

**North West - Preston Research Ethics Committee**

**Annual Report**

**01 April 2017 - 31 March 2018**



## Part 1 – Committee Membership and Training

<b>Name of REC:</b>	North West - Preston Research Ethics Committee
<b>Type of REC:</b>	Authorised
<b>Type of Flag:</b>	None
<b>Chair:</b>	Professor Carol Haigh
<b>Vice-Chair:</b>	Professor Karen Wright
<b>Alternate Vice-Chair:</b>	Ms Eleanor Jolley
<b>REC Manager:</b>	Mrs Carol Ebenezer until 31/01/2018 Vacant (01/02/2018 to present)
<b>REC Assistant:</b>	Ms Zainab Ahmed
<b>Committee Address:</b>	Barlow House 3rd Floor 4 Minshull Street Manchester M1 3DZ
<b>Telephone:</b>	0207 104 8006
<b>Email:</b>	nrescommittee.northwest-preston@nhs.net

## Chair's overview of the past year:

There has been a year of changes for this committee. We have appointed a new Chair and Vice chair from January 2018 and have lost a very experienced and highly valued administrator who has yet to be replaced. Zainab Tauqeer our REC Assistant is making a very good job of covering the vacant post.

The committee functions well as a group and are helpful, and supportive to each other and applicants. We have lost a few members and gained some new ones and I think they feel welcome onto the committee. We may lose someone else in the near future and that gives me slight concern regarding workload for remaining members until they are replaced and also concerns as to whether that may be a threat to the committee being quorate. We would welcome a focused strategy for managing follow up meetings when an inquorate meeting has been held, one that would balance the requirements of the ethics service with the 'real life demands of the committee members.

I have noted that, for one or two meetings we have been asked to consider 6 applications which seems excessive and had impacted upon the running time of the committee and this is something I intend to keep under review.

Overall, however, I am pleased to report that the committee runs smoothly and amicably. Personally I am very grateful for the support the committee offered when I took over the role of chair

## North West - Preston Research Ethics Committee Membership

Name	Profession	Expert or Lay	Dates	
			Appointed	Left
Mr David Abbotts	General Manager (retired)	Lay Plus	13/09/2010	
Dr Brenda Ashcroft	Expert Witness	Expert	01/02/2017	
Professor Anoop Chauhan	Consultant Cardiologist	Expert	10/07/2008	01/04/2017
Professor Carol Haigh	Professor of Nursing	Expert	02/06/2014	
Ms Eleanor Jolley	Learning Facilitator	Lay	01/10/2005	
Mrs Kate Kilshaw	Radiographer	Expert	25/09/2009	
Mrs Deborah Knight	Research Ethics Officer	Lay	09/10/2017	
Dr Rob Monks	Principal Lecturer in Nursing, Research and Innovation Lead	Expert	08/08/2009	31/12/2017
Mrs Susan Page	Senior Clinical Tutor	Expert	01/02/2017	
Professor Videsh Raut	Consultant Orthopaedic Surgeon	Expert	01/02/2007	31/01/2018
Dr Karen Rouse	Principal Lecturer, Postgraduate Programmes	Lay Plus	01/02/2016	
Mr Colin Thain	Retired Lecturer	Lay	09/10/2017	
Dr Gillian Thomson	Reader in Community and Midwifery	Expert	01/10/2016	
Mrs Vasanthi Vasudevan	Diabetes Research Nurse	Expert	12/01/2012	
Dr Hawys Williams	Research Governance Officer	Lay	05/07/2013	
Professor Karen Wright	Professor of Nursing	Expert	01/01/2015	

## North West - Preston Research Ethics Committee: Co-opted Members

Name	Profession	Status	Meeting date attended
Mr James Burns	Retired Lay member	Lay	27/10/2017
Dr Peter Owen	Retired Mathematics Lecturer	Lay Plus	26/05/2017, 22/09/2017 & 27/10/2017

