

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

Annual Report

01 April 2016 - 31 March 2017



Part 1 – Committee Membership and Training

Name of REC:	North West - Greater Manchester West Research Ethics Committee
Type of REC:	Authorised
Type of Flag:	Qualitative Research
Chair:	Dr Lorraine Lighton
Vice-Chair:	Dr Gideon Smith
Alternate Vice-Chair:	Mr Jonathan Deans
REC Manager:	Miss Anna Bannister
REC Assistant:	Miss Nafeesa Khanam (06.06.16 to 06.03.17) Mr Ewan Waters (from 07.03.17)
Committee Address:	Barlow House 3rd Floor 4 Minshull Street Manchester M1 3DZ
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Chair's overview of the past year:

In previous years we have struggled at times to ensure that meetings are quorate owing to low membership numbers and we have needed to co-opt members from other Committees to assist us. I am pleased to report that four new members have been appointed to GM West: expert members Julie Grindey, Anne-Helen Harding and Judith Ormrod, and lay member Christine Holly. Dr Barry Miller has taken leave from the REC for two years owing to professional commitments. We look forward to his return in 2019. This brings the current membership to 12 which has substantially reduced the need to co-opt members to ensure meetings are quorate.

We had ten full meetings during 2016/17 with 50 applications and also reviewed 22 applications by proportionate review sub-committee. 96% of applications for full review were completed within the stretch target of 40 days with a mean time to final decision of 25 days, and all but one of the proportionate review applications was completed within 21 days.

I should like to thank all the members for their commitment to preparing for and attending the meetings. I am always impressed by the thoroughness and quality of review and discussion, both by lead reviewers and the other members, leading to outcomes which both protect the welfare of research subjects and facilitate research. Most members now receive their papers electronically through the HARP portal, reducing the amount of paper used and enabling comments to be shared before the meeting. Although there were some difficulties earlier in the year with access to the web during meetings, these appear to have been resolved with improved wi-fi at Barlow House.

Finally, a big thank you to Anna Bannister, Nafeesa Khanam and Ewan Waters who have provided excellent support to the Committee, helping us to meet targets and prompting the Chair to action when necessary.

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	
Dr Anne-Helen Harding	Principal Epidemiologist	Expert	01/08/2016	
Mr Michael Harnor	Retired University Lecturer	Lay Plus	01/09/2009	
Mrs Christine Holly	Retired Librarian	Lay	01/11/2016	
Dr Lorraine Lighton	Retired Consultant in Communicable Disease Control	Expert	01/09/2009	
Dr Barry Miller	Consultant Anaesthetist	Expert	01/09/2009	
Dr Judith Ormrod	Lecturer	Expert	01/10/2016	
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	Meeting date attended
Dr George Gkimpas	Clinical Fellow	Expert	05/08/2016
Dr Barbra Potrata	Research Fellow	Lay Plus	05/08/2016

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

Name	Declaration of Interest	Date
Mrs Seonaid Beddows	Acting R&D manager from East Cheshire NHS Trust	06/01/2017
Dr Janice Christie	As part of my role I apply for research funding, support students' and colleagues' research and also peer review for the NIHR and a variety of professional and academic journals.	24/03/2017
Mr Jonathan Deans	None	03/02/2017
Dr Peter Donnelly	PPI member at HeRC	06/01/2017
Dr Anne-Helen Harding	Work as an epidemiologist/statistician for the Health & Safety Executive and are a principal investigator on two cohort studies (the Asbestos Workers Survey and the Prospective Investigator of pesticide Users' Health (PIPAH) study. Both studies are funded by HSE. The two studies are under GM Central and GM West. Under take peer review of journal manuscripts (for example for occupational medicine	03/08/2016
Mr Michael Harnor	Company Director & Trustee British Epilepsy Association Company Director Epilepsy UK, Company Director Epilepsy Action Shareholdings Astrazeneca, Smith and Nephew, GSK and GW Pharma Member at MHRA patient organisation Forum	03/03/2017
Mrs Christine Holly	None	03/10/2016
Dr Lorraine Lighton	None	03/02/2017
Dr Judith Ormrod	None	06/01/2017
Dr Peter Owen	None	06/01/2017
Dr Gideon Smith	Employed by Tameside & Glossop Single Commission for health & social care and may be asked to comment on research proposals, Chair of programme steering group for NIHR funded research programme at Liverpool University	06/01/2017
Mrs Julie Grindey	None	01/03/2017

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

Month	Date	Number of Members Present at Meeting
April	01/04/2016	8
May	06/05/2016	8
June	03/06/2016	8
August	05/08/2016	8
October	07/10/2016	10
November	04/11/2016	8
December	02/12/2016	8
January	06/01/2017	8
February	03/02/2017	8
March	03/03/2017	8

