

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

**Annual Report**

**01 April 2015 - 31 March 2016**



## Part 1 – Committee Membership and Training

<b>Name of REC:</b>	North West - Greater Manchester West Research Ethics Committee
<b>Type of REC:</b>	Authorised
<b>Type of Flag:</b>	Qualitative Research
<b>Chair:</b>	Dr Lorraine Lighton (Chair)
<b>Vice-Chair:</b>	Dr Gideon Smith (From 11/08/15)
<b>Alternate Vice-Chair:</b>	Mr Jonathan Deans
<b>REC Manager:</b>	Miss Anna Bannister
<b>REC Assistant:</b>	Miss Katie Southeard
<b>Committee Address:</b>	Barlow House 3rd Floor 4 Minshull Street Manchester M1 3DZ
<b>Telephone:</b>	0207 104 8021
<b>Email:</b>	nrescommittee.northwest-gmwest@nhs.net

## Chair's overview of the past year:

This year we were delighted to welcome Mrs Julie Grindey as a new member of the Committee and congratulate Dr Gideon Smith on his appointment as Vice Chair. We were sorry to say goodbye to Katie Southeard, REC Assistant, and wish her well in her future career.

The Committee still has only 10 members which has meant calling on the good nature of colleagues at other Committees to assist from time to time in order to ensure we are quorate. Despite this, we have successfully met timescales for ethical review.

Members have participated in the training events provided by HRA. The Committee has participated in the Shared Ethical Debate process which this year included a 'mystery shopper' exercise. We have also had presentations at the REC meetings on the ethics approvals process and on Patient and Public Involvement. Some, but not all, members have gone 'paperless' and are using the HARP system to access documents both before and during meetings. Despite a few teething problems we can see that this has great potential to improve access to documents and save forests!

I should like to thank the members for their continued commitment and the care they take in preparation for meetings and in undertaking ethical review. Many thanks too to co-opted members who have kindly given their time. Finally I should like to express my gratitude to Anna Bannister, REC Manager, who has ensured that the whole research ethics process runs smoothly, both for researchers and the Committee members and without whom we would certainly not have met our targets.

### North West - Greater Manchester West Research Ethics Committee Membership

Name	Profession	Expert or Lay	Dates	
			Appointed	Left
Mrs Seonaid Beddows	Research Governance and Administration Manager	Lay	01/12/2013	
Dr Janice Christie	Senior Nursing Lecturer	Expert	08/01/2015	
Mr Jonathan Deans	Consultant in Head & Neck Surgery	Expert	01/05/2013	
Dr Peter Donnelly	Semi-Retired Industrial Chemical Risk Assessor	Lay Plus	10/09/2009	
Mrs Julie Grindey	Research Midwife	Expert	14/04/2015	
Mr Michael Harnor	Lay Member	Lay Plus	01/09/2009	
Dr Lorraine Lighton (Chair)	Consultant in Communicable Diseases	Expert	01/09/2009	
Dr Barry Miller	Consultant Anaesthetist	Expert	01/09/2009	
Dr Peter Owen	Retired Mathematics Lecturer	Lay Plus	01/01/2012	
Dr Gideon Smith	Consultant in Public Health Medicine	Expert	20/08/2010	

### North West - Greater Manchester West Research Ethics Committee: Deputy Members

None

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

Name	Profession	Status	Full Main Meeting date attended
Mr John Addison	Retired Librarian	Lay Plus	05/06/2015 & 04/09/2015
Mr James Burns	Retired Lay Member	Lay	08/01/2016 & 04/03/2016
Mr Chris Houston	Retired Lay Member	Lay	08/01/2016
Mr Rodney Lighton	Retired Software Engineer	Lay Plus	04/12/2015
Mrs Frances Maders	Retired Clinical Trials Co-ordinator for Radiology	Expert	05/06/2015 & 04/12/2015
Dr Paul Mortimer	Retired Executive Principal of Academy school group	Lay	04/09/2015
Dr Karen Rouse	Senior Lecturer/Clinical Education Coordinator	Lay Plus	04/03/2016
Dr Jacques SinFat Tamin	Honorary Senior Lecturer in Occupational Medicine	Expert	01/05/2015
Mrs Julia Waddon	Advanced Nurse Practitioner	Expert	04/03/2016

