0375	Post-traumatic growth following spinal injury	28
17/NW/0379	Exploratory Study of User and Clinician Outcomes in Orthotic Practice	28
17/NW/0392	Diminishing drinking in dying people: the needs of family members	28
17/NW/0426	Evaluating the NHS Diabetes Prevention Programme (NHS DPP)	28
17/NW/0541	TRIBE; TKI therapy in RCC; Immune Biomarker Evaluation	28
17/NW/0719	Cultures of openness (Work stream 2: openness in practice)	32

Unfavourable Opinion

REC Reference	Title	Number of Days on Clock
17/NW/0418	Diagnosing the 'Cancer-Patient-In-Liverpool'	28
17/NW/0491	Development of a new measure of hope in mental health.	27
18/NW/0106	STEPS Study	30

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
17/NW/0442	A mixed methods evaluation of the NHS Highlands telehealth pilot	15
17/NW/0443	Blood donation for the development of the Microvisk PT/INR system	21
17/NW/0669	ASTIClite EBMT Follow-up	19

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
17/NW/0406	How can audiologists help people get more benefit from their HA?	21
17/NW/0617	Panretinal photocoagulation and ganglion cell layer thickness	9
17/NW/0671	Optimising consent for blood donors taking part in research	20
17/NW/0738	The Christie NHS Foundation Trust Breast Cancer Pathway Analytics	9
17/NW/0739	Cabozantinib PASS Study-F-FR-60000-001	17
18/NW/0069	USE OF HUMAN PRIMARY CELLS FOR DISCOVERY OF NOVEL CANCER THERAPEUTICS	7
18/NW/0072	Patient perceptions of medical student examinations (v1.0)	8

Favourable Opinion with Additional Conditions		
REC Reference	Title	Number of Days on Clock
17/NW/0409	BRAINs	21
17/NW/0539	PROACT: Patient Reported Opinions About Clinical Tolerability.	1
17/NW/0543	Use of baby-carriers for unwell babies in hospital	14
17/NW/0613	ENdPOInt -Patient's perception of natural progression of Endometriosis	2
17/NW/0664	Properties of B cells expressing different antibody subclasses	7
17/NW/0737	SUPPORT TIA	9
18/NW/0068	Lipoprotein Lipase Deficiency versus alternative aetiologies	8
18/NW/0231	Skeletal Tissue Engineering	21

Unfavourable Opinion		
REC Reference	Title	Number of Days on Clock

Provisional Opinion		
REC Reference	Title	Number of Days on Clock

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

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

Table 10.1: Breakdown of current status of all substantial amendments reviewed within the reporting period

Favourable opinion				
Amendment REC Reference	Title	Version	Date	Number of Days on Clock
11/NW/0090/AM11	Biomarkers of disease activity, neurocognition and CVD risk in SLE	10.0	29/03/2017	28
12/NW/0011/AM07	Proteomic and genomic analysis of rectal tumours	6	22/03/2017	23
13/NW/0100/AM02	BIOPROP20: Biologically optimised IMRT for prostate radiotherapy	2	11/05/2017	16
13/NW/0352/AM06	Analysis of collagen production in Dupuytren's fibrosis	4	02/11/2017	12
13/NW/0564/AM11	Lupus Extended Autoimmune Phenotype Study (LEAP)	07 12/03/2018	12/03/2018	24
14/NW/0035/AM10	REQUITE	6	22/06/2017	15
14/NW/0162/AM04	Collagen production in Dupuytren's fibrosis: Carpal Tunnel control	2	02/11/2017	13
14/NW/1492/AM04	ACUFOCIN (standard care alone or with acupuncture for CIPN)	Notice of Substantial Amendment 3	06/11/2017	13
14/NW/1500/AM03	HIPPO version 1.0	3	12/04/2017	17
15/NW/0586/AM05	ETNA-AF-Europe	4	05/06/2017	27
15/NW/0586/AM06	ETNA-AF-Europe	5	13/07/2017	21
15/NW/0735/AM02	North Staffordshire Health Study	2	27/04/2017	24
15/NW/0807/AM01	Gamification for Activation, Motivation and Engagement v1.0	1	30/01/2017	20
15/NW/0823/AM06	clozapine-induced hypersalivation - feasibility trial	5	01/08/2017	5
15/NW/0825/AM06	TARA-Prev	6	13/04/2017	20
15/NW/0825/AM08	TARA-Prev	7	07/10/2017	27
15/NW/0825/AM09	TARA-Prev	8	16/01/2018	3
15/NW/0825/AM10	TARA-Prev	9	15/02/2018	7
15/NW/0954/AM01	Shear wave elastography and soft tissue tumours	1	05/07/2017	5
16/NW/0104/AM03	352.2069 Observational Emphysema Progression Biomarker Study in COPD	Substantial amendment 2	05/05/2017	3
16/NW/0258/AM03	The Tommy's Rainbow Clinic Study	2	05/03/2018	4
16/NW/0278/AM03	IF-CBT Trial: Combined individual and family CBT compared with TAU V1	2	19/04/2017	15
16/NW/0278/AM05	IF-CBT Trial: Combined individual and family CBT compared with TAU V1	3	29/09/2017	8

