

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

Annual Report

01 April 2015 - 31 March 2016



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 Research
Chair:	Mr Francis Chan
Vice-Chair:	Professor Janet Marsden
Alternate Vice-Chair:	Dr Philip Lewis
REC Manager:	Ms Rachel Heron
REC Assistant:	Miss Jenna Woodburn
Committee Address:	3rd Floor, Barlow House 4 Minshull Street Manchester M1 3DZ
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Chair's overview of the past year:

Thanks to all the hard work of the committee members and the REC manager Rachel, we have been able to comply with majority of the workload within the time frame required.

The committee continues to participate in both full applications and PR applications. All committee members have been working extremely hard to fulfil their training requirement in addition to the above workload.

As a result, the committee has achieved its re-accreditation.

With regards to recruitment and retention of committee members, this remains a challenge due to the voluntary nature of the committee work. In 2015-6, we lost 3 committee members due to their other personal/ work commitments. Luckily, we have the addition of a member transfer from other committee. As he was a vice-chair in the previous committee, his experience and active participation has been proved to be invaluable.

Due to the committee composition of various members from different background, the pressure to achieve a consistent application result across various committees from a single application remains challenging although has been improving.

Once again, I would take this opportunity to thank all the hard work of my committee members and the REC manager Rachel. Without them, the committee would not be able to continue its success. It is sad to learn that Rachel would be leaving the committee in the near future. It will be difficult to find another person that can match Rachel's hard work and talent.



Dr Francis Chan, Chair of GM East REC

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	
Mr Francis Chan	Consultant Orthopaedic Surgeon	Expert	01/09/2009	
Dr Jacqueline Crowther	Honorary Research Associate	Expert	06/10/2009	
Dr Mary Dolan	Retired Nurse Lecturer	Lay	11/10/2009	
Dr Michael Hollingsworth	Retired Senior Lecturer in Pharmacology	Lay	05/10/2009	
Mr Christopher Houston	Retired Lay Member	Lay Plus	03/10/2009	
Mr Simon Jones	Paediatric 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	
Mr Ashok Patnaik	Doctoral Research Student	Lay Plus	01/01/2015	
Mrs Mary Speake	Workforce Development Lead and Nurse Manager	Expert	08/10/2009	
Miss Nessa Thomas	Senior Research Practitioner	Expert	01/09/2014	16/02/2016

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

Name	Profession	Status	Meeting date attended
Dr Tim Sprosen	Epidemiologist	Expert	11/01/2016
Dr Lorraine Lighton	Consultant in Communicable Disease Prevention	Expert	22/03/2016
Miss Stephanie Ellis	Retired Civil Servant	Lay	22/03/2016

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

Name	Declaration of Interest	Date
Mr David Asher	Member declared that he has shareholdings in pharmaceutical and healthcare companies as part of pooled investments in unit trusts	24/02/2016
Mr Ian Beaumont	No interests were declared for this period	15/03/2016
Mr R Trevor Benn	Board member of healthwatch Bolton Public member of North West DeNDRoN (Dementia and Neurodegenerative Diseases research Network) NIHR - public reviewer of funding bids (paid £200 per review, approx 3 per year) BMJ - lay reviewer of papers, no payment received	12/03/2016
Mr James Burns	No interests were declared for this period	15/03/2016
Mr Francis Chan	No interests declared	15/03/2016
Dr Jacqueline Crowther	Member declared that she is an honorary research associate at the University of Liverpool Member declared that she is a peer reviewer and external examiner Member declared that she is a volunteer for Age UK	15/03/2016
Dr Mary Dolan	No interests were declared for this period	30/03/2016
Dr Michael Hollingsworth	No interests were declared for this period	23/02/2016
Mr Christopher Houston	No interests were declared for this period	02/03/2016
Mr Simon Jones	No interests were declared for this period	23/02/2016
Dr Philip Lewis	Member declared that he is currently in discussion with Smart life medical which might lead to a research product .Also in discussion with University of Nottingham about a product which may be developed for medical research. Member declared that he is a member of Stockport NHS Foundation Trust R&D Committee	15/03/2016
Professor Janet Marsden	Member made the following declarations: Professor at MMUMODREC - Department of ethics and professoriate - Trustee at AHPO	30/03/2016
Mrs Mary Speake	Member declared following interests: Workforce development lead and nurse manager Principal - Danceworks, Altrincham Treasurer and Director of Broadheath Community Centre	31/03/2016
Mr Ashok Patnaik	None	31/03/2016

