

**North West - Lancaster Research Ethics  
Committee**

**Annual Report**

**01 April 2015 - 31 March 2016**



## Part 1 – Committee Membership and Training

<b>Name of REC:</b>	North West - Lancaster Research Ethics Committee
<b>Type of REC:</b>	Authorised
<b>Type of Flag:</b>	Paediatrics
<b>Chair:</b>	Dr Lisa Booth
<b>Vice-Chair:</b>	Professor Jois Stansfield
<b>Alternate Vice-Chair:</b>	Dr Anas Olabi
<b>REC Manager:</b>	Mrs Carol Ebenezer
<b>REC Assistant:</b>	Ms Zainab Ahmed from April 2016 Miss Regina Caden up to March 2016
<b>Committee Address:</b>	Barlow House 3rd Floor 4 Minshull Street Manchester M1 3DZ
<b>Telephone:</b>	020 71048008
<b>Email:</b>	nrescommittee.northwest-lancaster@nhs.net

## Chair's overview of the past year:

We lost another long standing committee member this year Mrs Andrina Lawrence, who had taken a break for medical reasons, though decided not to return after her surgery. As chair I would like to thank Andrina for her long years of service on the committee. We gained two new members Mrs Debbie Foord and Mrs Grace Hurford, and Mrs Val Skinner, Mr David Barber and Mr Gary Whittle had their service extended by 12 months as they were coming to the end of their tenure and did not wish to move to another REC. Dr. Laura Machin had her status changed from expert to lay plus following a query from the REC Manager and the Regional Manager.

Nine full committee meetings were held, where 44 applications were reviewed (49 applications last year). In addition to this 35 sub-committee meetings were held, reviewing 32 PRS applications (29 applications in the previous year) and 87 substantial amendments (compared to 67 in the previous year). Therefore, although the number of full meetings has decreased, as well as the number of full applications reviewed, there is still an exponential increase in the overall work undertaken by the committee, particularly for those who take part in sub-committee work. Despite these increases the Lancaster REC has reviewed all applications within the time allocated, I would like to extend my thanks to the committee for all their hard work in achieving this.

Thank you to all the REC members who give their time to attending meetings and their preparation for these meetings. A very big thank you to the staff at Barlow House, 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 smoothly.

## North West - Lancaster Research Ethics Committee Membership

Name	Profession	Expert or Lay	Dates	
			Appointed	Left
Dr Brenda Ashcroft	Retired Lecturer	Expert	09/09/2009	
Mr David Barber	Pharmacist	Expert	01/10/2005	Membership extended
Dr Lisa Booth	Senior Lecturer / Chair	Expert	01/09/2006	
Mrs Debbie Foord	Retired Community Psychiatric Nurse	Lay	01/10/2015	
Dr Grace Hurford	Senior Lecturer, public services leadership	Lay Plus	01/02/2016	
Mrs Andrina Lawrence	Retired Nurse	Lay	01/10/2005	03/08/2015
Dr Brenda Leese	Retired Health Researcher	Lay	10/03/2010	
Dr Laura Machin	Lecturer in Medical Ethics	Lay Plus	02/06/2014	
Dr Anas Olabi	Consultant Paediatrician	Expert	01/01/2007	
Mrs Susan Page	Senior Clinical Tutor	Expert	13/10/2011	
Mrs Gillian Rimington	Paralegal	Lay	23/03/2015	
Mrs Valerie Skinner	Nurse (Retired)	Lay	01/10/2005	Membership extended
Professor Jois Stansfield	Professor of Speech Pathology	Expert	11/09/2009	
Dr Gary Whittle	Consultant in Dental Public Health (retired)	Expert	01/10/2005	Membership extended

## North West - Lancaster Research Ethics Committee: Deputy Members

Name	Profession	Status	Meeting date attended
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## North West - Lancaster Research Ethics Committee: Co-opted Members

Name	Profession	Status	Meeting date attended
James Burns	Retired Consultant	Lay member	April, July, Dec 2015 and Jan 2016
Peter Owen	Retired Lecturer	Lay Plus	Sept 2015, March 2016
Carol Haigh	Lecturer	Expert	Sept 2015
Hannah Chambers	Retired Nurse	Lay	August 2015 PR
Debbie Foord	Community Psychiatric Nurse	Expert	July 2015