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

<b>Name</b>	<b>Declaration of Interest</b>	<b>Date</b>
Mr David Abbotts	None	13/02/2018
Dr Brenda Ashcroft	None	28/11/2017
Professor Carol Haigh	Peer reviewer for NIHR & Advisory Board Member – Pilgrim Projects	14/03/2018
Mrs Deborah Knight	Research Ethics Officer, Secretary of Faculty of Arts and Social Sciences & Lancaster University Management School Research Ethics Committee, Lancaster University Bailrigg Lancaster As an administrator I process some applications for 'sponsorship' for Lancaster University.	22/03/2018
Dr Rob Monks	Principal Lecturer at the University of Central Lancashire	28/11/2017
Mrs Susan Page	Sit on UCLAN ethics committee	22/03/2018
Professor Videsh Raut	Consultant to Bioventus Inc. USA	29/11/2017
Dr Karen Rouse	I am a Principal Lecturer in the School of Dentistry, Faculty of Clinical and Biomedical Sciences, University of Central Lancashire (UCLan) and I am involved in research in the School. I supervise PhD students and MSc/BSc dissertation students. I am the School of Dentistry Research Degrees Tutor and School Ethics Lead. I am the Chair of the STEMH e-Ethics Committee at UCLan. I attend the Faculty of Clinical and Biomedical Sciences Research and Innovation Committee and the University Ethics Committee.	29/03/2018
Mr Colin Thain	None	19/10/2017
Dr Gillian Thomson	I am a Trustee of a charity – Lauren's Forever Purple – but am not involved in conduct of research Normal within my research related role at the University	14/03/2018
Mrs Vasanthi Vasudevan	Research Nurse, Diabetes and Cardiothoracic, Blackpool Victoria Hospitals, Whinney Heys Road, Blackpool. FY3 8NR	20/03/2018
Professor Karen Wright	Nurse consultant for the Priory Hospital, Catforth, Preston	21/03/2018

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

Month	Date	Number of Members Present at Meeting
April	28/04/2017	10
May	26/05/2017	8
July	28/07/2017	9
September	22/09/2017	7
October	27/10/2017	9
November	24/11/2017	11
January	26/01/2018	8
February	23/02/2018	9
March	23/03/2018	8

9 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	28/04/2017	3
May	26/05/2017	3
June	23/06/2017	3
July	21/07/2017	3
September	22/09/2017	3
October	20/10/2017	3
November	17/11/2017	3
December	15/12/2017	3
January	19/01/2018	4
February	16/02/2018	4
March	16/03/2018	3

11 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	14/04/2017	2
April	28/04/2017	2
May	12/05/2017	2
May	26/05/2017	2
June	16/06/2017	2
July	14/07/2017	2
August	04/08/2017	2
September	07/09/2017	3
October	06/10/2017	2
October	27/10/2017	2
November	10/11/2017	2

November	24/11/2017	2
December	22/12/2017	2
January	19/01/2018	2
February	16/02/2018	2
March	02/03/2018	2
March	05/03/2018	2
March	27/03/2018	2

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

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

0

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

<b>Name</b>	<b>Number of Meetings Attended</b>
Mr David Abbotts	8
Dr Brenda Ashcroft	4
Professor Carol Haigh	7
Ms Eleanor Jolley	7
Mrs Kate Kilshaw	6
Mrs Deborah Knight	4
Dr Rob Monks	4
Mrs Susan Page	4
Professor Videsh Raut	3
Dr Karen Rouse	6
Mr Colin Thain	4
Dr Gillian Thomson	6
Mrs Vasanthi Vasudevan	4
Dr Hawys Williams	4
Professor Karen Wright	4

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

<b>Name</b>	<b>Number of Meetings Attended</b>
Mr David Abbotts	6
Professor Carol Haigh	6
Ms Eleanor Jolley	2
Mrs Kate Kilshaw	2
Dr Rob Monks	5
Mrs Susan Page	2
Professor Videsh Raut	1
Dr Karen Rouse	3
Dr Gillian Thomson	2
Mrs Vasanthi Vasudevan	2
Dr Hawys Williams	1
Professor Karen Wright	3

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

<b>Name</b>	<b>Number of Meetings Attended</b>
Mr David Abbotts	2
Professor Carol Haigh	18
Dr Rob Monks	13