10 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	01/04/2016	3
May	06/05/2016	3
June	03/06/2016	3
August	05/08/2016	3
September	02/09/2016	3
October	07/10/2016	3
November	04/11/2016	5
January	06/01/2017	3
February	03/02/2017	3
March	03/03/2017	3

10 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	08/04/2016	2
April	15/04/2016	2
May	03/05/2016	2
May	23/05/2016	2
June	10/06/2016	2
June	24/06/2016	2
June	27/06/2016	2
July	01/07/2016	2
July	28/07/2016	2
August	01/08/2016	2
August	09/08/2016	2

August	26/08/2016	2
September	09/09/2016	2
September	23/09/2016	2
September	30/09/2016	2
October	12/10/2016	2
October	17/10/2016	2
October	19/10/2016	2
November	01/11/2016	2
November	14/11/2016	2
November	20/11/2016	2
December	16/12/2016	2
January	20/01/2017	2
January	27/01/2017	3
February	03/02/2017	2
February	08/02/2017	2
February	17/02/2017	2
March	01/03/2017	2
March	10/03/2017	2

29 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
Mrs Seonaid Beddows	8
Dr Janice Christie	6
Mr Jonathan Deans	3
Dr Peter Donnelly	7
Mrs Julie Grindey	9
Dr Anne-Helen Harding	7
Mr Michael Harnor	5
Mrs Christine Holly	4
Dr Lorraine Lighton	9
Dr Barry Miller	2
Dr Judith Ormrod	4
Dr Peter Owen	10
Dr Gideon Smith	6

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

Name	Number of Meetings Attended
Mrs Seonaid Beddows	2
Dr Janice Christie	2
Mrs Julie Grindey	2
Dr Lorraine Lighton	9
Dr Peter Owen	9
Dr Gideon Smith	8

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

Name	Number of Meetings Attended
Mrs Seonaid Beddows	7
Dr Janice Christie	4
Mr Jonathan Deans	7
Dr Peter Donnelly	3
Dr Lorraine Lighton	28
Dr Peter Owen	4
Dr Gideon Smith	6

Training 01 April 2016 - 31 March 2017

Name of Member	Date	Event(s) attended
Dr Janice Christie	29/06/2016	Handling Health-Related Findings in Research
Dr Janice Christie	07/10/2016	Online Training Quantitative Research
Mr Jonathan Deans	07/10/2016	Online Training Quantitative Research
Dr Peter Donnelly	06/07/2016	Local Training Day - York
Dr Peter Donnelly	07/10/2016	Online Training Quantitative Research
Dr Peter Donnelly	22/03/2017	National Members Training Day
Mrs Julie Grindey	07/10/2016	Online Training Quantitative Research
Dr Anne-Helen Harding	07/10/2016	Online Training Quantitative Research
Dr Anne-Helen Harding	10/02/2017	Committee Members Induction
Dr Anne-Helen Harding	22/03/2017	National Members Training Day
Mr Michael Harnor	06/04/2016	Quantitative Research Methods and Statistics
Mr Michael Harnor	22/03/2017	National Members Training Day
Mrs Christine Holly	29/06/2016	Handling Health-Related Findings in Research
Dr Lorraine Lighton	06/07/2016	Local Training Day - York
Dr Lorraine Lighton	26/10/2016	Qualitative Research and Ethical Review
Dr Lorraine Lighton	22/03/2017	National Members Training Day
Dr Peter Owen	29/06/2016	Handling Health-Related Findings in Research
Dr Peter Owen	07/10/2016	Online Training Quantitative Research
Dr Gideon Smith	05/08/2016	Equality Diversity and Human Rights
Dr Gideon Smith	07/10/2016	Online Learning - Quantitative 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	50	100.00
Total Applications Reviewed	50	100

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

Number of applications made invalid by the REC Manager	2
Number of applications withdrawn prior to the meeting	0
Number of student applications reviewed	27
Number of paediatric applications reviewed	8
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	9

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	3	6.00
Favourable Opinion with Additional Conditions	24	48.00
Unfavourable Opinion	4	8.00
Provisional Opinion	19	38.00
Provisional Opinion Pending Consultation with Referee	0	0.00
Total	50	100
Number of studies sent back to full committee meeting for final opinion	0	

Table 4: Summary of current status of applications reviewed during the reporting period