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	10
June	16/06/2015	11
July	21/07/2015	8
September	15/09/2015	10
October	20/10/2015	12
November	17/11/2015	12
December	15/12/2015	12
February	16/02/2016	10
March	15/03/2016	9

11 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
May	01/05/2015	3
June	26/06/2015	3
July	31/07/2015	3
August	28/08/2015	3
September	25/09/2015	3
October	30/10/2015	3
November	27/11/2015	3
January	12/01/2016	4
February	23/02/2016	3
March	22/03/2016	3

10 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	22/04/2015	2
May	11/05/2015	2
June	01/06/2015	2
June	15/06/2015	2
July	02/07/2015	2
July	13/07/2015	2
July	13/07/2015	2
August	13/08/2015	2
September	07/09/2015	2
September	27/09/2015	3

November	02/11/2015	2
November	30/11/2015	2
December	02/12/2015	2
December	11/12/2015	2
January	06/01/2016	2
January	12/01/2016	3
February	11/02/2016	2
March	07/03/2016	2
March	21/03/2016	2

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

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

Date	Reason	Action taken

0

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

Name	Number of Meetings Attended
Mr David Asher	9
Mr Ian Beaumont	2
Mr R Trevor Benn	10
Mr James Burns	6
Mr Francis Chan	6
Dr Jacqueline Crowther	7
Dr Mary Dolan	9
Dr Michael Hollingsworth	9
Mr Christopher Houston	10
Mr Simon Jones	5
Dr Philip Lewis	8
Professor Janet Marsden	5
Mr Ashok Patnaik	6
Mrs Mary Speake	5
Miss Nessa Thomas	8

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

Name	Number of Meetings Attended
Mr David Asher	4
Mr Francis Chan	1
Dr Jacqueline Crowther	1
Dr Michael Hollingsworth	4
Mr Christopher Houston	6
Mr Simon Jones	5
Professor Janet Marsden	7

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

Name	Number of Meetings Attended
Mr David Asher	4
Mr Trevor Benn	1
Mr Francis Chan	7
Dr Jacqueline Crowther	2
Dr Michael Hollingsworth	8
Mr Simon Jones	4
Dr Philip Lewis	1
Professor Janet Marsden	15

Training 01 April 2015 - 31 March 2016

Name of Member	Date	Event(s) attended
Mr David Asher	14/04/2015	NHS CBRN Capabilities (CBRN stands for chemical, biological, radiological and nuclear.- the presentation was by Bolton NHS Trust re capabilities in the event of any of the above attacks)
Mr David Asher	04/08/2015	UNLOAD - UNLOAD is an organisation which helps service men to deal with trauma and PTSD
Mr David Asher	01/09/2015	Fighting Ebola in Sierra Leone – presentation and discussion
Mr Ian Beaumont	16/03/2016	Ethical guidelines on use of human tissue in research
Mr Ian Beaumont	17/03/2016	Read HRA guidance re language and exclusion
Mr James Burns	18/02/2016	National Members Training Day
Mr Francis Chan	09/02/2016	National Training Day for Chairs
Dr Jacqueline Crowther	19/05/2015	Research in the NHS: Infrastructure and Governance
Dr Jacqueline Crowther	16/03/2016	National Member Training Day
Dr Mary Dolan	19/05/2015	Research in the NHS: Infrastructure and Governance
Dr Mary Dolan	01/11/2015	Improving Healthcare through Clinical Research
Dr Michael Hollingsworth	19/05/2015	Research in the NHS: Infrastructure and Governance
Dr Michael Hollingsworth	30/11/2015	Improving Healthcare by Clinical Research
Dr Michael Hollingsworth	30/11/2015	Mentoring new committee member
Dr Michael Hollingsworth	04/03/2016	Equality and Diversity
Mr Christopher Houston	19/05/2015	Research in the NHS: Infrastructure and Governance
Mr Christopher Houston	16/03/2016	National Member Training Day
Mr Simon Jones	19/05/2015	Research in the NHS; Infrastructure and Governance
M Simon Jones	23/02/2016	Equality and Diversity
Dr Philip Lewis	19/05/2015	Research in the NHS: Infrastructure and Governance
Dr Philip Lewis	01/06/2015	GCP Update
Professor Janet Marsden	06/01/2016	MOD Research Ethics Committee Training
Professor Janet Marsden	22/02/2016	Online Equality and Diversity Training
Mr Ashok Patnaik	19/05/2015	Research in the NHS: Infrastructure and Governance
Mrs Mary Speake	19/05/2015	Research in the NHS: Infrastructure and Governance

