

**North West - Preston Research Ethics Committee**

**Annual Report**

**01 April 2016 - 31 March 2017**



## 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>	Dr Rob Monks
<b>Vice-Chair:</b>	Professor Carol Haigh
<b>Alternate Vice-Chair:</b>	Ms Eleanor Jolley
<b>REC Manager:</b>	Mrs Carol Ebenezer
<b>REC Assistant:</b>	Ms Zainab Ahmed
<b>Committee Address:</b>	Barlow House 3rd Floor 4 Minshull Street Manchester M1 3DZ
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## Chair's overview of the past year:

### **Committee Membership**

There have been some changes in the constitution of the REC over the past year, we have appointed a new Chair and Vice-Chair. Some REC members have come to the end of their office and we welcome some members from the Lancaster REC which recently closed. Currently we have 9 Expert Members (including the Chair & Vice Chair of the Committee), 2 Lay Plus Members and 2 Lay Members.

On a number of occasions this year we have had to co-opt members from other RECs to ensure that we were quorate for Full Committee meetings, may we thank Carol for ensuring that we are always quorate. Similarly, we have also had to co-opt members from other RECs to undertake some PR reviews (n=1). We would like to thank the co-opted members for their support throughout the year. We have successfully recruited more Lay-Plus members so that Mr Dave Abbotts does not need to undertake the majority of the PR and Sub-Committee work. We have devised a rota based system for PR so that the work can be spread out more evenly across the Committee, we will evaluate this in March 2018. The Sub Committee work is now mainly undertaken by the Chair and Vice-Chair. Despite the above issues the Committee and Sub-Committee have always remained quorate.

Carol continues to keep the Chair/Vice Chair in good order and to stated timescales, with reminders if necessary. She also ensures that the Committee runs smoothly and adheres to the REC SOPs. May the Committee thank Carol for her outstanding conscientiousness in keeping the Committee running smoothly.

### **Attendance of members**

Most members attend meeting as per allotted timescale per year. Some senior clinical staff sometimes find it difficult to attend full meetings but they supplement their attendance with PR. For the members who are at the lower end of what is required, the Chair reminds them of their duty of office to attend the appropriate number of meetings. Generally full meetings range between 4-6 applications

### **Training**

Members attend a range of training which should help them with regards to undertaking their duties on the Committee. These range from HRA training days, self-directed learning logs, to work-based learning.

### **Feedback**

We generally receive positive feedback from the researchers, especially those who attend the meetings. The thanks are usually related to the helpfulness of the Committee and the comments and suggestions that they receive with regards to their applications.

May we take this opportunity to thank the key staff we work with from Barlow House, especially to Carol and Zainab who provide excellent support to the REC members. Finally, thank you to all the REC members who give their time freely attending meetings and for the thorough preparation they obviously undertake, which ensures that each application is critically considered.

## 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	
Mr John Dalton	Consultant	Lay Plus	13/10/2005	31/07/2016
Professor Carol Haigh	Professor of Nursing	Expert	02/06/2014	
Ms Eleanor Jolley	Retired	Lay	01/10/2005	
Mrs Kate Kilshaw	Radiographer	Expert	25/09/2009	
Dr Rob Monks	Principal Lecturer in Nursing, Research and Innovation Lead	Expert	08/08/2009	
Mrs Susan Page	Senior Clinical Tutor	Expert	01/02/2017	
Mrs Sandra Perkins	Retired	Lay Plus	01/10/2016	08/01/2017
Professor Videsh Raut	Consultant Orthopaedic Surgeon	Expert	01/02/2007	
Dr Karen Rouse	Principal Postgrad Programmes	Lay Plus	01/02/2016	
Dr Gillian Thomson	(Ethics Advisor) Senior Researcher	Expert	01/10/2016	
Mrs Vasanthi Vasudevan	Diabetes Research Nurse	Expert	12/01/2012	
Dr Hawys Williams	Research Governance Officer	Lay	05/07/2013	
Dr Karen Wright	Head of School of Nursing	Expert	01/01/2015	