Status of applications at date of generation of report	Number	%
Further Information Favourable Opinion with Standard Conditions	17	34.00
Further Information Favourable Opinion with Additional Conditions	0	0.00
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	3	6.00
Favourable Opinion with Additional Conditions	24	48.00
Unfavourable Opinion	4	8.00
Provisional Opinion	2	4.00
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	50	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	12
Number of studies withdrawn prior to the meeting	1
Number of student applications reviewed	8
Number of paediatric applications reviewed	6
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

Decisions taken at proportionate review sub-committee meetings	Number	%
Favourable Opinion with Standard Conditions	6	27.27
Favourable Opinion with Additional Conditions	7	31.82
No Opinion transfer to full committee for review	6	27.27
Provisional Opinion	3	13.64
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	5.00
Number of completed applications for full ethical review	50
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	2
Number of completed applications over 40 days as a % of total	4.00%
Number of days taken to final decision – average (mean)	25
Number of completed proportionate review applications for ethical review	16
Number of completed proportionate review applications for ethical review over 14 days (Please note, the timelines for review of PR applications was extended from 14 to 21 calendar days in December 2016)	4
Number of completed proportionate review applications for ethical review over 21 days	1
Number of completed proportionate review applications over 14 days as a % of total	25.00%
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	58
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	4
Number of completed substantial amendments over 28 days as a % of total substantial amendments	6.90%
Number of modified amendments reviewed	1
Number of completed modified amendments over 14 days	0
Number of completed modified amendments over 14 days as a % of total modified amendments	0.00%
Number of non substantial amendments received	107
Number of substantial amendments received for information	0
Number of substantial amendments received for new	0

sites/PIs	
Number of annual progress reports received	39
Number of safety reports received	0
Number of Serious Adverse Events received	0
Number of final reports received	38

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/0231	What parents say about medicines that are not designed for children	22
16/NW/0298	Quantifying Plasma Refill During Ultrafiltration	37
16/NW/0330	EIB Mediator & VOC Study	30
16/NW/0370	Activity Monitor use in COPD Patients Undergoing Rehabilitation	36
16/NW/0395	Investigating the role of bioactive lipids in psoriasis	33
16/NW/0441	Understanding access to SPC in haematological cancer.	26
16/NW/0559	Myocardial effects of interleukin-2 therapy	29
16/NW/0590	Childhood Trauma, Self-concept Clarity & Psychosis (Version 3)	46
16/NW/0700	The PATCh Experiences Study - Positive and Traumatic Childbirth	33
16/NW/0715	A Simple Test of Pelvic Sensation	43
16/NW/0784	cfDNA copy number instability as a diagnostic for Breast Neoplasia	29
16/NW/0866	MRgFUS for the treatment of recurrent bone sarcomas	29
17/NW/0006	Alcohol addiction and help seeking attitudes	26
17/NW/0009	A PET study with 11C-BU99008 in Parkinson's disease dementia	34
17/NW/0059	Online Study of Interpersonal Resources In Self-Harm (OSIRIS)	37
17/NW/0154	Exploring Experiences of Hearing Voices for Young People & Caregivers	31
17/NW/0155	Latitude: study of patient choice and effectiveness of Bulkamid® in SUI	27

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/0447	Uplift website for depression: feasibility study	20
16/NW/0867	Assessing Group B Streptococcus awareness in pregnancy. version :1	22
17/NW/0014	Reduced Fetal Movement Intervention Trial (ReMIT-2)	21

Favourable Opinion with Additional Conditions		
REC Reference	Title	Number of Days on Clock
16/NW/0220	Intestinal dysmotility. A qualitative study of patient's experiences	20
16/NW/0226	Daily relationships between sleep, mood and suicidality	20
16/NW/0234	Understanding the experiences of patients with soft tissue sarcoma	20
16/NW/0240	Guidelines for Group music therapy in chronic depression	20
16/NW/0376	CP-led contraception intervention for WRO	23
16/NW/0440	PROMOTE- Procalcitonin monitoring in paediatric OPAT	20
16/NW/0552	NOTEPAD	25
16/NW/0560	Immunoabsorption therapy in Autoimmune Membranous Nephropathy	21
16/NW/0563	periodontal minimally invasive surgical techniques with or without EMD	25
16/NW/0575	Gelesis G-04 study	22
16/NW/0786	WS3-PATHWAY-HOME-MCT (RP-PG-1211-20011)	18
16/NW/0788	Exploring Genetic Predisposition to Foetal Anticonvulsant Syndromes	21
16/NW/0797	Understanding osteogenesis in health, development and disease. V1	18
16/NW/0868	Physical activity in palliative and neurological care	22
17/NW/0004	Validation of the Intestinal Gas Questionnaire (IGQ)	21
17/NW/0013	The KEATING trial	21
17/NW/0018	Experiences of transfer between child and adolescent psychiatry teams	28
17/NW/0074	CAPRI-Voc	24
17/NW/0083	Advanced head and neck cancer: unmet needs and health service usage	24
17/NW/0088	Experiences of difficult emotions in people with seizures	24
17/NW/0124	Quantifying the impact of taking medicines for long-term conditions	18
17/NW/0150	Voice hearing in an African and Caribbean population	18
17/NW/0151	EABR comparison study	18
17/NW/0161	Research into Adolescent Vulval Appearance	15