## North West - Lancaster Research Ethics Committee: Members' Declarations of Interest:

Name	Declaration of Interest	Date
Dr Brenda Ashcroft	None	20/01/2016
Mr David Barber	Employed by Lancashire Teaching Hospitals NHS Trust, a large organisation that means a lot of research trials. .	20/01/2016
Dr Lisa Booth	Senior Lecturer University of Cumbria.	04/01/2016
Ms Debbie Foord	None	14/01/2016
Dr Grace Hurford	Senior Lecturer University of Cumbria, Supervision of under and post graduate student dissertations/ PhDs at the University of Cumbria.	02/02/2016
Dr Brenda Leese	Holds shares in Angels PLC.	20/01/2016
Dr Laura Machin	Trustee of Institute of Medical Ethics. Associate of Research Ethics. Deputy Chair, FHM REC, Lancaster University. Member of Uni REC. Lancaster Medical School REC Member.	04/01/2016
Dr Anas Olabi	None	04/01/2016
Mrs Susan Page	Employed by University of Central Lancashire although not directly involved in research. Now possibly becoming a member of the University Ethics Committee. Will be a member of the University of Central Lancashire Ethics Committee in Jan 2016.	04/01/2016
Mrs Gillian Rimington	None.	04/01/2016
Mrs Valerie Skinner	None	20/01/2016
Professor Jois Stansfield	Trustee: Borough Care (Stockport Care Honorary Social Enterprise).Trustee: Total Communication (Learning Disability Social Enterprise).Professor of Speech Pathology MMU.	04/01/2016
Dr Gary Whittle	None	04/01/2016

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

Month	Date	Number of Members Present at Meeting
April	09/04/2015	10
May	14/05/2015	8
July	09/07/2015	8
September	10/09/2015	8
October	08/10/2015	10
December	10/12/2015	8
January	14/01/2016	9
February	11/02/2016	11
March	10/03/2016	10

9 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	23/04/2015	3
May	14/05/2015	8
June	11/06/2015	5
July	13/07/2015	3
August	14/08/2015	3
September	18/09/2015	4
October	15/10/2015	3
December	17/12/2015	3
January	22/01/2016	3
February	23/02/2016	4
March	23/03/2016	3

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

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

Month	Date	Number of Members Present at Meeting
April	17/04/2015	2
May	01/05/2015	3
May	08/05/2015	2
May	15/05/2015	2
May	29/05/2015	2
June	12/06/2015	2
June	19/06/2015	2
June	26/06/2015	3
July	03/07/2015	2
July	17/07/2015	2
July	24/07/2015	2

August	14/08/2015	2
August	21/08/2015	3
August	28/08/2015	2
September	11/09/2015	2
September	18/09/2015	2
October	09/10/2015	2
October	23/10/2015	2
October	30/10/2015	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	3
January	15/01/2016	2
January	22/01/2016	3
January	29/01/2016	2
February	05/02/2016	2
February	12/02/2016	2
February	26/02/2016	2
March	04/03/2016	2
March	11/03/2016	2
March	24/03/2016	2

35 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>
Dr Brenda Ashcroft	7
Mr David Barber	7
Dr Lisa Booth	5
Mrs Debbie Foord	4
Dr Grace Hurford	1
Dr Brenda Leese	7
Dr Laura Machin	4
Dr Anas Olabi	5
Mrs Susan Page	5
Mrs Gillian Rimington	7
Mrs Valerie Skinner	8
Professor Jois Stansfield	7
Dr Gary Whittle	8

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

<b>Name</b>	<b>Number of Meetings Attended</b>
Dr Brenda Ashcroft	1
Dr Lisa Booth	8
Dr Brenda Leese	8
Dr Laura Machin	1
Mrs Susan Page	3
Mrs Gillian Rimington	9
Mrs Valerie Skinner	2
Professor Jois Stansfield	8
Dr Gary Whittle	1

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

<b>Name</b>	<b>Number of Meetings Attended</b>
Dr Lisa Booth	35
Dr Brenda Leese	5
Professor Jois Stansfield	35