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

Name	Profession	Status	Meeting date attended
Mr Jimmy Burns	Retired	Lay	28/10/2016, 27/01/2017
Mr Christopher Houston	Retired	Lay Plus	23/09/2016
Dr Peter Owen	Retired Mathematics Lecturer	Lay Plus	22/07/2016, 23/09/2016
Dr Nader Touqan	Speciality Training Registrar - Surgery	Expert	24/06/2016
Dr Brenda Ashcroft	Expert Witness	Expert	27/01/2017
Mrs Susan Page	Senior Clinical Tutor	Expert	27/01/2017
Ann Williams	Senior Improvement Officer	Lay Plus	PRSC 27/05/2016
Gillian Rimington	Paralegal	Lay	PRSC 27/05/2016, 29/06/2017

**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	24/02/2017
Professor Anoop Chauhan	I hold shares in BTG, Vectura, and GSK. Consultant cardiologist Blackpool Teaching Hospitals.	08/12/2016
Professor Carol Haigh	On board of CTT (Childhood Tumour Trust)Edgehill University Ethics Faculty Head of Ethics MMU	27/01/2017
Ms Eleanor Jolley	none	27/01/2017
Mrs Kate Kilshaw	none	24/02/2017
Dr Rob Monks	I am a Principal Lecturer at the University of Lancashire and Research and Innovation Lead. Thus I work with research staff who sometimes submit ethical applications. If this happens I will declare any interest at the REC meeting. I will also declare any interest with regards to student applications.	06/12/2016
Mrs Susan Page	Sit on UCLAN ethics committee	10/12/2016
Professor Videsh Raut	Consultant to Bioventus Inc., USAI am on the Editorial Board and Reviewer of Articles for a number of International Peer- Reviewed Journals.	06/12/2016
Dr Karen Rouse	I am a principal lecturer in the School of Dentistry, College of Clinical and Biomedical Sciences, University of Central Lancashire. I am involved in research taking place in the school, also supervise PhD studies and NSc, BSc dissertation students.	06/12/2016
Dr Gillian Thomson	Involvement within an academic institution in terms of supporting/supervising postgraduate students, and liaising with academics in other institutions re funding applications/research studies.	12/10/2016
Mrs Vasanthi Vasudevan	Research Nurse, Diabetes and Cardiothoracic, Blackpool Victoria Hospitals, Whinney Heys Road, Blackpool. FY3 8NR	06/12/2016
Dr Karen Wright	Head of School of Nursing at the university of Central Lancashire	06/12/2016
Dr Hawys Williams	None	31/03/2017
Dr Brenda Ashcroft	None	31/03/2017

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

Month	Date	Number of Members Present at Meeting
April	22/04/2016	9
May	27/05/2016	8
June	24/06/2016	9
July	22/07/2016	9
September	23/09/2016	7
October	28/10/2016	9
November	25/11/2016	9
January	27/01/2017	9
February	24/02/2017	7
March	24/03/2017	11

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	29/04/2016	3
May	27/05/2016	4
June	29/06/2016	4
July	28/07/2016	3
September	29/09/2016	3
October	28/10/2016	3
November	22/11/2016	3
December	15/12/2016	3
January	16/01/2017	3
March	28/03/2017	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	01/04/2016	2
April	08/04/2016	2
April	15/04/2016	2
April	22/04/2016	2
April	29/04/2016	2
May	06/05/2016	2
May	13/05/2016	2
June	03/06/2016	2
June	10/06/2016	2
July	01/07/2016	2
July	22/07/2016	2

August	12/08/2016	2
September	02/09/2016	2
September	23/09/2016	2
September	30/09/2016	2
October	28/10/2016	2
November	04/11/2016	2
November	25/11/2016	2
December	02/12/2016	2
December	23/12/2016	2
January	20/01/2017	2
February	03/02/2017	2
February	24/02/2017	2
March	17/03/2017	2

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

**Details of inquorate meeting held:01 April 2016 - 31 March 2017**

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

<b>Name</b>	<b>Number of Meetings Attended</b>
Mr David Abbotts	7
Dr Brenda Ashcroft	1
Professor Anoop Chauhan	3
Professor Carol Haigh	9
Ms Eleanor Jolley	5
Mrs Kate Kilshaw	6
Dr Rob Monks	10
Mrs Susan Page	1
Sandra Perkins	2
Professor Videsh Raut	5
Dr Karen Rouse	9
Dr Gillian Thomson	3
Mrs Vasanthi Vasudevan	8
Dr Hawys Williams	2
Dr Karen Wright	7

