

**North West - Preston Research Ethics Committee**

**Annual Report**

**01 April 2015 - 31 March 2016**



## 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>	Vacant
<b>Alternate Vice-Chair:</b>	Ms Eleanor Jolley
<b>REC Manager:</b>	Mrs Carol Ebenezer
<b>REC Assistant:</b>	Ms Zainab Ahmed – from April 2016 Regina Caden up to March 2016
<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 as two members have completed their term of office and two new members have been recruited to the Committee. Currently we have 7 Expert Members (including the Chair of the Committee), 3 Lay Plus Members and 2 Lay Members. The Chair of the committee completed her term of office in September 2015 but kindly undertook a further 6 months' service, finally ending her role on the Committee on the 31<sup>st</sup> March 2016. The Committee would like to thank Dr Patricia Wilkinson for her outstanding contribution to the Preston REC which has spanned 10.5 years. Ms Debbie Foord also left the Committee after 10 years of excellent service, and we would like to thank Debbie for her contribution to the Committee and give her our best wishes as she takes up a position on the Lancaster REC. We welcome two new members to the Committee Dr Karen Wright (Expert) and Dr Karen Rouse (Lay Plus), they are being closely mentored by the Chair (RM) to help them to settle into the Committee. Dr Rob Monks has now moved from Vice-Chair to Chair of the Committee. We are currently actively seeking to recruit a Vice Chair from the current REC members.

On a number of occasions this year (6) we have had to co-opt members from other REC's to ensure that we were quorate for Full Committee meetings. Similarly, we have also had to co-opt members from other RECs to undertake some PR reviews (3). We would like to thank the co-opted members for their support throughout the year. We are seeking to recruit another Lay-Plus member as Mr Dave Abbotts is currently undertaking a significant proportion of PR and Sub-Committee work. The Chair would like to thank Dave for undertaking this work in this interim period until we recruit a Vice Chair and new Lay Plus members. The Sub Committee work seems to be mainly myself with 2 or 3 other people being involved. We do encourage all members to share the workload with varying success; we may revisit the way PR is distributed in the coming year once we recruit new members. Despite the above issues the Committee has always remained quorate. The REC Assistant Regina left this year and we would like to thank her for all her hard work and wish her well in her new post. Ms Zainab Ahmed is our new REC Assistant and she appears to settling into the role very well.

Carol continues to keep the 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 and tireless work.

### **Attendance of members**

Most members attend between 7-9 meetings per year, some members are at the lower end of what is required and 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 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. We recently received a letter of gratitude from a researcher who could not attend but who we had communications with over the Phone. She thanked us for our comments, help, suggestions and courteousness. Moreover, at the Operational Management Group meeting there was a review of the Annual Management Information data for the last financial year. It was acknowledged that 'our Committee is one of only thirteen Committees in England that has met the Key Performance Indicators for Full REC Review, Proportionate Review and Substantial Amendments over 95% of the time'. Mrs Margaret Hutchinson, Deputy Regional Manager attended the meeting for observance and we are waiting formal feedback.

Finally, a very big thank you to all the staff at Barlow House, especially to Carol and Zainab, who provide excellent support for meetings, sub-Committees, communications with applicants and members, and all the many other activities which ensure the research ethics process runs as smoothly as practicable. 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 fervent consideration is given to each application.

## North West - Preston Research Ethics Committee Membership

Name	Profession	Expert or Lay	Dates	
			Appointed	Left
Mr David Abbotts	Retired Lay member	Lay Plus	13/09/2010	
Professor Anoop Chauhan	Consultant Cardiologist	Expert	10/07/2008	
Mr John Dalton	Consultant	Lay Plus	13/10/2005	
Mrs Debbie Foord	Community Psychiatric Nurse	Expert	01/10/2005	30/09/2015
Professor Carol Haigh	Professor of Nursing	Expert	02/06/2014	
Ms Eleanor Jolley	Lay Member	Lay	01/10/2005	
Mrs Kate Kilshaw	Radiographer	Expert	25/09/2009	
Dr Rob Monks	Principial Lecturer in Health Sciences	Expert	08/08/2009	
Professor Videsh Raut	Consultant Orthopaedic Surgeon	Expert	01/02/2007	
Dr Karen Rouse	Senior Lecturer/Clinical Education Coordinator	Lay Plus	01/02/2016	
Mrs Vasanthi Vasudevan (break in service)	Diabetes Research Nurse	Expert	12/01/2012	
Dr Patricia Wilkinson	General Practitioner/Chair	Expert	01/10/2005	31/03/2016
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
James Burns	Retired consultant	Lay	Sept, Oct 2015, Jan March 2016
Sue Fitzpatrick	Director	Lay	Oct 2015
Val Skinner	Retired Nurse	Lay	June, July, Sept 2015 and May 2015 PRS
Peter Walton	Retired Lecturer	Lay	July 2015
Hannah Chambers	Retired Nurse	Lay	June 2015 PRS
Gillian Rimington	Paralegal	Lay	Dec 2015 PRS