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

<b>Name</b>	<b>Declaration of Interest</b>	<b>Date</b>
Mrs Seonaid Beddows	Research Administration Manager for CRN: GM – Supporting any NIHR teams in Manchester with processes to facilitate NIHR portfolio studies in their study management. R&D lead at East Cheshire NHS Trust.	08/01/2016
Dr Janice Christie	I conduct Cochrane systematic reviews and am involved in writing grant bids for wound care research. I supervise students, teach research methods, review research articles for a wide range of national and international health care journals; also I peer review application for NIHR funding and other funding bodies.	11/12/2015
Mr Jonathan Deans	None	03/12/2015
Dr Peter Donnelly	PPI member on a number of university of Manchester research groups	04/12/2015
Mrs Julie Grindey	Currently employment is a research midwife. Recruiting women and their families to research studies on the UK portfolio database	04/12/2015
Mr Michael Harnor	Trustee and company director, British Epilepsy Association (working name Epilepsy Action) (Former national Chairman.) The lay member for the 'Neurology, Pain and Psychiatry Expert Advisory Group,' Commission on Human Medicines. (Hosted by MHRA) Member of the Lay members Forum, MHRA Former public Governor	31/03/2016
Dr Lorraine Lighton (Chair)	Honorary Research Fellow University of Liverpool. No involvement in R&D management or support or R&D committees/peer review bodies.	03/12/2015
Dr Barry Miller	Vice Dean of the Faculty of Pain Medicine of the Royal College of Anaesthetists. Peer review for the British Journal of Anaesthesia. Occasional book reviews for the British Medical Journal	03/12/2015
Dr Peter Owen	None	03/12/2015
Dr Gideon Smith	Independent Chair of NIHR funded research programme board with Liverpool University	31/03/2016

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

Month	Date	Number of Members Present at Meeting
April	10/04/2015	7
May	01/05/2015	7
June	05/06/2015	9
July	03/07/2015	8
September	04/09/2015	9
October	02/10/2015	9
November	06/11/2015	9
December	04/12/2015	8
January	08/01/2016	8
March	04/03/2016	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	02/04/2015	3
May	06/05/2015	3
June	05/06/2015	3
July	03/07/2015	3
September	04/09/2015	3
October	02/10/2015	3
November	06/11/2015	3
December	04/12/2015	3
January	08/01/2016	3
February	04/02/2016	3
March	04/03/2016	3

11 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	17/04/2015	3
May	28/05/2015	2
June	01/06/2015	2
June	24/06/2015	2
July	10/07/2015	2
August	06/08/2015	3
August	14/08/2015	2
September	04/09/2015	2
September	18/09/2015	2
October	13/10/2015	2

October	23/10/2015	2
November	13/11/2015	2
November	25/11/2015	3
December	14/12/2015	3
December	21/12/2015	2
December	29/12/2015	2
January	20/01/2016	2
February	05/02/2016	2
February	26/02/2016	2
March	01/03/2016	3
March	14/03/2016	2

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

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

0

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

<b>Name</b>	<b>Number of Meetings Attended</b>
Mrs Seonaid Beddows	9
Dr Janice Christie	8
Mr Jonathan Deans	4
Dr Peter Donnelly	8
Mrs Julie Grindey	5
Mr Michael Harnor	6
Dr Lorraine Lighton (Chair)	10
Dr Barry Miller	4
Dr Peter Owen	9
Dr Gideon Smith	8