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

<b>Name</b>	<b>Number of Meetings Attended</b>
Mr David Abbotts	4
Mr John Dalton	2
Professor Carol Haigh	8
Ms Eleanor Jolley	1
Dr Rob Monks	10
Dr Karen Rouse	1
Dr Hawys Williams	2
Dr Karen Wright	1

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

<b>Name</b>	<b>Number of Meetings Attended</b>
Mr David Abbotts	14
Professor Carol Haigh	9
Dr Rob Monks	24
Dr Patricia Wilkinson	1



**Training 01 April 2016 - 31 March 2017**

<b>Name of Member</b>	<b>Date</b>	<b>Event(s) attended</b>
Professor Anoop Chauhan	07/04/2016	Good Clinical Practice (Secondary Care)
Professor Carol Haigh	09/11/2016	Training for new REC chairs
Dr Rob Monks	11/05/2016	- Assessing the Consequences (benefits and harms) of Research
Dr Rob Monks	16/06/2016	Researcher Training Day
Mrs Susan Page	31/03/2017	Bad Pharma: How Medicine is Broken, and How We Can Fix It When Breath Becomes Air
Dr Karen Rouse	20/04/2016	Equality and Diversity
Dr Karen Rouse	15/09/2016	Member Induction
Dr Gillian Thomson	10/01/2017	Member Induction
Mrs Vasanthi Vasudevan	16/06/2016	Researchers Training Day
Mrs Vasanthi Vasudevan	27/09/2016	Human Tissue Act
Dr Karen Wright	12/07/2016	Adults lacking capacity
Dr Karen Wright	27/09/2016	Human Tissue Act - Introductory Level

## 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	46	100.00
<b>Total Applications Reviewed</b>	<b>46</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	0
Number of applications withdrawn prior to the meeting	0
Number of student applications reviewed	20
Number of paediatric applications reviewed	4
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**

<b>Decisions taken at meetings following review of applications</b>	<b>Number</b>	<b>%</b>
Favourable Opinion with Standard Conditions	2	4.35
Favourable Opinion with Additional Conditions	14	30.43
Unfavourable Opinion	3	6.52
Provisional Opinion	27	58.70
Provisional Opinion Pending Consultation with Referee	0	0.00
<b>Total</b>	<b>46</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	58.70
Further Information Favourable Opinion with Additional Conditions	0	0.00
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	2	4.35
Favourable Opinion with Additional Conditions	14	30.43
Unfavourable Opinion	3	6.52
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>46</b>	<b>100</b>

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

<b>Total Applications Reviewed</b>	<b>26</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	8
Number of studies withdrawn prior to the meeting	1
Number of student applications reviewed	14
Number of paediatric applications reviewed	4
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	14	53.85
Favourable Opinion with Additional Conditions	4	15.38
No Opinion transfer to full committee for review	2	7.69
Provisional Opinion	6	23.08
Unfavourable Opinion	0	0.00
<b>Total</b>	<b>26</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>	4.60
<b>Number of completed applications for full ethical review</b>	46
<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>	1
<b>Number of completed applications over 40 days as a % of total</b>	2.17%
<b>Number of days taken to final decision – average (mean)</b>	22
<b>Number of completed proportionate review applications for ethical review</b>	24
<b>Number of completed proportionate review applications for ethical review over 14 days (please note the timeline for proportionate review applications for ethical review was extended from 14 to 21 calendar days in December 2016)</b>	2
<b>Number of proportionate review applications for ethical review over 21 days</b>	1
<b>Number of completed proportionate review applications over 14 days as a % of total</b>	8.33%
<b>Number of SSAs (non-Phase 1) reviewed</b>	2
<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>	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>	0
<b>Number of completed substantial amendments over 28 days as a % of total substantial amendments</b>	0.00%
<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>	51