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

<b>Name</b>	<b>Declaration of Interest</b>	<b>Date</b>
Professor Anoop Chauhan	Shareholdings in GSK, BTG and Vectura. Consultant Cardiologist, Blackpool Teaching Hospitals. Involved in research at Blackpool Teaching Hospitals.	01/02/2016
Mr John Dalton	Owner Stonehill Consultants Ltd. Any connection with, including the position of authority, in a charity or voluntary body in the field of health and social care involved in or possibly seeking to be involved in the conduct of research - Genital Autonomy and 15 Square.	01/02/2016
Professor Carol Haigh	Reviewer for NIHR Faculty head of Health, faculty health Psychology & Social Care MMUI	22/12/2015
Ms Eleanor Jolley	None	01/02/2016
Mrs Kate Kilshaw	None	01/02/2016
Dr Rob Monks	Senior Lecturer at the University of Central Lancashire	22/12/2015
Professor Videsh Raut	Consultant to Bioventus Inc. Consultancy with GLC. Consultancy with Alphasights. Shares in a number of companies.	01/02/2016
Dr Karen Rouse	Senior lecturer in the School of Dentistry, college of clinical and biomedical sciences, University of Central Lancashire Involved in research in the school and supervisor of dissertation students	04/02/2016
Mrs Vasanthi Vasudevan	Research Nurse Blackpool Victoria Hospital, Clinical Research Nurse	31/03/2016
Dr Patricia Wilkinson	none	22/12/2015
Dr Karen Wright	Private consultancy work for the Priory Hospital (clinical supervision /NUBE consultancy).	01/02/2016
Dr Hawys Williams	Works in patient and public involvement and engagement within the University of Manchester.	31/03/2016

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

Month	Date	Number of Members Present at Meeting
April	24/04/2015	8
June	26/06/2015	8
July	24/07/2015	8
August	28/08/2015	9
September	25/09/2015	8
October	23/10/2015	8
November	27/11/2015	10
January	22/01/2016	9
February	26/02/2016	10
March	18/03/2016	7

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	24/04/2015	4
May	22/05/2015	3
June	26/06/2015	3
July	24/07/2015	3
August	21/08/2015	5
September	25/09/2015	3
October	23/10/2015	7
November	27/11/2015	3
December	15/12/2015	3
March	31/03/2015	3

10 proportionate review sub-committee meetings were held during the reporting period.

### Sub-Committee Meetings held during 01 April 2015 - 31 March 2016:

Month	Date	Number of Members Present at Meeting
April	10/04/2015	2
April	17/04/2015	2
May	08/05/2015	2
May	29/05/2015	2
June	05/06/2015	2
June	12/06/2015	2
July	03/07/2015	2
July	10/07/2015	2
July	17/07/2015	2
July	31/07/2015	2
August	14/08/2015	2

August	21/08/2015	2
August	28/08/2015	2
September	04/09/2015	2
September	11/09/2015	2
October	02/10/2015	2
October	16/10/2015	2
October	23/10/2015	2
November	13/11/2015	2
November	20/11/2015	2
November	27/11/2015	2
December	04/12/2015	2
December	11/12/2015	2
December	18/12/2015	2
December	24/12/2015	2
January	08/01/2016	2
January	29/01/2016	2
February	05/02/2016	2
February	12/02/2016	2
February	19/02/2016	2
February	26/02/2016	3
March	04/03/2016	2
March	24/03/2016	2

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

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

None

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

<b>Name</b>	<b>Number of Meetings Attended</b>
Mr David Abbotts	8
Professor Anoop Chauhan	6
Mr John Dalton	3
Mrs Debbie Foord	4
Professor Carol Haigh	8
Ms Eleanor Jolley	8
Mrs Kate Kilshaw	7
Dr Rob Monks	9
Professor Videsh Raut	3
Dr Karen Rouse	1
Dr Patricia Wilkinson	7
Dr Hawys Williams	5
Dr Karen Wright	7