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

<b>Name</b>	<b>Number of Meetings Attended</b>
Mrs Seonaid Beddows	1
Dr Janice Christie	4
Mrs Julie Grindey	1
Mr Michael Harnor	1
Dr Lorraine Lighton (Chair)	11
Dr Barry Miller	1
Dr Peter Owen	10
Dr Gideon Smith	4

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

<b>Name</b>	<b>Number of Meetings Attended</b>
Mrs Seonaid Beddows	2
Dr Janice Christie	2
Mr Jonathan Deans	4
Dr Peter Donnelly	8
Dr Lorraine Lighton (Chair)	21
Dr Peter Owen	4
Dr Gideon Smith	6



## Training 01 April 2015 - 31 March 2016

<b>Name of Member</b>	<b>Date</b>	<b>Event(s) attended</b>
Mrs Seonaid Beddows	15/10/2015	Assessing the Consequences of Research
Dr Janice Christie	06/10/2015	Quantitative Research Methods and Statistics
Dr Janice Christie	15/10/2015	Assessing the Consequences of Research
Dr Peter Donnelly	16/03/2016	National Members Training Day
Mrs Julie Grindey	15/06/2015	Member Induction
Mr Michael Harnor	16/03/2016	National Members Training Day
Dr Lorraine Lighton (Chair)	16/04/2015	Equality and Diversity: Essentials
Dr Lorraine Lighton (Chair)	24/07/2015	Personal Data in Research - A Workshop
Dr Peter Owen	24/07/2015	Personal Data in Research - A Workshop
Dr Peter Owen	16/03/2016	National Members Training Day
Dr Gideon Smith	09/12/2015	National Training Day for Committee Chairs
Dr Gideon Smith	14/01/2016	Training for New Chairs

## PART 2: REC WORKLOAD AND ACTIVITY DURING THE REPORTING PERIOD

**Table 1: Applications assigned to a full committee meeting held within the reporting period:**

<b>Applications for full ethical review – Study Type</b>	<b>Number</b>	<b>%</b>
Clinical Trial of Investigational Medicinal Product	0	0.00
Phase 1	0	0.00
Gene Therapy	0	0.00
Research Tissue Bank (including renewals)	0	0.00
Research Database (including renewals)	1	2.04
Others	48	97.96
<b>Total Applications Reviewed</b>	<b>49</b>	<b>100</b>

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

Number of applications made invalid by the REC Manager	3
Number of applications withdrawn prior to the meeting	0
Number of student applications reviewed	23
Number of paediatric applications reviewed	2
Number of device applications reviewed	6
Number of prisoner applications reviewed	1
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**

<b>Decisions taken at meetings following review of applications</b>	<b>Number</b>	<b>%</b>
Favourable Opinion with Standard Conditions	3	6.12
Favourable Opinion with Additional Conditions	18	36.73
Unfavourable Opinion	2	4.08
Provisional Opinion	26	53.06
Provisional Opinion Pending Consultation with Referee	0	0.00
<b>Total</b>	<b>49</b>	<b>100</b>
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**

<b>Status of applications at date of generation of report</b>	<b>Number</b>	<b>%</b>
Further Information Favourable Opinion with Standard Conditions	26	53.06
Further Information Favourable Opinion with Additional Conditions	0	0.00
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	3	6.12
Favourable Opinion with Additional Conditions	18	36.73
Unfavourable Opinion	2	4.08
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
<b>Total</b>	<b>49</b>	<b>100</b>

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

<b>Total Applications Reviewed</b>	<b>31</b>
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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	9
Number of studies withdrawn prior to the meeting	2
Number of student applications reviewed	12
Number of paediatric applications reviewed	3
Number of device applications reviewed	0
Number of qualitative applications reviewed	5

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

<b>Decisions taken at proportionate review sub-committee meetings</b>	<b>Number</b>	<b>%</b>
Favourable Opinion with Standard Conditions	8	25.81
Favourable Opinion with Additional Conditions	10	32.26
No Opinion transfer to full committee for review	6	19.35
Provisional Opinion	6	19.35
Unfavourable Opinion	1	3.23
<b>Total</b>	<b>31</b>	<b>100</b>