<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>	37
<b>Number of safety reports received</b>	0
<b>Number of Serious Adverse Events received</b>	0
<b>Number of final reports received</b>	15

**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>
16/NW/0273	EN- PENS for chronic neuropathic pain (version 1)	19
16/NW/0286	Using patient experiences to develop services for chronic pain.	19
16/NW/0299	SUPPORTED	37
16/NW/0320	Itch in psoriasis: central processing and the effect of levocetirizine	24
16/NW/0416	LiverPRIMEi & LiverPRIMEii	24
16/NW/0434	Supported self-management for follow-up care in gynaecological cancers	26
16/NW/0435	STELLAREX VASCULAR E-REGISTRY (SAVER)	18
16/NW/0491	Imaging Possible Appendicitis with CT	21
16/NW/0502	A novel approach using biospectroscopy for the Investigation of CVID	30
16/NW/0542	Hemianopia Adaptation Study (HAST) Version 2	31
16/NW/0555	INSIGHT: Information & Support Needs of Curative-Intent NSCLC patients	27
16/NW/0556	Evaluation of Lancashire and Cumbria Innovation Alliance Testbed	25
16/NW/0665	Psychopathy and developmental trauma V1	19
16/NW/0669	Sleep and aggression: understanding and intervening	25
16/NW/0685	SENSE-Cog Intervention Field Trial [version 1]	19
16/NW/0759	Evaluation: Implementating routine enquiry about childhood adversity	20
16/NW/0836	Endotypes in highly symptomatic COPD	22
16/NW/0844	Cross-education for proximal humerus fracture rehabilitation	17
17/NW/0080	Diagnostic and prognostic value of aCCP and RF isotypes in RA (V1)	20
17/NW/0081	NMES of the calf and thigh in OA knee - version 1.0	25
17/NW/0130	Development of an internet / mobile phone service pathway for T2DM	23
17/NW/0131	Enterogel <sup>®</sup> in the treatment of atopic dermatitis in adults (v.1.0)	29
17/NW/0134	Experiences of Supporting a Partner through Heart Transplant	24
17/NW/0143	WAKIX PASS -Post Authorisation Safety Study	46
17/NW/0193	IntAct- IFA to prevent anastomotic leak in rectal cancer surgery	30
17/NW/0199	Older People's Day Care - Feasibility	16
17/NW/0201	Adapting invitation letters to increase cervical screening attendance	15

<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
16/NW/0277	The diagnostic use of plasma CRP in intrapartum/postpartum sepsis 1.0	18
16/NW/0773	HOAX: A cross-media project to tackle stigma in mental health	20

**Favourable Opinion with Additional Conditions**

REC Reference	Title	Number of Days on Clock
16/NW/0432	A public health service to promote safe sex	17
16/NW/0489	Barriers and facilitators of physical activity in stroke survivors 1	18
16/NW/0494	Obesity Paradox and Epigenetics in Cardiac Surgery	15
16/NW/0546	Prediction of Lupus treatment response Study (PLANS)	19
16/NW/0687	INC-HHD	14
16/NW/0692	BIO MASTER.Ilivia Family / Plexa	18
16/NW/0775	The influence of educational materials :a phenomenological study	16
16/NW/0782	Gestational diabetes	10
16/NW/0824	Plastic vs glass capillary tubes for neonatal blood gas sampling (V1)	16
16/NW/0848	Skin Testing for Atopic eczema Risk (STAR)	29
17/NW/0066	Patients' Experiences of Psoriasis-related Social Interactions (PEPSI)	20
17/NW/0140	The Role of Eosinophils and Basophils in Chronic Spontaneous Urticaria	20
17/NW/0191	subjective experiences of symptoms of schizophrenia version 1.0	21
17/NW/0200	To what extent does social support influence alcohol dependency	9

**Unfavourable Opinion**

REC Reference	Title	Number of Days on Clock
16/NW/0317	DevPROMs	19
16/NW/0554	HOAX: A cross-media project to tackle stigma in mental health	19
17/NW/0070	Older People's Day Care - Feasibility	20

**Provisional Opinion**



REC Reference	Title	Number of Days on Clock
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#### Provisional Opinion Pending Consultation with Referee