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

<b>Name</b>	<b>Number of Meetings Attended</b>
Mr David Abbotts	6
Professor Anoop Chauhan	1
Mrs Debbie Foord	1
Professor Carol Haigh	5
Ms Eleanor Jolley	1
Dr Rob Monks	6
Professor Videsh Raut	3
Dr Patricia Wilkinson	9
Dr Hawys Williams	2

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

<b>Name</b>	<b>Number of Meetings Attended</b>
Mr David Abbotts	2
Dr Rob Monks	31
Dr Patricia Wilkinson	33



**Training 01 April 2015 - 31 March 2016**

<b>Name of Member</b>	<b>Date</b>	<b>Event(s) attended</b>
Professor Anoop Chauhan	25/08/2015	Equality and Diversity on line training
Professor Anoop Chauhan	31/03/2016	Self-directed learning log Children and clinical research ethical issues' produced by the Nuffield Council on Bioethics, 2015.
Professor Carol Haigh	29/05/2015	Equality and Diversity
Professor Carol Haigh	30/03/2016	Self-Directed Learning Log Edge Hill University's University ethics committee HTA training session held at Edge Hill university Ran fringe event on publication ethics for health care
Mrs Kate Kilshaw	30/06/2015	Human Tissue Act
Dr Rob Monks	22/05/2015	Equality and Diversity
Dr Rob Monks	09/12/2015	National Chairs Training Day
Professor Videsh Raut	31/03/2016	Self-directed learning log Raining in my heart. TV documentary on GOSH and inclusion of children in cancer trials Children and clinical research ethical issues Nuffield bioethics council report
Dr Karen Rouse	17/02/2016	on line member induction training
Dr Karen Rouse	04/03/2016	Public Patient Involvement (Jim Elliott)
Dr Patricia Wilkinson	22/10/2015	Equality and Diversity
Dr Patricia Wilkinson	09/12/2015	National Chairs Training Day
Dr Hawys Williams	30/07/2015	Equality and Diversity

## 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	49	100.00
<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	0
Number of applications withdrawn prior to the meeting	1
Number of student applications reviewed	24
Number of paediatric applications reviewed	7
Number of device applications reviewed	3
Number of prisoner applications reviewed	2
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	12

**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	10	20.41
Unfavourable Opinion	2	4.08
Provisional Opinion	34	69.39
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	31	63.27
Further Information Favourable Opinion with Additional Conditions	1	2.04
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	3	6.12
Favourable Opinion with Additional Conditions	10	20.41
Unfavourable Opinion	2	4.08
Provisional Opinion	1	2.04
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	2.04
<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	5
Number of studies withdrawn prior to the meeting	3
Number of student applications reviewed	17
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	10	32.26
Favourable Opinion with Additional Conditions	13	41.94
No Opinion transfer to full committee for review	2	6.45
Provisional Opinion	6	19.35
Unfavourable Opinion	0	0.00
<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>	48
<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>	0
<b>Number of completed applications over 40 days as a % of total</b>	0.00%
<b>Number of days taken to final decision – average (mean)</b>	24
<b>Number of completed proportionate review applications for ethical review</b>	29
<b>Number of completed proportionate review applications for ethical review over 14 days</b>	0
<b>Number of completed proportionate review applications over 14 days as a % of total</b>	0.00%
<b>Number of SSAs (non-Phase 1) reviewed</b>	5
<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>	58
<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>	2
<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>	29
<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>	56
<b>Number of safety reports received</b>	0

<b>Number of Serious Adverse Events received</b>	2
<b>Number of final reports received</b>	37