Training 01 April 2015 - 31 March 2016

Name of Member	Date	Event(s) attended
Dr Lisa Booth	31/03/2016	Self directed learning log. NREAP for updates on HRA initiatives. Reading on research without prior consent (deferred consent) in trials investigating the emergency treatment of critically ill children
Ms Debbie Foord	31/03/2016	Self directed learning log – RES document defining research, RES language and exclusion, Confidentiality and Research, from Social Scientist, MRC Human Tissue legislation, summary of consent, licensing, Access to health records act
Dr Brenda Leese	01/01/2016	'Children and clinical research ethical issues' produced by the Nuffield Council on Bioethics, 2015.
Dr Laura Machin	30/06/2015	Human Tissue Introduction
Dr Laura Machin	06/10/2015	Quantitative Research Methods and Statistics: A Health Research Authority Workshop
Dr Anas Olabi	31/03/2016	Self directed learning log UK policy framework for health and social care research Children and clinical research ethical issues' produced by the Nuffield Council on Bioethics, 2015.
Mrs Susan Page	15/10/2015	Assessing the consequences of research
Mrs Gillian Rimington	03/12/2015	Pragmatic or Point of Care trials
Professor Jois Stansfield	31/03/2016	Self Directed learning log Ethical perspectives of direct to consumer genetic testing. BPS Code of human research ethics Social media and clinical care, ethical professional and social implications Ethical considerations in projects
Dr Gary Whittle	17/03/2016	Self-directed learning log Bad Pharma: How drug companies mislead doctors and harm patients by Ben Goldacre

## 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	44	100.00
<b>Total Applications Reviewed</b>	<b>44</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	0
Number of student applications reviewed	22
Number of paediatric applications reviewed	5
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**

<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	13	29.55
Unfavourable Opinion	1	2.27
Provisional Opinion	30	68.18
Provisional Opinion Pending Consultation with Referee	0	0.00
<b>Total</b>	<b>44</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	28	63.64
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	13	29.55
Unfavourable Opinion	1	2.27
Provisional Opinion	1	2.27
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	2.27
<b>Total</b>	<b>44</b>	<b>100</b>

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

<b>Total Applications Reviewed</b>	<b>32</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	14
Number of studies withdrawn prior to the meeting	3
Number of student applications reviewed	12
Number of paediatric applications reviewed	6
Number of device applications reviewed	1
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	16	50.00
Favourable Opinion with Additional Conditions	6	18.75
No Opinion transfer to full committee for review	1	3.13
Provisional Opinion	9	28.13
Unfavourable Opinion	0	0.00
<b>Total</b>	<b>32</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>	4.89
<b>Number of completed applications for full ethical review</b>	43
<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>	25
<b>Number of completed proportionate review applications for ethical review</b>	31
<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>	6
<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>	87
<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>	1
<b>Number of completed substantial amendments over 28 days as a % of total substantial amendments</b>	1.15%
<b>Number of modified amendments reviewed</b>	1
<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>	27
<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>	31

<b>Number of safety reports received</b>	0
<b>Number of Serious Adverse Events received</b>	0
<b>Number of final reports received</b>	14

**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/0273	Does Dietary intervention reduce Nausea and Vomiting in Pregnancy?	24
15/NW/0288	Psychological impact of macular degeneration management (POPPIES)	32
15/NW/0313	Exploring experiences of frailty in older adults who have fallen	31
15/NW/0388	Version 1 Reassurance seeking	32
15/NW/0571	The Clinical Research Nurse and Patient Experience	17
15/NW/0575	GiVE: external pilot randomised controlled trial	19
15/NW/0715	The hep C fingerprick study v1	25
15/NW/0725	Zimmer MotionLoc in Distal Tibia Fractures: An Observational Study	31
15/NW/0728	Overweight Adults Case Study (OACS)	36
15/NW/0733	Proportion of Endometrial Tumours Associated Lynch Syndrome (PETALS)	20
15/NW/0791	Using patient experiences to improve recovery after critical illness	23
15/NW/0797	SMART Feasibility Study	30
15/NW/0801	Cardiopulmonary exercise test in arterial disease	32
15/NW/0804	Determining adolescent/parent priorities in hypodontia	28
15/NW/0946	ADHD diagnosis, self-identity and personal relationships: Version 1	20
15/NW/0958	Cognitive functioning and moderating factors in epilepsy	16
15/NW/0967	Impact of child's co-morbid difficulties on caregivers	31
15/NW/0988	Time-limited transdiagnostic CBT pre-post analysis v.1	38
15/NW/0990	RPE65 Natural History Study	37
15/NW/0997	VOCA and stroke in the acute setting	29
16/NW/0025	The impact of causal beliefs on stigma.	33
16/NW/0038	CISKO; CT Imaging Study for Knee Osteotomy	29
16/NW/0094	S-REF and suicidal ideation ESM	21
16/NW/0116	Biotech BetaGlycans AS; WOULGAN BIOGEL; WBG-03	16
16/NW/0117	Vaginal self-sampling for non-attenders v1.1	15
16/NW/0145	Delirium in critical care and key personnel experiences	29
16/NW/0179	Aircast Ankle Brace versus Below Knee POP: Patient Satisfaction	28
16/NW/0193	Shared Decision Making in Mental Health	23