**Table 8: Other Management Information based on the number of completed applications for the reporting period:**

<b>Average number of applications reviewed per full meeting</b>	4.90
<b>Number of completed applications for full ethical review</b>	49
<b>Number of completed applications for full ethical review over 60 days</b>	0
<b>Number of completed applications over 60 days as a % of total</b>	0.00%
<b>Number of completed applications for full ethical review over 40 days</b>	2
<b>Number of completed applications over 40 days as a % of total</b>	4.08%
<b>Number of days taken to final decision – average (mean)</b>	25
<b>Number of completed proportionate review applications for ethical review</b>	25
<b>Number of completed proportionate review applications for ethical review over 14 days</b>	1
<b>Number of completed proportionate review applications over 14 days as a % of total</b>	4.00%
<b>Number of SSAs (non-Phase 1) reviewed</b>	0
<b>Number of completed applications for SSA review over 25 days</b>	0
<b>Number of completed applications for SSA review over 25 days as % of all non- Phase 1 SSAs</b>	0.00%
<b>Number of SSAs (Phase 1) reviewed</b>	0
<b>Number of completed applications for SSA review over 14 days</b>	0
<b>Number of completed applications for SSA review over 14 days as % of all Phase 1 SSAs</b>	0.00%
<b>Number of substantial amendments reviewed</b>	76
<b>Number of completed substantial amendments over 35 days</b>	0
<b>Number of completed substantial amendments over 35 days as a % of total substantial amendments</b>	0.00%
<b>Number of completed substantial amendments over 28 days</b>	3
<b>Number of completed substantial amendments over 28 days as a % of total substantial amendments</b>	3.95%
<b>Number of modified amendments reviewed</b>	4
<b>Number of completed modified amendments over 14 days</b>	0
<b>Number of completed modified amendments over 14 days as a % of total modified amendments</b>	0.00%
<b>Number of minor amendments received</b>	71
<b>Number of substantial amendments received for information</b>	0
<b>Number of substantial amendments received for new sites/PIs</b>	0
<b>Number of annual progress reports received</b>	114
<b>Number of safety reports received</b>	0
<b>Number of Serious Adverse Events received</b>	0

<b>Number of final reports received</b>	45
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**Table 9.1: Breakdown of current status of all full applications reviewed within the reporting period**

<b>Further Information Favourable Opinion with Standard Conditions</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
15/NW/0306	Does intra-operative Marginprobe use reduce re-excision rates?	22
15/NW/0324	SPECIAL: Standard or Palliative Care In Advanced Lung cancer (V1.0)	30
15/NW/0357	Validation of a questionnaire in Pancreatic Exocrine Insufficiency	43
15/NW/0361	V1: Health-related internet use among primary care attenders	34
15/NW/0364	PAT-DILI	26
15/NW/0373	Neuropsychological morbidity in premature skin ageing	40
15/NW/0457	meriT-V 1.1.0	27
15/NW/0458	Paediatric Maladaptive Perfectionism Mediator Project	21
15/NW/0460	Correlation of IAP & IPP	23
15/NW/0464	BLUS ACV	23
15/NW/0536	Brain connectivity in CWP and high risk group	42
15/NW/0644	EEG investigation of the pain in Parkinson's disease and controls	28
15/NW/0655	GOR in CF	21
15/NW/0703	Proximal upper limb recovery	26
15/NW/0708	Mapping and evaluating Specialist Autism Team service models	20
15/NW/0722	HIPACE	19
15/NW/0800	Evaluating Specific Plans to Increase Smoking Quit Attempts in Prison	27
15/NW/0821	Calprotectin in IBD ORI-CAL-01 v1.0	36
15/NW/0829	The Tommy's Project	28
15/NW/0845	myAirCoach Quantification Campaign	25
15/NW/0930	Pulmonary vein Reconnection following Ablation Index-guided ablation	23
15/NW/0933	Peripheral Blood Transcriptome Study	23
16/NW/0013	Early Detection of Lung Disease Pilot	27
16/NW/0024	Vascular adaptation to weight gain in young adults	37
16/NW/0123	PIPSMILL project	22
16/NW/0168	A Feasibility Study of the Family Connections programme	26