**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/0330	Recovery focused CBT for older adults with bipolar disorder	18
15/NW/0347	Web Support for Exercise Referral Schemes (e-coachER) version 1.0	20
15/NW/0348	Blood Coagulation Device	20
15/NW/0349	Focus group to develop positive psychology app	27
15/NW/0515	Understanding the self-harm of others	22
15/NW/0531	Protective Factors for Mental Health Difficulties in Young People	20
15/NW/0593	MBCT for social anxiety in visible skin conditions	22
15/NW/0600	Knowledge of epilepsy during transition for young people with epilepsy	21
15/NW/0612	Cough frequency and patterns in children.	32
15/NW/0643	The six month post-stroke review for care home residents (Version 1)	27
15/NW/0646	An Observational Registry of Abatacept in Patients with JIA	26
15/NW/0659	Reflecting on an attempted suicide	24
15/NW/0743	Male prisoners' experiences of psychological formulation	22
15/NW/0746	Reveal LINQâ„¢ In-Office 2 (RIO 2) International Study	33
15/NW/0749	SOFIA	24
15/NW/0757	A diagnostic accuracy study comparing Duplex ultrasound and Transonics	21
15/NW/0762	MUIMME	22
15/NW/0790	Patient involvement in diagnosing cancer in primary care	25
15/NW/0840	Parental participation in decision-making in NICU	17
15/NW/0908	Contrast Enhanced Ultrasound, Endoleak Detection following EVAR v1.3	23
15/NW/0911	PET-CT in Idiopathic Pulmonary Fibrosis	26
15/NW/0920	Post-diagnostic support for people with dementia	20
16/NW/0042	Carer experiences of providing bladder & bowel care in palliative care	26
16/NW/0046	Attachment styles in 16-19yr old CKD patients	26
16/NW/0047	Audiologist-delivered psychological intervention for tinnitus	21
16/NW/0050	Development of questionnaires to assess health beliefs in OCD	26
16/NW/0051	The EXTOD Mechanisms study	30
16/NW/0057	Distributed toothpaste & toothbrushing programme for at risk children	21
16/NW/0132	Ammonia breath test studies	30
16/NW/0135	SATIN Satiety Diet - Proof of Concept V7	32
16/NW/0138	Powered Vascular Stapler in Video-Assisted Thoracoscopic Lobectomies	26

<b>Further Information Favourable Opinion with Additional Conditions</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
15/NW/0642	Daily Activities Project Version 1	26

<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>
15/NW/0476	Psoriasis and emotional response following treatment (PsERT)	35
15/NW/0517	Impact of a peer delivered psycho-educational video on self-stigma	18
16/NW/0061	ISDR WS F phase II version 1	25

<b>Favourable Opinion with Additional Conditions</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
15/NW/0289	How is tuberculosis immunity altered by household air pollution TB-HAP	28
15/NW/0511	SUPERSTAR Version 1.0	18
15/NW/0538	Parents and Carers Experiences of the Incredible Years baby programme	18
15/NW/0590	PRODIGY (Definitive RCT): Version 1	15
15/NW/0630	Experiences of patients with Idiopathic Pulmonary Fibrosis (IPF)	21
15/NW/0653	Smartphone imaging the retina for glaucoma screening and monitoring	21
15/NW/0921	Living well with young onset dementia	15
15/NW/0928	The effects of old and new dialysis modalities on drug kinetics	14
16/NW/0163	EDDMO Version 1	25
16/NW/0209	Evaluation of fetal growth in pregnancies complicated by diabetes	25

<b>Unfavourable Opinion</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
16/NW/0136	Exploring Mood Fluctuations	25
16/NW/0194	The Neurodevelopmental outcome of Complicated Twin Pregnancies	25



<b>Provisional Opinion</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
16/NW/0210	ToAST; Investigating the effects of bronchial thermoplasty on cough	n/a

<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>
15/NW/0557	Effect of Female Hormones on Tinnitus: A Feasibility Study	35

**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/0363	Neuropathic pain medications and their effect on the ability to drive.	13
15/NW/0635	Enhancing diagnosis and prevention of CV disease in Newham	6
15/NW/0701	Glycaemic influences on FGF23/PTH/Vitamin D in Diabetes	12
16/NW/0244	The impact of executive functioning on attention to threat	8
16/NW/0265	Accelerated Platform 2	8

<b>Further Information Favourable Opinion with Additional Conditions</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
15/NW/0455	Prescribing, dispensing and administration of oral prednisolone	4