<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>
15/NW/0238	MBCT for people with Huntington's disease	34
15/NW/0292	School readiness in children with HIE	21
15/NW/0369	Radio-labelled excision of lung nodules	14
15/NW/0417	STARS project	18
15/NW/0553	The PROTECT study	18
15/NW/0564	Communication and adolescents with type 1 diabetes	18
15/NW/0572	Developing a PROM for people with NMO 2	18
15/NW/0732	REACT Trial	19
15/NW/0784	205072 Occluding Dentifrice Efficacy for Dentinal Hypersensitivity	31
15/NW/0941	Measuring Severe Harm	19
15/NW/0989	Preparing to Care for Baby	28
16/NW/0143	Does early mobilisation improve outcomes after rotator cuff repair?	22
16/NW/0190	Patients experiences' of genomic testing for early stage breast cancer	22

<b>Unfavourable Opinion</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
15/NW/0806	Skin Camouflage for Women Prisoners with Self-Harm Scarring	25

<b>Provisional Opinion</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
16/NW/0165	I-ASC: Identifying Appropriate Symbol Communication	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>
16/NW/0088	What is the impact of discharge from day case surgery on carers?	14

**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/0365	Parental Experience of DEFO Suit in Children with Cerebral Palsy.	10
15/NW/0380	Long term outcomes following childhood circumcision	9
15/NW/0438	Event perception in children with Autism	6
15/NW/0439	Validating the content of the Keeping Birth Normal Tool	5
15/NW/0504	Mental Health Service Users' Views of Practitioners Version 1	10
15/NW/0519	P11-282 LEGACY Version Amendment 2 dated 24 June 2014	13
15/NW/0527	Canine Olfactory Detection of Human Urological Cancer	3
15/NW/0844	Surgeon Outcomes	12

<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>
15/NW/0366	The GP-Prompt study	11
15/NW/0368	HCMV glycoproteins glycosylation role in disease pathogenesis	8
15/NW/0437	Pilot study to assess the effects of haemodialysis treatments on blood	5
15/NW/0503	National neonatal demand and capacity modelling	5
15/NW/0513	PEAR: Experimental Outcomes	7
15/NW/0525	Enzyme SPRCA assay in alloantibody identification	4
15/NW/0759	Optimal Head and Neck Position for Intubation during Videolaryngoscopy	6
15/NW/0763	Investigating maternal and fetal outcomes for women with GDM	2
15/NW/0768	Pseudomonas study	2
15/NW/0843	Digital pathology algorithm development	2
15/NW/0993	Devon webGP pilot evaluation	3
16/NW/0074	The healthWorks Project 2015-2017 V1	7
16/NW/0152	OAMS	6
16/NW/0157	The use of blood samples from donors to develop new cancer therapies	2
16/NW/0159	Enhancing patient involvement in undergraduate medical education	1
16/NW/0225	Parents'/carers' views of receiving lifestyle behaviour change advice	10

<b>Favourable Opinion with Additional Conditions</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
15/NW/0595	Factors influencing satisfaction with orthodontic treatment in adults	4
15/NW/0597	Medicines in Schools – A Survey of Stakeholders	7
15/NW/0675	Outcome feedback feasibility study	6
15/NW/0678	Smile aesthetics perception - impacted canines	4
16/NW/0077	Establishing the predictive validity of the MiC questionnaire	2
16/NW/0227	Developing an app for children and young people self-managing CKD	6