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

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

REC Reference	Title	Number of Days on Clock
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**Table 9.2: Breakdown of current status of all PRS applications reviewed within the reporting period**

#### Further Information Favourable Opinion with Standard Conditions

REC Reference	Title	Number of Days on Clock
16/NW/0523	Comparing the sensory acuity of diabetes and non-diabetes populations	7
16/NW/0594	Dynamic lip function of cleft patients	7
16/NW/0796	Role of maternal adverse/risk outcomes on offspring's body composition	5
16/NW/0800	The implementation of the Open Dialogue approach in the UK	13
16/NW/0855	Patients' & Health Professionals' views on post-surgical pain relief	19
17/NW/0048	What factors influence clinical decision making in heart failure.	29

#### Further Information Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
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#### Further Information Unfavourable Opinion

REC Reference	Title	Number of Days on Clock
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<b>Favourable Opinion with Standard Conditions</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
16/NW/0443	Pharmacists management of allergic rhinitis	12
16/NW/0444	The Tip of the Iceberg	11
16/NW/0457	Accuracy of 3D computer generated models from DBT images	6
16/NW/0520	Physiotherapy amenable pulmonary complications V1.0	7
16/NW/0527	Detection rate of Atrial Fibrillation in patients implanted with ILRs	7
16/NW/0793	Views and experiences of patients using the exercise app 'Salaso'	5
16/NW/0853	Investigating effects of IL-1Ra on B-cell function after stroke	2
16/NW/0895	Physical activity feasibility study in breast cancer survivors	6
17/NW/0052	Measuring the impacts of Sexually Transmitted Infections (STIs).	3
17/NW/0063	Assessing the Outcomes of Foot and Ankle Surgery. Version 1	3
17/NW/0065	Injectate Distribution in Cadaveric Lateral Elbow Tendons	3
17/NW/0203	The Diabetes Essentials Care Survey	2
17/NW/0204	Orthodontic Longitudinal Cohort	2
17/NW/0205	Tomographic ultrasound imaging of vascular disease	5

<b>Favourable Opinion with Additional Conditions</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
16/NW/0362	XALKORI PASS Survey	10
16/NW/0595	Living well with insulin-dependent diabetes in adolescence	6
16/NW/0850	Prevalence of periodontal disease, erosion and sensitivity, v1	3
16/NW/0897	Coronary Physiology	11

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

<b>Provisional Opinion</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 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>
11/NW/0308/AM04	Does Carotid Artery Plaque Volume and Morphology predict Stroke? V1	3	28/04/2016	6
13/NW/0400/AM04	CIUDo: Clinical Utility of Capsaicin Dose Response Curves	4	21/09/2016	6
13/NW/0554/AM01	The Parkinson's Pain Study	1	13/12/2016	1
14/NW/0034/AM06	Individual risk based screening for diabetic retinopathy: WS E	3	25/05/2016	4
14/NW/0230/AM07	DeCoDeR Debt Counselling for Depression Randomised Controlled Trial	6	08/03/2016	11
14/NW/0252/AM01	Mutational markers for Barrett's progression	1	11/08/2016	10
14/NW/1146/AM03	The UK-PBC Nested Cohort Study (version 1)	2	05/08/2016	1
14/NW/1146/AM04	The UK-PBC Nested Cohort Study (version 1)	3	17/02/2017	5
14/NW/1192/AM02	TechCare	2	23/11/2016	5
14/NW/1392/AM02	Randomised Trial into Prevention of Preterm Birth: Feasibility Study	2	05/07/2016	8
15/NW/0078/AM01	Tumour Characterisation to Guide Experimental Targeted Therapy	1	11/11/2016	14
15/NW/0158/AM05	IN RESPOND	3	11/05/2016	22
15/NW/0158/AM07	IN RESPOND	4	24/11/2016	6
15/NW/0163/AM05	PATHWAY VERSION 1 DATE 13/02/2015 (RP-PG-1211-20011)	5	09/05/2016	2
15/NW/0163/AM09	PATHWAY VERSION 1 DATE 13/02/2015 (RP-PG-1211-20011)	6	22/08/2016	11
15/NW/0193/AM01	EndoStim PATIENT REGISTRY CS500	1	01/12/2016	4
15/NW/0198/AM05	The Walkability Post Stroke Study	5	06/05/2016	5
15/NW/0236/AM05	GM-11: gammaCore nVNS episodic migraine study	5	23/03/2016	9
15/NW/0236/AM06	GM-11: gammaCore nVNS episodic migraine study	6	13/04/2016	7
15/NW/0236/AM10	GM-11: gammaCore nVNS episodic migraine study	7	14/10/2016	14
15/NW/0330/AM01	Recovery focused CBT for older adults with bipolar disorder	1	17/01/2017	7
15/NW/0330/AM02	Recovery focused CBT for older adults with bipolar disorder	2	02/02/2017	6
15/NW/0330/AM03	Recovery focused CBT for older adults with bipolar disorder	3	15/02/2017	1
15/NW/0347/AM03	Web Support for Exercise Referral Schemes (e-coachER) version 1.0	3	23/03/2016	7