## Training 01 April 2017 - 31 March 2018

Name of Member	Date	Event(s) attended
Professor Carol Haigh	05/09/2017	Monthly Ethics Surgeries
Professor Carol Haigh	16/01/2018	External academic representative
Ms Eleanor Jolley	31/01/2018	Complex Cases
Mrs Kate Kilshaw	03/01/2018	Governance arrangements for Research ethics committees: a harmonised edition (Updated 2012)
Mrs Kate Kilshaw	17/03/2018	Book Ethics in Social Science Research: Becoming Culturally Responsive Maria K E Lahman
Mrs Deborah Knight	16/11/2017	Online induction
Mrs Deborah Knight	15/02/2018	Training - Committee Members Induction
Mrs Susan Page	17/05/2017	Adults Lacking Capacity
Mrs Susan Page	18/05/2017	Equality and Diversity
Mrs Susan Page	18/05/2017	Anti-fraud awareness
Mrs Susan Page	18/05/2017	Bribery Act
Mrs Susan Page	18/05/2017	Learning log - Adults lacking capacity – on-line toolkit.
Mrs Susan Page	04/07/2017	Mental Capacity Act and DOLs
Mrs Susan Page	18/07/2017	Information Governance
Mrs Susan Page	19/07/2017	Equality and Diversity
Mrs Susan Page	22/09/2017	IRMER rules and regulations
Mrs Susan Page	22/09/2017	Safeguarding Vulnerable adults
Mrs Susan Page	27/09/2017	Child Protection
Mrs Susan Page	29/09/2017	Radiography and Radiation Protection
Mrs Susan Page	29/09/2017	Statistics "A statistician reads and IRAS form"
Mrs Susan Page	29/09/2017	Qualitative Research "Thinking on your Feet"
Mrs Susan Page	29/09/2017	Human Tissue Act
Mrs Susan Page	29/09/2017	Members Regional Training Day
Dr Karen Rouse	26/09/2017	Assessing the Consequences (benefits and harms) of research
Dr Karen Rouse	31/01/2018	Complex Cases
Mr Colin Thain	19/10/2017	Online member induction
Mr Colin Thain	15/02/2018	Member Induction
Dr Gillian Thomson	21/03/2018	GDPR Online Training
Dr Gillian Thomson	21/03/2018	Online Information Security & Safeguarding
Professor Karen Wright	18/01/2018	- Quantitative Research Methods and Statistics
Professor Karen Wright	13/02/2018	The ethical issues of Research Involving Children

## 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)	0	0.00
Others	34	100.00
<b>Total Applications Reviewed</b>	<b>34</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	2
Number of applications withdrawn prior to the meeting	4
Number of student applications reviewed	18
Number of paediatric applications reviewed	4
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	5

**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	0	0.00
Favourable Opinion with Additional Conditions	5	14.71
Unfavourable Opinion	1	2.94
Provisional Opinion	28	82.35
Provisional Opinion Pending Consultation with Referee	0	0.00
<b>Total</b>	<b>34</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	27	79.41
Further Information Favourable Opinion with Additional Conditions	0	0.00
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	0	0.00
Favourable Opinion with Additional Conditions	5	14.71
Unfavourable Opinion	1	2.94
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	1	2.94
<b>Total</b>	<b>34</b>	<b>100</b>

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

<b>Total Applications Reviewed</b>	<b>29</b>
------------------------------------	-----------

**Table 6: Breakdown of PRS applications and other activity during reporting period:**

Number of applications made invalid by the REC Manager	2
Number of studies withdrawn prior to the meeting	2
Number of student applications reviewed	10
Number of paediatric applications reviewed	3
Number of device applications reviewed	0
Number of qualitative applications reviewed	4

**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	27.59
Favourable Opinion with Additional Conditions	3	10.34
No Opinion transfer to full committee for review	3	10.34
Provisional Opinion	14	48.28
Unfavourable Opinion	1	3.45
<b>Total</b>	<b>29</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>	3.78
<b>Number of completed applications for full ethical review</b>	33
<b>Number of completed applications for full ethical review over 60 days</b>	2
<b>Number of completed applications over 60 days as a % of total</b>	5.88%
<b>Number of days taken to final decision – average (mean)</b>	35
<b>Number of completed proportionate review applications for ethical review</b>	26
<b>Number of completed proportionate review applications for ethical review over 21 days</b>	2
<b>Number of completed proportionate review applications over 21 days as a % of total</b>	7.69%
<b>Number of SSAs (non-Phase 1) reviewed</b>	1
<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>	51
<b>Number of completed substantial amendments over 35 days</b>	1
<b>Number of completed substantial amendments over 35 days as a % of total substantial amendments</b>	1.96%
<b>Number of modified amendments reviewed</b>	0
<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 non substantial amendments received</b>	69
<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>	26
<b>Number of safety reports received</b>	0
<b>Number of Serious Adverse Events received</b>	1
<b>Number of final reports received</b>	12