Miss Nessa Thomas	19/05/2015	Research in the NHS: Infrastructure and Governance
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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
Phase 1	0	0
Gene Therapy	0	0
Research Tissue Bank (including renewals)	0	0
Research Database (including renewals)	1	1.92
Others	51	98.08
Total Applications Reviewed	52	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	16
Number of paediatric applications reviewed	5
Number of device applications reviewed	5
Number of prisoner applications reviewed	0
Number of applications involving adults unable consent reviewed	0
Number of applications reviewed that are funded by the US DHHS	0
Number of qualitative applications reviewed	7

Table 3: Decisions given at meetings held within the reporting period

Decisions taken at meetings following review of applications	Number	%
Favourable Opinion with Standard Conditions	2	3.85
Favourable Opinion with Additional Conditions	21	40.38
Unfavourable Opinion	0	0
Provisional Opinion	29	55.77
Provisional Opinion Pending Consultation with Referee	0	0
Total	52	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	27	51.92
Further Information Favourable Opinion with Additional Conditions	1	1.92
Further Information Unfavourable Opinion	0	0
Favourable Opinion with Standard Conditions	2	3.85
Favourable Opinion with Additional Conditions	21	40.38
Unfavourable Opinion	0	0
Provisional Opinion	1	1.92
Provisional Opinion Pending Consultation with Referee	0	0
Further Information response not complete	0	0
No decision entered on system	0	0
Number of studies withdrawn after the meeting	0	0
Total	52	100

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

Total Applications Reviewed	21
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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	10
Number of studies withdrawn prior to the meeting	2
Number of student applications reviewed	8
Number of paediatric applications reviewed	3
Number of device applications reviewed	0
Number of qualitative applications reviewed	0

Table 7: Decisions given at proportionate review sub-committee meetings held within the reporting period

Decisions taken at proportionate review sub-committee meetings	Number	%
Favourable Opinion with Standard Conditions	10	47.62
Favourable Opinion with Additional Conditions	5	23.81
No Opinion transfer to full committee for review	3	14.29
Provisional Opinion	2	9.52
Unfavourable Opinion	1	4.76
Total	21	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	5.20
Number of completed applications for full ethical review	52
Number of completed applications for full ethical review over 60 days	2
Number of completed applications over 60 days as a % of total	3.85%
Number of completed applications for full ethical review over 40 days	5
Number of completed applications over 40 days as a % of total	9.62%
Number of days taken to final decision – average (mean)	26

Number of completed proportionate review applications for ethical review	18
Number of completed proportionate review applications for ethical review over 14 days	3* (1)
Number of completed proportionate review applications over 14 days as a % of total	16.67%* (5.56%)

**Please note that two of these studies were part of the Proportionate Review Pilot which has been set up to test whether allowing REC staff increased time to work with applicants to ensure that the study documentation is clear, accurate and complete, as well as allowing a minimum number of days for REC members to undertake the ethical review is preferable against set evaluation criteria. One of the objectives of the pilot is to assess the impact of extending the length of review to 21 calendar days rather than 14 calendar days. The numbers in red are the figures excluding any applications which were part of the Proportionate Review pilot*

Number of SSAs (non-Phase 1) reviewed	2
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	0.0%

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	0.0%

Number of substantial amendments reviewed	55
Number of completed substantial amendments over 35 days	0
Number of completed substantial amendments over 35 days as a % of total substantial amendments	0.0%
Number of completed substantial amendments over 28 days	0
Number of completed substantial amendments over 28 days as a % of total substantial amendments	0.0%

Number of modified amendments reviewed	6
Number of completed modified amendments over 14 days	1

Number of completed modified amendments over 14 days as a % of total modified amendments	16.67%
Number of minor amendments received	45
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	0
Number of final reports received	31