<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>
15/NW/0362	Physiological response to IV paracetamol in critically ill patients V1	6
15/NW/0370	Exploring technology use by those living with motor neurone disease	7
15/NW/0456	Reactivation of varicella zoster virus and risk of vascular disease	2
15/NW/0559	Hypoxia gene signature as a biomarker in prostate cancer	7
15/NW/0633	LAA thrombi prevalence by TOE - Correlation with CHA2DS2-VASC score	5
15/NW/0782	Are women having VBAC predisposed to sustaining OASIS?	8
15/NW/0799	Urinary micronutrient profile as AKI biomarker in coronary angiography	7
15/NW/0850	Predicting Hearing Aid Benefit	5
15/NW/0855	Colorectal signet ring cell carcinoma molecular path study	7
15/NW/0940	Calcium Phosphate Crystal Screening for Aortic Stenosis Pilot Study	7

<b>Favourable Opinion with Additional Conditions</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
15/NW/0372	Dreaming autoimmunity	5
15/NW/0445	Response to synacthen test in women with PCOS	6
15/NW/0563	Evaluation of a phase-based treatment for complex PTSD - v.1	7
15/NW/0632	bioCSL Influenza Vaccine PASS 2015	6
15/NW/0634	Closer to Home chemotherapy for Haemato-oncology patients	6
15/NW/0688	Shared decision making within goal setting in intermediate care	3
15/NW/0689	Paediatric Granulomatous Arthritis Outcome Cohort Study	6
15/NW/0789	The Liver project: The life-cycle of service reconfiguration	8
15/NW/0796	ImRs: Mechanisms of Action in Treatment for PTSD (Version One)	8
15/NW/0853	SLS: Follow-up Interviews on Patient-Centred Outcomes (Asthma)	11
15/NW/0944	Content of UK palliative care day services	6
15/NW/0949	A qualitative study exploring women's confidence for birth	5
15/NW/0983	Exploring walking in people with intermittent claudication	9

**Unfavourable Opinion**

REC Reference	Title	Number of Days on Clock
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**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>
10/H1016/25/AM06	A protocol for donation of blood and urine samples	Amendment 6	29/02/2016	3
13/NW/0202/AM11	Incinerators Biomonitoring Study-Version 1	11	05/05/2015	0
13/NW/0357/AM01	Monitoring of metal-backed glenoid components using RSA	1	20/05/2015	5
13/NW/0357/AM02	Monitoring of metal-backed glenoid components using RSA	2	29/07/2015	9
13/NW/0400/AM03	CIUDo: Clinical Utility of Capsaicin Dose Response Curves	3.0	28/08/2015	0
13/NW/0859/AM01	Detecting muscle twitches with ultrasound imaging	1	30/11/2015	4
14/NW/0034/AM04	Individual risk based screening for diabetic retinopathy: WS E	2	18/11/2015	2
14/NW/0041/AM04	Cognitive therapy Or Medication for Psychosis: A Randomised Evaluation	4	07/10/2015	2
14/NW/0121/AM12	An exploratory study to establish a rhinovirus challenge model	2	06/08/2015	7
14/NW/0170/AM02	Investigating outcome in children with CFS/ME	2	17/03/2015	6
14/NW/0230/AM05	DeCoDeR Debt Counselling for Depression Randomised Controlled Trial	5	01/05/2015	6
14/NW/0328/AM02	Auditory Function in Diabetes	1	17/10/2015	11
14/NW/0341/AM04	Alopecia areata and emotions	3	17/09/2015	11
14/NW/1048/AM02	E-PUFA Study (version 1)	2	20/08/2015	6
14/NW/1051/AM01	Transcripts in Nasal Angiofibroma (TiNA study)	1	01/04/2015	5
14/NW/1125/AM02	Ultrasound& Capillaroscopy to measure scleroderma finger ulcers	1	20/08/2015	7
14/NW/1146/AM02	The UK-PBC Nested Cohort Study (version 1)	1	13/01/2016	7
14/NW/1192/AM01	TechCare	1	08/09/2015	6
14/NW/1272/AM01	SCRIPT: Skin Change Risk In Patients after Transplant	1	02/09/2015	4
14/NW/1389/AM01	Investigating MBCT mechanisms	1	01/06/2015	1
14/NW/1389/AM02	Investigating MBCT mechanisms	2	26/08/2015	6
14/NW/1389/AM03	Investigating MBCT mechanisms	3	04/11/2015	4
14/NW/1392/AM01	Randomised Trial into Prevention of Preterm Birth: Feasibility Study	1	29/07/2015	8
14/NW/1408/AM02	Decision-making in breast cancer prevention: The ENGAGE study	2	17/07/2015	3
14/NW/1463/AM01	Feasibility RCT of ACT self-help for depression in haemodialysis	1	27/07/2015	4