**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>
17/NW/0268	ENHANCE	29
17/NW/0271	Biology of Juvenile Myoclonic Epilepsy: Pedigree Study	42
17/NW/0272	EmbryoGlue as an embryo transfer medium	39
17/NW/0316	Self-compassion and psychological distress in breast cancer (V1)	31
17/NW/0325	CAT and LD case series	25
17/NW/0333	Faecal volatiles in children with inflammatory bowel disease	30
17/NW/0440	Family History Lifestyle Study	24
17/NW/0453	STREAM - Feasibility study	24
17/NW/0459	QUANTUMS	31
17/NW/0464	SANOFI Pasteur EPSS 2017	36
17/NW/0536	Client experiences of 'The Decider'- v1	85
17/NW/0568	Developing a programme of safer care for aortic surgery	23
17/NW/0600	Investigating the spinal projection pathway of C-Tactile afferents	21
17/NW/0610	The UK Complex Aneurysm Study (UK-COMPASS)	24
17/NW/0630	A Compassion-Focused intervention for exercise shame.	22
17/NW/0631	The TRISTAN ILD Study	21
17/NW/0633	Talking With Voices	25
17/NW/0672	Adjustment in Working-Age Dementia Dyads	56
17/NW/0682	Attachment, information processing, and distress in psychosis	86
18/NW/0039	Evaluation of a co-developed physical activity referral scheme	40
18/NW/0070	Assessment and post-treatment evaluation of absence epilepsy seizures	36
18/NW/0125	The RESPECT-PAD Trial	48
18/NW/0135	TRIUMPH v1.0	38
18/NW/0142	T-CTAS-002	32
18/NW/0169	MoDal Study	40
18/NW/0234	Developing a Support Needs Approach for Patients (SNAP2) - Stages 2-3	39
18/NW/0236	AspiRATE study: Development of new technology to assess swallow safety	45

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

<b>Further Information Unfavourable Opinion</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>

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

<b>Favourable Opinion with Additional Conditions</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
17/NW/0454	The experience of COPD in working age adults: A framework analysis	20
17/NW/0457	Expression of tumour markers in tissue samples	20
17/NW/0559	Single-session group CBT post sexual assault: an outcome study	28
17/NW/0667	Psychological adaptation to CFSPID diagnosis	24
18/NW/0071	Affective Cognition in Depression & Schizophrenia Study, Version 1.0	28

<b>Unfavourable Opinion</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
18/NW/0145	Factors influencing self-referral to NHS staff counselling service	32

<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>



17/NW/0263	Effects of long term low dose Ketamine in chronic pain patients V1	24
------------	--	----

**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>
17/NW/0265	Evaluation of patient-rated comfort scores in colonoscopy	13
17/NW/0391	Healthcare transition experiences of young people with IBD	7
17/NW/0396	Attitudes and acceptability of extra-genital Chlamydia testing	5
17/NW/0444	Mindfulness and its possible effects on the experience of chronic pain	17
17/NW/0448	Renal Dialysis: A Comparative Study Of Home vs In-Centre Treatment	13
17/NW/0668	Biomechanical and psychosocial factors in low back pain	9
17/NW/0670	A Pilot Evaluation of Early Positive Approaches to Support	20
17/NW/0714	Apixaban and vascular health in atrial fibrillation study (AVAS)	5
17/NW/0718	Observational study in Gastric patients receiving Nivolumab in EAMS	11
18/NW/0108	Value of bitewings in managing carious primary molars: version 1	22
18/NW/0111	BIOPEX follow-up study	21
18/NW/0117	MHPP - PACAP version number 1.0	17
18/NW/0190	Recruiting for lung cancer screening	17