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/NW/0251	12-lead Holter monitoring for the detection of Brugada Syndrome.	24
15/NW/0336	Cognitive Behavioural Therapy for Bipolar At Risk: A feasibility Study	22
15/NW/0482	Vessel Wall Imaging Study	20
15/NW/0487	Standardised Rhinovirus Challenge in Asthma Patients	24
15/NW/0494	OxHIP	24
15/NW/0570	Light-pacing strip reliability of an incremental shuttle walk test	34
15/NW/0581	A Novel method for assessing Infant Multiple Breath Washout (NIMBus)	23
15/NW/0583	The Diagnostic Accuracy of Laser Doppler Flowmetry in Children	41
15/NW/0721	Bowel Dysfunction in MS	27
15/NW/0736	Improving clinical practice for babies with hearing loss	21
15/NW/0785	Positive Deviance - Patient experience	22
15/NW/0807	Gamification for Activation, Motivation and Engagement v1.0	37
15/NW/0817	Oxygen-enhanced MRI and filtration fraction in chronic kidney disease	22
15/NW/0825	TARA-Prev	64
15/NW/0851	Bi-planar x-ray imaging of the human foot	41
15/NW/0874	Physical activity and brown adipose tissue	66
15/NW/0901	Early post-operative outcomes using the game ready cooling compression	19
15/NW/0925	Emotional Distress Experienced by Breast Cancer Survivors - Version 1.	22
15/NW/0957	Predictors of Carer Burden for parents of individuals with BPD traits	16
15/NW/0970	Chronic Pelvic Pain in women from South Asian backgrounds	18
15/NW/0971	CORMAC: Core Outcome Research Measures in Anal Cancer	17
16/NW/0091	Investigating the Cognitive Attentional Syndrome in psychosis	39
16/NW/0104	352.2069 Observational Emphysema Progression Biomarker Study in COPD	39
16/NW/0114	Public and private space in forensic mental health accommodation v1	32
16/NW/0202	A feasibility study of the pharos group work programme	44
16/NW/0206	Home Monitoring of hypertension in Pregnancy (HaMPtoN)	36
16/NW/0207	Young SMILES: An intervention for children with mentally ill parents	22

Further Information Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
16/NW/0198	Safety and efficacy of a novel cartilage repair construct (CARE01)	24

Favourable Opinion with Standard Conditions

REC Reference	Title	Number of Days on Clock
15/NW/0341	Optimised T cell targeting of cancer	18
16/NW/0122	How do adults make sense of which treatment to commence for their MS?	23

Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
15/NW/0281	High Intensity Interval Training within Cardiac Rehabilitation	22
15/NW/0327	Psychological support for people with dementia: an exploratory study	18
15/NW/0335	ENHANCE	18
15/NW/0360	Trans-venous occlusion of pelvic vein incompetence	27
15/NW/0415	STOMACH Trial	27
15/NW/0421	BARD-Q v1.0	27
15/NW/0471	SoDiUM Study	20
15/NW/0485	GIFT TRIAL	20
15/NW/0488	ACT for Chronic Pain	20
15/NW/0576	Living with short bowel syndrome: The patient journey & family impact	20
15/NW/0586	ETNA-AF-Europe	20
15/NW/0587	Experiences of Heart Failure Patients With a History of Cancer	20
15/NW/0724	Validation of the Fast Fill Technique for AAR in the Anal Canal	21
15/NW/0735	North Staffordshire Health Study	25
15/NW/0816	Optimisation of Myocardial Perfusion Imaging	21
15/NW/0820	OMAC Study	21
15/NW/0823	clozapine-induced hypersalivation - feasibility trial	28
15/NW/0872	Spinal anaesthesia versus rectus sheath block for donor nephrectomy	31
15/NW/0897	Investigating the role of portable VR intervention in phantom limb pai	23
15/NW/0954	Shear wave elastography and soft tissue tumours	16
16/NW/0115	GHRH-arginine Test To Confirm Isolated GHD after SAH	23

Unfavourable Opinion		
REC Reference	Title	Number of Days on Clock

Provisional Opinion		
REC Reference	Title	Number of Days on Clock
15/NW/0862	The paediatric patient journey to and through the emergency department	n/a

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

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

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/NW/0394	Support groups for postnatal mothers using coaching approaches. v2.0	8
15/NW/0641	Clinical proof of concept of PDMSD product (v.1.0)	15

Favourable Opinion with Standard Conditions		
REC Reference	Title	Number of Days on Clock
15/NW/0560	UCLH Health Informatics Collaborative Programme version 1	3
15/NW/0719	Automated reading of brain scan reports for epidemiology (WARBLER)	3
15/NW/0781	Progression Evaluation in Glaucoma (PEG)	7
15/NW/0792	Salford MedicAtion Safety dashboard (SMASH) Trial	3