<b>Further Information Favourable Opinion with Additional Conditions</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>

**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/NW/0371	ReaDySpeech: A feasibility study	24
15/NW/0939	What matters most about the arm & how it affects life after stroke?v1	23
16/NW/0173	Advance decisions, mental capacity, and suicidal behaviour	21

**Favourable Opinion with Additional Conditions**

REC Reference	Title	Number of Days on Clock
15/NW/0249	Randomised study comparing brain cooling in cardiac surgery.	20
15/NW/0298	What helps and hinders people moving on from secure psychiatric care?	20
15/NW/0374	Experiences of 1:1 therapy with clinical psychologists. Views from LD.	24
15/NW/0426	The consequences of motor unit remodelling for motor control	21
15/NW/0429	Detecting inflammation in vestibular schwannomas with PET	21
15/NW/0501	The E.A.V.E (Experience of an Anorexic VoicE) Study	26
15/NW/0516	Survey to assess occupational exposure to lead	26
15/NW/0532	Understanding and Helping Families: Parents with Psychosis - Version 1	26
15/NW/0547	PET/MRI Imaging in sIBM/PM	23
15/NW/0705	Discussing functioning with EI and EDIT service users	21
15/NW/0740	Access to General Practice in Tameside and Glossop, Version 1	21
15/NW/0744	Host Transcriptomic Changes During Clinical Infection With Ebola Virus	8
15/NW/0766	Suicide and homicide in patients with personality disorder	21
15/NW/0772	Using a mindfulness app to improve anxiety and sleep quality in GAD.	23
15/NW/0916	Evaluation of the rectal reflex using Anal Acoustic Reflectometry	23
15/NW/0984	Caregiver obligations, preparedness and willingness to care	22
16/NW/0021	Diagnosis of herpes simplex keratitis	22
16/NW/0023	Investigation of polarisation sensitive optical coherence tomography	31

**Unfavourable Opinion**

REC Reference	Title	Number of Days on Clock
15/NW/0526	Discharge and Risk Assessment in Acute Medicine: A Case Study	26



15/NW/0835	The impact of causal beliefs on stigma	37
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<b>Provisional Opinion</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>

<b>Provisional Opinion Pending Consultation with Referee</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>

<b>Further information response not complete</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>

<b>Withdrawn after the meeting</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>

**Table 9.2: Breakdown of current status of all PRS applications reviewed within the reporting period**

<b>Further Information Favourable Opinion with Standard Conditions</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
15/NW/0318	QTc Study	11
15/NW/0325	Pregabalin and Gabapentin abuse: a qualitative study	14
15/NW/0397	Observational Study to Evaluate the Effectiveness of Lenalidomide	14
15/NW/0400	Acromegaly & Clot Dynamics	11
15/NW/0579	The value of clinical research to acute NHS Trusts	14
15/NW/0580	Caesarean Section and Myometrial Hypertrophy (CMH Study)	11

<b>Further Information Favourable Opinion with Additional Conditions</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>

**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/NW/0402	The challenges in Diagnosing 1o & 2o lung SCC – a new approach v1.0	12
15/NW/0486	Association between subcutaneous fat & abnormal MR signal at the knee	12
15/NW/0489	Predictive value of smooth muscle autoantibodies	11
15/NW/0814	Field testing of an app for exercises after breast cancer surgery.	10
15/NW/0889	Redx Immunology NRES application	8
16/NW/0030	Development of oral health initiatives to improve glycaemic control v1	21
16/NW/0191	Role of therapies on epigenetic modifications in MPNs	8
16/NW/0192	Localisation of human hypothalamic obesity genes in the brain. (V1)	11