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

<b>Further Information Unfavourable Opinion</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>

<b>Favourable Opinion with Standard Conditions</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
17/NW/0267	Type-2 diabetes: risk perceptions and self-management behaviour.	12
17/NW/0344	3D animation and models to aid management of fetal CDH	18

17/NW/0441	alfapump & Malignant Ascites, Version 1, 29 June 2017	8
17/NW/0446	The CF & SVN Joint Claudication Study	11
17/NW/0566	Neuromuscular Function and Joint Coordination in Transtibial Amputees	17
17/NW/0709	A clinical stability index to help providers determine KMC eligibility	2
17/NW/0713	Somatic Mutations in Individuals with Inherited Cancer Predisposition	1
18/NW/0051	Nasal swabs for development of R-ID assay_V1	34

#### **Favourable Opinion with Additional Conditions**

<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
17/NW/0565	The TASQ Registry	21
17/NW/0612	Pneumococcal antibody absorption by conjugate vaccine	6
17/NW/0618	Examination of video reflexive ethnography in an acute medical unit	17

#### **Unfavourable Opinion**

<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
18/NW/0049	The use of biological products in surgery: a consenting conundrum	21

#### **Provisional Opinion**

<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
18/NW/0193	Investigating tissue destruction and immune response to tuberculosis.	n/a

#### **Further information response not complete**

<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
----------------------	--------------	--------------------------------

#### **Withdrawn after the meeting**

<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
----------------------	--------------	--------------------------------

**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>
10/H1016/25/AM08	Protocol for Donation of blood, urine, stool, sputum and nasal samples by Healthy Volunteers and Patient Volunteers for Laboratory Research"	10	28/12/2017	13
11/NW/0308/AM05	Does Carotid Artery Plaque Volume and Morphology predict Stroke? V1	4	19/12/2017	14
14/NW/0034/AM08	Individual risk based screening for diabetic retinopathy: WS E	Substantial Amendment 4	06/02/2018	19
14/NW/1146/AM06	The UK-PBC Nested Cohort Study (version 1)	4	14/07/2017	24
15/NW/0163/AM12	PATHWAY VERSION 1 DATE 13/02/2015 (RP-PG-1211-20011)	5	20/09/2017	35
15/NW/0236/AM11	GM-11: gammaCore nVNS episodic migraine study	8	25/09/2017	5
15/NW/0330/AM04	Recovery focused CBT for older adults with bipolar disorder	4	22/06/2017	4
15/NW/0330/AM05	Recovery focused CBT for older adults with bipolar disorder	5	23/08/2017	7
15/NW/0330/AM06	Recovery focused CBT for older adults with bipolar disorder	Substantial Amendment 6	23/02/2018	36
15/NW/0511/AM03	SUPERSTARCH Version 1.0	2	17/03/2017	6
15/NW/0590/AM04	PRODIGY (Definitive RCT): Version 1	3	22/08/2017	4
15/NW/0646/AM01	An Observational Registry of Abatacept in Patients with JIA	1	19/09/2017	20
15/NW/0749/AM03	SOFIA	3	16/08/2017	4
16/NW/0057/AM05	Distributed toothpaste & toothbrushing programme for at risk children	4	03/08/2017	22
16/NW/0132/AM01	Ammonia breath test studies	1	10/11/2017	4
16/NW/0209/AM02	Evaluation of fetal growth in pregnancies complicated by diabetes	2	14/02/2017	2
16/NW/0210/AM02	ToAST; Investigating the effects of bronchial thermoplasty on cough	Prot v4	27/12/2017	22
16/NW/0265/AM01	Accelerated Platform 2	1	11/01/2018	33
16/NW/0416/AM01	LiverPRIMEi & LiverPRIMEii	1	10/09/2017	3
16/NW/0432/AM04	A public health service to promote safe sex	2	27/11/2017	13
16/NW/0435/AM08	STELLAREX VASCULAR E-REGISTRY (SAVER)	1	03/07/2017	2
16/NW/0489/AM01	Barriers and facilitators of physical activity in stroke survivors 1	1	03/04/2017	14