15/NW/0943	Impact of the advanced nurse practitioner role on frail elderly care.	6
15/NW/0947	Cerebrospinal fluid in delirium after hip fracture extension study	8
16/NW/0037	Lung Health in Opiate Misusers: A retrospective cohort study	2
16/NW/0155	A Retrospective analysis of outcomes of Auto-transplanted teeth	8
16/NW/0223	What are important therapy outcomes for children who stammer?	11
16/NW/0241	Custom-made NIV masks for children - use of imaging data	15

Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
15/NW/0783	The clinical feasibility of recording CAEPs in cochlear implant users	3
15/NW/0942	Early Cardiac MRI markers of diabetic cardiomyopathy (CMR-DC)	7
16/NW/0032	Is lactate a biomarker of tumour metabolism in breast cancer?	5
16/NW/0039	Self-Monitoring of Blood Glucose among Adults with Type 1 Diabetes	5
16/NW/0221	Is profiling cell size a potential biomarker for breast cancer?	15

Unfavourable Opinion

REC Reference	Title	Number of Days on Clock
15/NW/0401	Strengthening local babies' futures by community led action	4

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
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04/Q1401/15/AM08	Abbott Diabetes Care Blood Ketone Performance Test	7	03/12/2015	27
05/Q1402/25/AM03	Study of breast cancer stem cells and their regulation	3	16/06/2015	15
05/Q1402/41/AM22	Airway inflammation in smokers - a longitudinal cohort study	19	26/02/2016	28
09/H1013/78/AM10	CNS Inflammation in Depression and Schizophrenia	6	01/06/2015	13
10/H1013/27/AM02	Bone marrow-derived and adipose-derived stromal cell differentiation	1	28/05/2015	19
10/H1017/88/AM02	ZAG in liver and adipose tissue in patients undergoing surgery	2	21/07/2015	22
11/NW/0053/AM02	A biomechanical and histological study of the vertebral artery	2	13/11/2015	18
11/NW/0090/AM08	Biomarkers of disease activity, neurocognition and CVD risk in SLE	8.0	17/06/2015	6
11/NW/0649/AM04	GemTrans	2	02/02/2016	6
12/NW/0136/AM03	Analysis of urine for bacteraemia in ICU	2	25/02/2016	28
13/NW/0434/AM04	Energy cost of walking in diabetes	3	19/05/2015	12
13/NW/0571/AM02	CaFI:Family Intervention for African Caribbeans with schizophrenia-V1	1	12/03/2015	18
13/NW/0571/AM03	CaFI:Family Intervention for African Caribbeans with schizophrenia-V1	2	18/05/2015	15
13/NW/0571/AM04	CaFI:Family Intervention for African Caribbeans with schizophrenia-V1	3	26/05/2015	6
13/NW/0649/AM07	Diabetic foot ulcer prevention	3	04/02/2016	24
13/NW/0782/AM04	TERSC (version 1.0)	9-15	01/02/2015	14
13/NW/0782/AM07	TERSC (version 1.0)	21 - 22	04/02/2016	27
13/NW/0784/AM03	iBeep: Investigating the Benefits of Exercise in Early Psychosis	4	08/05/2015	12
13/NW/0784/AM04	iBeep: Investigating the Benefits of Exercise in Early Psychosis	5	01/09/2015	13
14/NW/0035/AM07	REQUITE	04	11/05/2015	20
14/NW/0093/AM05	PROPANE STUDY	2	03/02/2015	15
14/NW/0160/AM01	Primary Care Trial Efficacy of Alternative Modalities (PCTEAM)	1	06/05/2015	7
14/NW/0197/AM06	PRIMA-eDS/MoMMs trial (Management of Multiple Medications)	6	13/04/2015	11
14/NW/0228/AM05	FACTS, Version 1	4 (SA03)	19/08/2015	20
14/NW/0308/AM02	801- Screening study to evaluate positive screening rate of MPS	2	28/04/2015	21
14/NW/1123/AM01	DSD Life	2	22/07/2015	17
14/NW/1309/AM02	Manchester Asthma and Allergy Study:18 plus follow up	2	22/04/2015	20
14/NW/1309/AM03	Manchester Asthma and Allergy Study:18 plus follow up	3	15/10/2015	28
14/NW/1492/AM01	ACUFOCIN (standard care alone or with acupuncture for	1	06/10/2015	22