Unfavourable Opinion		
REC Reference	Title	Number of Days on Clock
16/NW/0229	The role of sport and exercise in prisons; a sociological analysis	20
16/NW/0360	The psychological reaction of patients to their first diagnosis (ADHD)	23
16/NW/0688	The Ex-Frail Study	28
17/NW/0028	FICUS - faecal incontinence cost utilisation study	21

Provisional Opinion		
REC Reference	Title	Number of Days on Clock
16/NW/0833	DE-MRI-Guided vs. Conventional Catheter Ablation of AF (DECAAF II)	n/a
17/NW/0069	Pilot study of Emoticom tool for new mothers	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
16/NW/0382	Influence of rewards on behaviour in Anorexia Nervosa version 1	15
17/NW/0091	THORACIC	15
17/NW/0094	AMG 145-Observational Study to Evaluate the Safety in Pregnancy	24

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/0252	IMPROVING CLINICAL PRACTICE FOR PATIENTS WITH A BLOOD CLOT	13
16/NW/0257	Women's experience of breast reconstruction version 1.0	7
16/NW/0614	Neurodegenerative proteinopathy in Glaucoma	12
16/NW/0817	Descriptive study of occupational asthma due to cleaning agents	9
17/NW/0024	A qualitative study of an intervention to reduce diabetic foot ulcers	8
17/NW/0026	Fever observational study v1.0	8

Favourable Opinion with Additional Conditions		
REC Reference	Title	Number of Days on Clock
16/NW/0469	Intentional Non-adherence	7
16/NW/0659	ePRIME - patient-reported AEs in early phase trials: phase 1	14
16/NW/0660	Detect study	10
17/NW/0027	Patients experience of education in outpatient cardiac rehabilitation	8
17/NW/0092	Air Pollution Particles in Placenta	21
17/NW/0152	iCHEC: Identifying Children with HEreditary Coagulation disorders	14
17/NW/0157	Infant respiratory infections and subsequent asthma	8

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
09/H1006/38/AM12	OPHTHALMIC MARKERS OF DIABETIC NEUROPATHY	10	24/10/2016	21
11/H1014/4/AM17	TAM-Prev - Tamoxifen Prevention Study	10	10/10/2016	21
11/NW/0426/AM03	MAViS Manchester Antenatal Vascular Service	4	18/08/2016	5
11/NW/0723/AM08	Saccadic Eye Movements in Alzheimer's disease	4	11/11/2016	17
11/NW/0743/AM18	Trajectories of Outcome in Neurological Conditions V1	8	05/08/2016	2
12/NW/0172/AM11	At-work limitations/productivity loss in arthritis	SA3	10/01/2017	9
12/NW/0525/AM05	HYST	Three	10/03/2016	32
12/NW/0525/AM06	HYST	4	21/12/2016	28
12/NW/0553/AM03	Therapeutic mAb Generation	Change of CI	01/07/2016	2
12/NW/0553/AM04	Therapeutic mAb Generation		05/10/2016	9
12/NW/0553/AM05	Therapeutic mAb Generation		07/11/2016	10
12/NW/0553/AM06	Therapeutic mAb Generation	6	17/01/2017	12
13/NW/0298/AM02	Electrical remodelling of the sinus node in athletes	2	07/07/2016	7
13/NW/0310/AM05	AMEND-IT (version-1)	4	17/02/2017	19
14/NW/0053/AM01	Digital breast tomosynthesis in screening younger higher risk women	One	20/03/2016	34
14/NW/0152/AM02	Characterisation of human IL-10-secreting T cells	1	05/05/2016	8
14/NW/0154/AM01	Circulating Neuroblastoma Tumour Cell Study (Version 2.0)	1	19/05/2016	28
14/NW/1316/AM04	The influence of childbirth on pelvic sensory innervation	5	20/06/2016	9
14/NW/1396/AM04	B-AHEAD 3; Breast - Activity and Healthy Eating After Diagnosis - 3	4	30/03/2016	7
14/NW/1471/AM05	EXPRESS 2 - longitudinal feasibility study	3	01/06/2016	5
15/NW/0043/AM03	Towards a mobile health device for Parkinson's disease	Substantial amendment 3	23/05/2016	7
15/NW/0043/AM04	Towards a mobile health device for Parkinson's disease		4	23/08/2016
15/NW/0086/AM03	Social networks in African Caribbean & Black Africans with psychosis	2	07/10/2016	8
15/NW/0157/AM03	Dysphagia in Huntington's disease: a multimodal imaging study / v1.0	Two	16/02/2016	14
15/NW/0306/AM04	Does intra-operative Marginprobe use reduce re-excision rates?	4	30/09/2016	21