14/NW/1467/AM01	Respiratory Virus Point-Of-Care Testing Pilot (ResPOC Trial) v1.0	1	09/07/2015	8
14/NW/1467/AM02	Respiratory Virus Point-Of-Care Testing Pilot (ResPOC Trial) v1.0	2	02/02/2016	2
15/NW/0087/AM02	FreeStyle Libre Pro Use in Primary and Secondary Care; Revision A	2	21/05/2015	6
15/NW/0092/AM02	Comprehensive moUth-care to reduce Post-operative Pneumonia (CUPPA)	1	08/07/2015	9
15/NW/0158/AM02	IN RESPOND	1	17/06/2015	1
15/NW/0158/AM04	IN RESPOND	2	02/02/2016	3
15/NW/0163/AM01	PATHWAY VERSION 1 DATE 13/02/2015 (RP-PG-1211-20011)	1	07/04/2015	4
15/NW/0163/AM02	PATHWAY VERSION 1 DATE 13/02/2015 (RP-PG-1211-20011)	2	26/05/2015	3
15/NW/0163/AM03	PATHWAY VERSION 1 DATE 13/02/2015 (RP-PG-1211-20011)	Third Amendment	24/06/2015	1
15/NW/0163/AM04	PATHWAY VERSION 1 DATE 13/02/2015 (RP-PG-1211-20011)	4	24/08/2015	9
15/NW/0195/AM01	Is aspirin use associated with reduced growth of VS? V1	1	07/04/2015	5
15/NW/0198/AM02	The Walkability Post Stroke Study	2	03/06/2015	1
15/NW/0198/AM03	The Walkability Post Stroke Study	3	06/07/2015	2
15/NW/0198/AM04	The Walkability Post Stroke Study	4	18/03/2016	3
15/NW/0236/AM01	GM-11: gammaCore nVNS episodic migraine study	1.0	27/05/2015	5
15/NW/0236/AM02	GM-11: gammaCore nVNS episodic migraine study	2.0	04/08/2015	8
15/NW/0236/AM03	GM-11: gammaCore nVNS episodic migraine study	3.0	13/10/2015	8
15/NW/0236/AM04	GM-11: gammaCore nVNS episodic migraine study	4	12/02/2016	7
15/NW/0278/AM01	Ambulatory fetal heart rate monitoring in small babies	1	15/02/2016	0
15/NW/0347/AM01	Web Support for Exercise Referral Schemes (e-coachER) version 1.0	01	18/06/2015	6
15/NW/0347/AM02	Web Support for Exercise Referral Schemes (e-coachER) version 1.0	2	20/11/2015	13
15/NW/0349/AM01	Focus group to develop positive psychology app	1	04/09/2015	4
15/NW/0517/AM01	Impact of a peer delivered psycho-educational video on self-stigma	1	17/08/2015	6
15/NW/0517/AM02	Impact of a peer delivered psycho-educational video on self-stigma	2	20/01/2016	3

15/NW/0590/AM01	PRODIGY (Definitive RCT): Version 1	1	12/02/2016	8
15/NW/0593/AM01	MBCT for social anxiety in visible skin conditions	1	20/11/2015	7
15/NW/0593/AM02	MBCT for social anxiety in visible skin conditions	2	04/01/2016	1
15/NW/0643/AM01	The six month post-stroke review for care home residents (Version 1)	1	22/09/2015	8
15/NW/0749/AM01	SOFIA	1	26/02/2016	3
15/NW/0790/AM01	Patient involvement in diagnosing cancer in primary care	1	03/02/2016	4
15/NW/0853/AM01	SLS: Follow-up Interviews on Patient-Centred Outcomes (Asthma)	1	10/11/2015	8
16/NW/0057/AM01	Distributed toothpaste & toothbrushing programme for at risk children	1	09/02/2016	5

#### Unfavourable opinion

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
09/H1016/126/AM10	Validation of risk assessments for patients from MSS (VoRAMSS)	7	13/11/2015	7

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

#### Favourable opinion timeline

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
09/H1016/126/AM10/1	Validation of risk assessments for patients from MSS (VoRAMSS)	7	24/11/2015	2
14/NW/1048/AM01/1	E-PUFA Study (version 1)	1	01/04/2015	8

#### 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 14 day timeline**

REC Reference	Title	Number of Days on Clock
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**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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