**Favourable Opinion with Additional Conditions**

REC Reference	Title	Number of Days on Clock
15/NW/0729	PAPERPAC	11
15/NW/0730	Cross sectional analyses of the CERTAIN registry cohort	11
15/NW/0731	Objective measurement of gait and physical activity after stroke	11
15/NW/0891	Activity and fatigue during chemotherapy for Oesophagogastric cancer	8
16/NW/0026	Measurement of mutant p53 protein using flow cytometry	8
16/NW/0028	Point of care platelet function testing in vascular disease	8
16/NW/0029	Public and patient views of laboratory grown red blood cells	8
16/NW/0100	Understanding symptom burden in patients with bronchiectasis	4
16/NW/0101	Studying Antibiotic resistance in lung disease	4
16/NW/0195	Utility study in diffuse large B-cell lymphoma	11

**Unfavourable Opinion**

REC Reference	Title	Number of Days on Clock
15/NW/0894	A pilot study to investigate the effect of Krill oil on skin function	7

**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**

<b>Favourable opinion</b>				
<b>Amendment REC Reference</b>	<b>Title</b>	<b>Version</b>	<b>Date</b>	<b>Number of Days on Clock</b>
02/049(a)/AM05	Quality control of MediSense products	Five	20/10/2015	18
03/NM/288/AM06	SLICC - inception cohort	Seven	10/06/2015	1
09/H1011/47/AM04	Is coagulation prognostic in cancer? Version 1	Four	23/06/2015	14
09/H1014/2/AM09	Identification of Biomarkers in Cutaneous Wounds (V1)	Three	26/11/2015	1
09/H1014/64/AM11	BILAG Biologics Prospective Cohort	Three	10/07/2015	18
11/NW/0220/AM03	Pre-surgical fMRI for brain tumour, DES and neuropsychological outcome	2	21/09/2015	2
11/NW/0220/AM04	Pre-surgical fMRI for brain tumour, DES and neuropsychological outcome	3	19/01/2016	3
11/NW/0743/AM15	Trajectories of Outcome in Neurological Conditions V1	Seven	14/03/2016	1
12/NW/0172/AM10	At-work limitations/productivity loss in arthritis	Two	26/11/2015	30
12/NW/0528/AM03	MRiADP Study	Two	07/07/2015	24
12/NW/0553/AM02	Therapeutic mAb Generation		04/06/2015	5
12/NW/0619/AM08	Investigating Medication Adherence in Psoriasis (iMAP)	Five	22/06/2015	12
12/NW/0654/AM06	The PIPAH Study	3 (Revised)	25/08/2015	20
12/NW/0867/AM07	PREVeNT RA	Three	07/04/2015	27
13/NW/0580/AM05	NIPSIGEN - Clinical translation of NIPD for single gene disorders.	Four	12/03/2015	24
13/NW/0758/AM06	Experience Led Commissioning for specialist maternity services	Three	01/04/2015	13
13/NW/0759/AM03	Delivering dignity for older people during chemotherapy	3	11/08/2015	7
13/NW/0797/AM01	Skin Barrier in Polymorphic Light Eruption	One	13/04/2015	1
13/NW/0870/AM01	The Manchester Parent-Child Preparation Study. Version 1.0	One	01/06/2015	3
13/NW/0888/AM03	Evaluating a planner to aid a community weight management programme	Two	27/05/2015	1
14/NW/0074/AM01	Prognostic Value of MCE and SPECT version 1	One	29/06/2015	8
14/NW/0195/AM01	Longitudinal placental MRI changes in complicated pregnancies	One	28/10/2015	3
14/NW/1109/AM01	Exploring experiences and issues of Young Adults with CF	1	24/04/2015	24
14/NW/1193/AM06	IBD Transition study	One	08/10/2015	5
14/NW/1193/AM08	IBD Transition study	Two	21/10/2015	0