	CIPN)			
14/NW/1506/AM01	BLUEWIND OAB	7	16/06/2015	13
15/NW/0054/AM01	A study to understand the changes after 1 year of smoking cessation	1	01/04/2015	15
15/NW/0054/AM02	A study to understand the changes after 1 year of smoking cessation	1, Protocol V5	27/08/2015	27
15/NW/0054/AM03	A study to understand the changes after 1 year of smoking cessation	Protocol amendment 2	19/01/2016	22
15/NW/0109/AM01	INFORMMED INvestigation into Fear Of biRth using Mixed Methods Design	1	30/09/2015	20
15/NW/0114/AM01	The impact of ambulatory emergency care on experience of stakeholders.	1	29/01/2016	20
15/NW/0218/AM01	Urine testing for HPV	1	17/07/2015	27
15/NW/0230/AM01	Increasing awareness and adherence to infection control in NICU	1	24/07/2015	6
15/NW/0233/AM02	Integrate	1	14/07/2015	28
15/NW/0233/AM05	Integrate	2	09/10/2015	20
15/NW/0233/AM06	Integrate	3	04/02/2016	6
15/NW/0281/AM01	High Intensity Interval Training within Cardiac Rehabilitation	1	05/05/2015	11
15/NW/0335/AM03	ENHANCE	3	13/10/2015	19
15/NW/0336/AM01	Cognitive Behavioural Therapy for Bipolar At Risk: A feasibility Study	2	13/08/2015	28
15/NW/0336/AM02	Cognitive Behavioural Therapy for Bipolar At Risk: A feasibility Study	2	14/12/2015	25
15/NW/0488/AM01	ACT for Chronic Pain	1	19/11/2015	9
15/NW/0583/AM01	The Diagnostic Accuracy of Laser Doppler Flowmetry in Children	1	28/02/2016	18
15/NW/0823/AM01	clozapine-induced hypersalivation - feasibility trial	1	22/02/2016	15
15/NW/0957/AM01	Predictors of Carer Burden for parents of individuals with BPD traits	2	04/02/2016	24
16/NW/0039/AM01	Self-Monitoring of Blood Glucose among Adults with Type 1 Diabetes	2	12/03/2016	8

Unfavourable opinion

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
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04/Q1402/11/AM05	Implant-supported prostheses (their maintenance post-insertion)	5	10/11/2015	28
13/NW/0564/AM03	Lupus Extended Autoimmune Phenotype Study (LEAP)	3	21/07/2015	28
13/NW/0571/AM05	CaFI:Family Intervention for African Caribbeans with schizophrenia-V1	4	26/01/2016	10
14/NW/0040/AM04	ExOTIC study (Exploration of Tele-monitoring in COPD)	4	13/08/2015	27
15/NW/0060/AM05	CTC tumourgenicity in early stage NSCLC	1	06/11/2015	22
15/NW/0736/AM02	Improving clinical practice for babies with hearing loss	1	29/01/2016	14

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
09/H1013/15/AM01/1	Randomised study of varicocele treatment in adolescents	1	16/04/2015	11
13/NW/0564/AM03/1	Lupus Extended Autoimmune Phenotype Study (LEAP)	1	15/09/2015	16
13/NW/0571/AM05/1	CaFI:Family Intervention for African Caribbeans with schizophrenia-V1	1	01/03/2016	4
14/NW/0040/AM04/1	ExOTIC study (Exploration of Tele-monitoring in COPD)	1	04/08/2015	11
14/NW/0197/AM02/1	PRIMA-eDS/MoMMs trial (Management of Multiple Medications)	1	10/06/2015	2
15/NW/0736/AM02/1	Improving clinical practice for babies with hearing loss	1	24/02/2016	9

Table 11: Items exceeding timelines

Full applications for ethical review over 60 day timeline		
REC Reference	Title	Number of Days on Clock

15/NW/0825	TARA-Prev	64
15/NW/0874	Physical activity and brown adipose tissue	66

Proportionate review applications for ethical review over 14 day timeline

REC Reference	Title	Number of Days on Clock
15/NW/0641	Clinical proof of concept of PDMSD product (v.1.0)	15
16/NW/0221	Is profiling cell size a potential biomarker for breast cancer?	15*
16/NW/0241	Custom-made NIV masks for children - use of imaging data	15*

**Please note, that this study was part of the Proportionate Review Pilot (please refer to explanation at table 8)*

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
13/NW/0564/AM03/1	Lupus Extended Autoimmune Phenotype Study (LEAP)	Am3/1	15/09/2015	16