16/NW/0546/AM04	Prediction of Lupus treatment response Study (PLANS)	3.0	22/08/2017	4
16/NW/0594/AM01	Dynamic lip function of cleft patients	2	08/09/2017	6
16/NW/0594/AM02	Dynamic lip function of cleft patients	Substantial Amendment 3	30/01/2018	8
16/NW/0669/AM01	Sleep and aggression: understanding and intervening	1	10/07/2017	4
16/NW/0793/AM01	Views and experiences of patients using the exercise app 'Salaso'	1	03/05/2017	9
16/NW/0793/AM02	Views and experiences of patients using the exercise app 'Salaso'	2	26/08/2017	6
16/NW/0796/AM01	Role of maternal adverse/risk outcomes on offspring's body composition	1	28/07/2017	17
16/NW/0848/AM02	Skin Testing for Atopic eczema Risk (STAR)	2	02/11/2017	10
16/NW/0897/AM01	Coronary Physiology	1	08/05/2017	3
17/NW/0063/AM01	Assessing the Outcomes of Foot and Ankle Surgery. Version 1	1	06/04/2017	13
17/NW/0130/AM01	Development of an internet / mobile phone service pathway for T2DM	1	15/09/2017	2
17/NW/0191/AM01	subjective experiences of symptoms of schizophrenia version 1.0	1	12/05/2017	4
17/NW/0193/AM02	IntAct- IFA to prevent anastomotic leak in rectal cancer surgery	1	18/07/2017	0
17/NW/0193/AM03	IntAct- IFA to prevent anastomotic leak in rectal cancer surgery	2	02/11/2017	7
17/NW/0204/AM01	Orthodontic Longitudinal Cohort	1	16/05/2017	13
17/NW/0316/AM01	Self-compassion and psychological distress in breast cancer (V1)	1	29/11/2017	23
17/NW/0316/AM02	Self-compassion and psychological distress in breast cancer (V1)	Substantial Amendment 3	15/02/2018	22
17/NW/0325/AM01	CAT and LD case series	1	04/07/2017	3
17/NW/0333/AM01	Faecal volatiles in children with inflammatory bowel disease	01	23/10/2017	9
17/NW/0396/AM01	Attitudes and acceptability of extra-genital Chlamydia testing	01	24/10/2017	3
17/NW/0440/AM02	Family History Lifestyle Study	Substantial Amendment 2	30/01/2018	13
17/NW/0441/AM01	alfapump & Malignant Ascites, Version 1, 29 June 2017	1	27/07/2017	15
17/NW/0453/AM01	STREAM - Feasibility study	1	04/08/2017	7
17/NW/0453/AM04	STREAM - Feasibility study	Substantial Amendment 2	05/02/2018	6
17/NW/0559/AM01	Single-session group CBT post sexual assault: an outcome study	Substantial Amendment 1	23/02/2018	34

17/NW/0568/AM01	Developing a programme of safer care for aortic surgery	1	19/01/2018	10
17/NW/0631/AM01	The TRISTAN ILD Study	Substantial Amendment 1	22/02/2018	14
17/NW/0633/AM01	Talking With Voices	1	23/11/2017	5
17/NW/0633/AM04	Talking With Voices	Substantial Amendment 2	12/02/2018	27

<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>

**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>

<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
17/NW/0536	Client experiences of 'The Decider'- v1	85
17/NW/0682	Attachment, information processing, and distress in psychosis	86

**Proportionate review applications for ethical review over 21 day timeline**

REC Reference	Title	Number of Days on Clock
18/NW/0051	Nasal swabs for development of R-ID assay_V1	34
18/NW/0108	Value of bitewings in managing carious primary molars: version 1	22

**SSAs (non Phase 1) over 25 day timeline**

REC Reference	Title	Number of Days on Clock
---------------	-------	-------------------------

**SSAs (Phase 1) over 14 day timeline**

REC Reference	Title	Number of Days on Clock
---------------	-------	-------------------------

**Substantial Amendments over 35 day timeline**

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
15/NW/0330/AM06	Recovery focused CBT for older adults with bipolar disorder	Substantial Amendment 6	23/02/2018	36

**Modified Amendments over 14 day timeline**

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
-------------------------	-------	---------	------	-------------------------