14/NW/1233/AM01	Characterisation of immune and inflammatory reactions in dandruff	1	30/04/2015	17
14/NW/1233/AM02	Characterisation of immune and inflammatory reactions in dandruff	Two	16/11/2015	16
14/NW/1262/AM01	Evaluating Specific Plans to Increase Smoking Quit Attempts	One	24/06/2015	11
14/NW/1311/AM01	Hospital discharge in advanced disease:supporting family carers V1	One	21/05/2015	1
14/NW/1316/AM03	The influence of childbirth on pelvic sensory innervation	Two	06/01/2016	1
14/NW/1396/AM01	B-AHEAD 3; Breast - Activity and Healthy Eating After Diagnosis - 3	One	25/03/2015	7
14/NW/1396/AM02	B-AHEAD 3; Breast - Activity and Healthy Eating After Diagnosis - 3	2	05/08/2015	3
14/NW/1396/AM03	B-AHEAD 3; Breast - Activity and Healthy Eating After Diagnosis - 3	Three	24/09/2015	7
14/NW/1471/AM03	EXPRESS 2 - longitudinal feasibility study	Two	12/11/2015	1
15/NW/0042/AM01	Measurement of chlamydia antibodies using residual GUM specimens	1	06/08/2015	0
15/NW/0043/AM01	Towards a mobile health device for Parkinson's disease	One	02/07/2015	4
15/NW/0043/AM02	Towards a mobile health device for Parkinson's disease	Two	18/01/2016	1
15/NW/0046/AM03	BPD perceptions of interventions to prevent self-harm	One	30/07/2015	0
15/NW/0071/AM01	ARTFORCE Head & Neck (2-arm study)	One	29/09/2015	3
15/NW/0086/AM01	Social networks in African Caribbean & Black Africans with psychosis	One	17/04/2015	6
15/NW/0133/AM01	Hidden hearing loss in unexplained listening difficulties and tinnitus	One	26/03/2015	15
15/NW/0133/AM02	Hidden hearing loss in unexplained listening difficulties and tinnitus	Two	01/02/2016	12
15/NW/0157/AM01	Dysphagia in Huntington's disease: a multimodal imaging study / v1.0	One	24/06/2015	13
15/NW/0306/AM01	Does intra-operative Marginprobe use reduce re-excision rates?	One	02/07/2015	10
15/NW/0306/AM02	Does intra-operative Marginprobe use reduce re-excision rates?	SA2	09/12/2015	12
15/NW/0306/AM03	Does intra-operative Marginprobe use reduce re-excision rates?	Three	11/02/2016	4
15/NW/0324/AM03	SPECIAL: Standard or PalliativE Care In Advanced Lung	One	22/07/2015	9