16/NW/0278/AM06	IF-CBT Trial: Combined individual and family CBT compared with TAU V1	4	24/01/2018	5
16/NW/0282/AM03	Investigating the use of digital legacies with people affected by MND	197318-CLAB-2017/3 04/05/2017	04/05/2017	17
16/NW/0518/AM03	Biomarkers for hypoglycaemia in diabetes	Amendment 1	18/09/2017	22
16/NW/0651/AM01	SENSE-Cog care and assessment needs focus group	1	19/05/2017	19
16/NW/0651/AM03	SENSE-Cog care and assessment needs focus group	2	15/11/2017	3
16/NW/0673/AM01	Arm cycling in FSHD	1	19/07/2017	5
16/NW/0885/AM01	We Can: A web-based skills package for carers of people with ANv1.0	1	28/03/2017	18
16/NW/0885/AM02	We Can: A web-based skills package for carers of people with ANv1.0	2	24/08/2017	33
16/NW/0888/AM01	everyBody Plus: Web-based self-help programme for BN, BED and OSFED	1	21/03/2017	14
16/NW/0888/AM03	everyBody Plus: Web-based self-help programme for BN, BED and OSFED	3.0	20/10/2017	3
16/NW/0888/AM06	everyBody Plus: Web-based self-help programme for BN, BED and OSFED	4.0	15/12/2017	14
16/NW/0888/AM09	everyBody Plus: Web-based self-help programme for BN, BED and OSFED	7.0; SA 4.0	15/03/2018	27
16/NW/0890/AM01	CHESS Main Randomised Controlled Trial	1	25/05/2017	9
16/NW/0890/AM02	CHESS Main Randomised Controlled Trial	2	21/04/2017	1
16/NW/0890/AM03	CHESS Main Randomised Controlled Trial	3	20/07/2017	1
16/NW/0890/AM04	CHESS Main Randomised Controlled Trial	4	02/11/2017	15
16/NW/0890/AM05	CHESS Main Randomised Controlled Trial	5	15/12/2017	14
16/NW/0893/AM03	Managing Adolescent first episode Psychosis: a feasibility Study	Amendment 2	24/04/2017	14
16/NW/0893/AM06	Managing Adolescent first episode Psychosis: a feasibility Study	3	22/09/2017	6
16/NW/0893/AM09	Managing Adolescent first episode Psychosis: a feasibility Study	4	19/10/2017	7
17/NW/0117/AM01	The psychosocial support for male partners of women admitted to MBUs	1	18/05/2017	18
17/NW/0121/AM01	MO29978 NIS PD-L1 Expression in Cyto & Histo Samples in NSCLC & SCLC	1	05/04/2017	15
17/NW/0122/AM02	The Extended Salford Lung Study ("Ex-SLS") Data Access	SA1	12/01/2018	7

	Project			
17/NW/0126/AM01	Understanding the effect of neurodegeneration on later life depression	1.0	05/06/2017	11
17/NW/0126/AM02	Understanding the effect of neurodegeneration on later life depression	2.0	04/10/2017	5
17/NW/0153/AM01	The Manchester BabyGRO Study	1	03/08/2017	19
17/NW/0153/AM02	The Manchester BabyGRO Study	2	14/12/2017	4
17/NW/0229/AM01	INVEST	1	26/10/2017	19
17/NW/0251/AM01	Sensor validation study - quality assurance	1	24/10/2017	0
17/NW/0253/AM01	Managing active and healthy ageing with use of caring service robots	1	21/08/2017	28
17/NW/0357/AM01	Obesity-related cardiovascular risk and bariatric surgery	Amendment 1, 16/01/2018	16/01/2018	13
17/NW/0375/AM01	Post-traumatic growth following spinal injury	1	18/09/2017	0
17/NW/0406/AM02	How can audiologists help people get more benefit from their HA?	Amendment 2	20/09/2017	3
17/NW/0414/AM01	Take up of psychosocial interventions for early stage dementia	Amendment 1	01/02/2018	6
17/NW/0426/AM01	Evaluating the NHS Diabetes Prevention Programme (NHS DPP)	1	05/10/2017	12
17/NW/0426/AM02	Evaluating the NHS Diabetes Prevention Programme (NHS DPP)	2	15/11/2017	5
17/NW/0426/AM03	Evaluating the NHS Diabetes Prevention Programme (NHS DPP)	3	21/11/2017	3
17/NW/0426/AM04	Evaluating the NHS Diabetes Prevention Programme (NHS DPP)	4	01/12/2017	3
17/NW/0426/AM05	Evaluating the NHS Diabetes Prevention Programme (NHS DPP)	5	03/01/2018	7
17/NW/0426/AM06	Evaluating the NHS Diabetes Prevention Programme (NHS DPP)	6	17/01/2018	2
17/NW/0501/AM05	QOL in couples starting dialysis	1	11/12/2017	1
17/NW/0547/AM01	Study of Rectal Prolapse with AAR parameters and RAIR	1.0	04/01/2018	1
17/NW/0604/AM01	PERSUADE	Substantial Amendment1	23/01/2018	3
17/NW/0738/AM01	The Christie NHS Foundation Trust Breast Cancer Pathway Analytics	1	24/01/2018	4

Unfavourable opinion				
Amendment REC Reference	Title	Version	Date	Number of Days on Clock
15/NW/0823/AM05	clozapine-induced hypersalivation - feasibility trial	4	01/07/2017	23
17/NW/0117/AM02	The psychosocial support for male partners of women admitted to MBUs	2	23/08/2017	1
17/NW/0250/AM03	CLASP: Renewed Online Feasibility Study	1	13/09/2017	10
17/NW/0251/AM02	Sensor validation study - quality assurance	2	21/12/2017	12
17/NW/0406/AM01	How can audiologists help people get more benefit from their HA?	1	02/08/2017	17

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
17/NW/0117/AM02/1	The psychosocial support for male partners of women admitted to MBUs	Amendment 2(modified)	13/09/2017	14
17/NW/0251/AM02/1	Sensor validation study - quality assurance	Substantial Amendment 2	21/12/2017	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 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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