15/NW/0306/AM05	Does intra-operative Marginprobe use reduce re-excision rates?	5	12/01/2017	7
15/NW/0324/AM06	SPECIAL: Standard or Palliative Care In Advanced Lung cancer (V1.0)	2	11/05/2016	24
15/NW/0501/AM09	The E.A.V.E (Experience of an Anorexic Voice) Study	5.0	13/05/2016	3
15/NW/0501/AM10	The E.A.V.E (Experience of an Anorexic Voice) Study	6.0	28/10/2016	6
15/NW/0536/AM04	Brain connectivity in CWP and high risk group	2	01/09/2016	8
15/NW/0536/AM06	Brain connectivity in CWP and high risk group	3	17/01/2017	4
15/NW/0644/AM01	EEG investigation of the pain in Parkinson's disease and controls	1	21/11/2016	16
15/NW/0644/AM02	EEG investigation of the pain in Parkinson's disease and controls	2	19/01/2017	15
15/NW/0655/AM02	GOR in CF	3	12/09/2016	7
15/NW/0708/AM07	Mapping and evaluating Specialist Autism Team service models	7	01/04/2016	27
15/NW/0708/AM08	Mapping and evaluating Specialist Autism Team service models	8	11/04/2016	21
15/NW/0708/AM09	Mapping and evaluating Specialist Autism Team service models	9	13/10/2016	14
15/NW/0708/AM10	Mapping and evaluating Specialist Autism Team service models	10	14/02/2017	13
15/NW/0766/AM01	Suicide and homicide in patients with personality disorder	1	04/04/2016	6
15/NW/0821/AM02	Calprotectin in IBD ORI-CAL-01 v1.0	1	25/07/2016	4
15/NW/0821/AM03	Calprotectin in IBD ORI-CAL-01 v1.0	2	12/08/2016	6
15/NW/0821/AM04	Calprotectin in IBD ORI-CAL-01 v1.0	2	05/10/2016	7
15/NW/0829/AM03	The Tommy's Project	SA2	03/03/2017	31
15/NW/0845/AM02	myAirCoach Quantification Campaign	1	26/05/2016	4
15/NW/0845/AM03	myAirCoach Quantification Campaign	2	12/12/2016	12
15/NW/0916/AM02	Evaluation of the rectal reflex using Anal Acoustic Reflectometry	1	12/05/2016	32
15/NW/0916/AM03	Evaluation of the rectal reflex using Anal Acoustic Reflectometry	2	14/07/2016	6
15/NW/0933/AM01	Peripheral Blood Transcriptome Study	1	30/07/2016	15
16/NW/0024/AM01	Vascular adaptation to weight gain in young adults	1	18/01/2017	21
16/NW/0029/AM01	Public and patient views of laboratory grown red blood cells	One	11/03/2016	8
16/NW/0029/AM02	Public and patient views of laboratory grown red blood cells	3	17/01/2017	8

16/NW/0220/AM01	Intestinal dysmotility. A qualitative study of patient's experiences	1	11/05/2016	7
16/NW/0226/AM01	Daily relationships between sleep, mood and suicidality	1	19/07/2016	11
16/NW/0226/AM05	Daily relationships between sleep, mood and suicidality	2	23/02/2017	14
16/NW/0376/AM03	CP-led contraception intervention for WRO	1	05/10/2016	7
16/NW/0395/AM03	Investigating the role of bioactive lipids in psoriasis	1	15/11/2016	8
16/NW/0560/AM01	Immunoabsorption therapy in Autoimmune Membranous Nephropathy	1	06/01/2017	22
16/NW/0660/AM01	Detect study	1	21/12/2016	9

Unfavourable opinion

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
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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
11/NW/0802/AM03/1	Clinical study of the PyroTITAN shoulder resurfacing prosthesis V1	Modified sub-amendment 2	11/05/2016	13

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
17/NW/0094	AMG 145-Observational Study to Evaluate the Safety in Pregnancy	24

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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