	cancer (V1.0)			
15/NW/0357/AM01	Validation of a questionnaire in Pancreatic Exocrine Insufficiency	One	02/11/2015	11
15/NW/0364/AM01	PAT-DILI	One	01/09/2015	2
15/NW/0373/AM01	Neuropsychological morbidity in premature skin ageing	One	11/08/2015	20
15/NW/0374/AM01	Experiences of 1:1 therapy with clinical psychologists. Views from LD.	1	04/08/2015	18
15/NW/0426/AM01	The consequences of motor unit remodelling for motor control	One	26/11/2015	15
15/NW/0429/AM01	Detecting inflammation in vestibular schwannomas with PET	One	17/06/2015	28
15/NW/0458/AM04	Paediatric Maladaptive Perfectionism Mediator Project		07/03/2016	1
15/NW/0501/AM02	The E.A.V.E (Experience of an Anorexic Voice) Study	One	05/08/2015	4
15/NW/0501/AM05	The E.A.V.E (Experience of an Anorexic Voice) Study	Two	02/10/2015	1
15/NW/0501/AM06	The E.A.V.E (Experience of an Anorexic Voice) Study	Three	05/11/2015	7
15/NW/0501/AM08	The E.A.V.E (Experience of an Anorexic Voice) Study	Four	24/02/2016	1
15/NW/0536/AM02	Brain connectivity in CWP and high risk group	One	19/02/2016	5
15/NW/0655/AM01	GOR in CF	One	19/02/2016	1
15/NW/0703/AM01	Proximal upper limb recovery	1	14/12/2015	1
15/NW/0705/AM02	Discussing functioning with EI and EDIT service users	1	20/01/2016	1
15/NW/0708/AM01	Mapping and evaluating Specialist Autism Team service models	1	23/11/2015	9
15/NW/0708/AM02	Mapping and evaluating Specialist Autism Team service models	Two	02/12/2015	1
15/NW/0708/AM03	Mapping and evaluating Specialist Autism Team service models	Three	22/12/2015	1
15/NW/0708/AM04	Mapping and evaluating Specialist Autism Team service models	Four	19/01/2016	0
15/NW/0708/AM05	Mapping and evaluating Specialist Autism Team service models	Five	04/02/2016	10
15/NW/0708/AM06	Mapping and evaluating Specialist Autism Team service models	Six	15/02/2016	0
15/NW/0744/AM01	Host Transcriptomic Changes During Clinical Infection With Ebola Virus	One	27/11/2015	34
15/NW/0814/AM01	Field testing of an app for exercises after breast cancer surgery.	One	17/11/2015	3
15/NW/0829/AM01	The Tommy's Project	One	29/12/2015	3
16/NW/0023/AM01	Investigation of polarisation sensitive optical coherence	One	12/02/2016	1

	tomography			
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<b>Unfavourable opinion</b>				
<b>Amendment REC Reference</b>	<b>Title</b>	<b>Version</b>	<b>Date</b>	<b>Number of Days on Clock</b>
07/H1014/84/AM04	PLK1 mediated oesophagogastric cancer development	Two	19/06/2015	13
13/NW/0580/AM06	NIPSIGEN - Clinical translation of NIPD for single gene disorders.	6	07/08/2015	35
15/NW/0373/AM02	Neuropsychological morbidity in premature skin ageing	2	15/12/2015	5
15/NW/0532/AM02	Understanding and Helping Families: Parents with Psychosis - Version 1	One	17/11/2015	6

**Table 10.2: Breakdown of current status of all modified amendments reviewed within the reporting period**

<b>Favourable opinion timeline</b>				
<b>Amendment REC Reference</b>	<b>Title</b>	<b>Version</b>	<b>Date</b>	<b>Number of Days on Clock</b>
07/H1014/84/AM04/1	PLK1 mediated oesophagogastric cancer development	Modified Amendment	13/07/2015	1
13/NW/0580/AM06/1	NIPSIGEN - Clinical translation of NIPD for single gene disorders.	Modified Amendment	14/10/2015	6
15/NW/0373/AM02/1	Neuropsychological morbidity in premature skin ageing	Modified Amendment	15/12/2015	6
15/NW/0532/AM02/1	Understanding and Helping Families: Parents with Psychosis - Version 1	Modified Amendment	30/11/2015	2

<b>Unfavourable opinion timeline</b>				
<b>Amendment REC Reference</b>	<b>Title</b>	<b>Version</b>	<b>Date</b>	<b>Number of Days on Clock</b>

**Table 11: Items exceeding timelines**

**Full applications for ethical review over 60 day timeline**

REC Reference	Title	Number of Days on Clock
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**Proportionate review applications for ethical review over 14 day timeline**

REC Reference	Title	Number of Days on Clock
16/NW/0030	Development of oral health initiatives to improve glycaemic control v1	21

**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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