15/NW/0347/AM04	Web Support for Exercise Referral Schemes (e-coachER) version 1.0	4	16/01/2017	9
15/NW/0476/AM01	Psoriasis and emotional response following treatment (PsERT)	1	26/01/2016	9
15/NW/0511/AM02	SUPERSTARCh Version 1.0	1	08/08/2016	3
15/NW/0590/AM02	PRODIGY (Definitive RCT): Version 1	2	04/04/2016	2
15/NW/0593/AM03	MBCT for social anxiety in visible skin conditions	3	13/04/2016	7
15/NW/0746/AM01	Reveal LINQ In-Office 2 (RIO 2) International Study	1	26/04/2016	1
15/NW/0749/AM02	SOFIA	2	04/10/2016	9
15/NW/0944/AM02	Content of UK palliative care day services	version 4	26/04/2016	10
15/NW/0949/AM01	A qualitative study exploring women's confidence for birth	2	05/04/2016	0
16/NW/0042/AM01	Carer experiences of providing bladder & bowel care in palliative care	1	27/06/2016	1
16/NW/0047/AM01	Audiologist-delivered psychological intervention for tinnitus	1	19/08/2016	7
16/NW/0047/AM02	Audiologist-delivered psychological intervention for tinnitus	2	19/09/2016	1
16/NW/0050/AM01	Development of questionnaires to assess health beliefs in OCD	1	29/04/2016	4
16/NW/0050/AM02	Development of questionnaires to assess health beliefs in OCD	2	12/12/2016	5
16/NW/0057/AM03	Distributed toothpaste & toothbrushing programme for at risk children	2	08/09/2016	11
16/NW/0057/AM04	Distributed toothpaste & toothbrushing programme for at risk children	3	10/01/2017	7
16/NW/0163/AM01	EDDMO Version 1	v3	07/10/2016	13
16/NW/0209/AM01	Evaluation of fetal growth in pregnancies complicated by diabetes	1	18/04/2016	2
16/NW/0210/AM01	ToAST; Investigating the effects of bronchial thermoplasty on cough	1	08/09/2016	16
16/NW/0273/AM01	EN- PENS for chronic neuropathic pain (version 1)	1	20/10/2016	5
16/NW/0277/AM01	The diagnostic use of plasma CRP in intrapartum/postpartum sepsis 1.0	1	17/06/2016	6
16/NW/0432/AM02	A public health service to promote safe sex	1	15/01/2017	7
16/NW/0520/AM01	Physiotherapy amenable pulmonary complications V1.0	1	05/07/2016	14
16/NW/0546/AM02	Prediction of Lupus treatment response Study (PLANS)	1	19/12/2016	13
16/NW/0546/AM03	Prediction of Lupus treatment response Study (PLANS)	2	05/02/2017	6
16/NW/0687/AM01	INC-HHD	1.1	26/01/2017	5
16/NW/0692/AM01	BIO MASTER.Illivia Family / Plexa	1	14/11/2016	3

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

REC Reference	Title	Number of Days on Clock
17/NW/0048	What factors influence clinical decision making in heart failure.	29

**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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