<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>

16/NW/0224	Patient reported outcomes after MIRPN to treat acute pancreatitis	n/a
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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>
09/H1015/81/AM03	Eye tracking as a measure of young infants' knowledge of objects	2	24/07/2015	22
12/NW/0384/AM02	TAVI QL	3	27/04/2015	1
12/NW/0384/AM04	TAVI QL	4	01/10/2015	24
12/NW/0520/AM07	Focusing on Clozapine Unresponsive Symptoms	6	30/04/2015	8
13/NW/0040/AM01	Investigating the microenvironment of lymphoproliferative disorders	1.0	20/08/2015	7
13/NW/0120/AM05	Use of computer games to test visual fields in children (v1)	4	05/06/2015	4
13/NW/0247/AM03	QulBs - Quantitative Imaging Biomarkers derived from MRI	1	11/06/2015	0
13/NW/0247/AM04	QulBs - Quantitative Imaging Biomarkers derived from MRI	2	20/08/2015	0
13/NW/0432/AM04	Characteristics of a successful imagery rescript.	3	10/05/2015	2
13/NW/0432/AM05	Characteristics of a successful imagery rescript.	4	21/08/2015	18
13/NW/0504/AM04	INSITE - INpatient Suicide Intervention and Therapy Evaluation	4	20/01/2016	7
13/NW/0695/AM01	Improving the outcome of stoma reversal surgery.	1	23/04/2015	1
14/NW/0206/AM07	Comprehensive Longitudinal Assessment of Salford Integrated Care	6	15/05/2015	14
14/NW/0206/AM08	Comprehensive Longitudinal Assessment of Salford Integrated Care	7	18/06/2015	14
14/NW/0206/AM10	Comprehensive Longitudinal Assessment of Salford Integrated Care	8	10/11/2015	12
14/NW/0206/AM11	Comprehensive Longitudinal Assessment of Salford Integrated Care	9	19/11/2015	3
14/NW/0206/AM12	Comprehensive Longitudinal Assessment of Salford Integrated Care	10	09/12/2015	9
14/NW/0218/AM01	Finesse vs. Pen for Bolus Insulin in T2 DM, revision C	1	15/04/2015	7
14/NW/0218/AM02	Finesse vs. Pen for Bolus Insulin in T2 DM, revision C	II	21/07/2015	2
14/NW/0218/AM03	Finesse vs. Pen for Bolus Insulin in T2 DM, revision C	III	11/08/2015	14
14/NW/0218/AM05	Finesse vs. Pen for Bolus Insulin in T2 DM, revision C	V	29/09/2015	6
14/NW/0218/AM06	Finesse vs. Pen for Bolus Insulin in T2 DM, revision C	VI	16/11/2015	6
14/NW/0297/AM11	EQUIP: Clinical Randomised Control Trial and Process Evaluation	9	31/03/2015	19

14/NW/0297/AM12	EQUIP: Clinical Randomised Control Trial and Process Evaluation	#10	03/06/2015	8
14/NW/0297/AM16	EQUIP: Clinical Randomised Control Trial and Process Evaluation	12	21/07/2015	7
14/NW/0297/AM17	EQUIP: Clinical Randomised Control Trial and Process Evaluation	13	11/01/2016	2
14/NW/0298/AM03	Cortical glutamate/GABA and inflammation in psychosis (CGIP)	3	17/04/2015	13
14/NW/0298/AM05	Cortical glutamate/GABA and inflammation in psychosis (CGIP)	4	11/09/2015	6
14/NW/0298/AM06	Cortical glutamate/GABA and inflammation in psychosis (CGIP)	5	23/09/2015	2
14/NW/0298/AM07	Cortical glutamate/GABA and inflammation in psychosis (CGIP)	6	15/12/2015	8
14/NW/0298/AM08	Cortical glutamate/GABA and inflammation in psychosis (CGIP)	7	28/02/2016	6
14/NW/0353/AM04	Birth Companions Research Project	2	23/04/2015	5
14/NW/1113/AM02	Community-based Prevention of Diabetes (ComPoD) trial [version 1]	2	24/04/2015	1
14/NW/1195/AM02	LCI-SEARCH	2	21/08/2015	15
14/NW/1254/AM03	HPV, sexual behaviour and carcinoma of the mouth and throat	2	12/10/2015	6
14/NW/1254/AM04	HPV, sexual behaviour and carcinoma of the mouth and throat	3	25/01/2016	8
14/NW/1270/AM01	The PEPEX Study	Amendment 2	16/03/2015	29
14/NW/1274/AM03	Haemodynamics in preterm babies with PDA: an observational study	2	18/05/2015	0
14/NW/1351/AM03	REACH HF - Main trial	02	25/06/2015	22
14/NW/1377/AM01	Cefoxitin resistance - Clinical Significance in ICU	1	26/05/2015	1
14/NW/1418/AM02	Siblings' experiences of childhood acquired brain injury	2	01/05/2015	6
14/NW/1418/AM04	Siblings' experiences of childhood acquired brain injury	3	22/06/2015	2
14/NW/1425/AM01	Social care in prison: A needs assessment	1	30/03/2015	4
14/NW/1425/AM02	Social care in prison: A needs assessment	2	22/06/2015	7
14/NW/1429/AM01	Identification of bacterial 'signatures'	1	14/08/2015	7
14/NW/1429/AM02	Identification of bacterial 'signatures'	2	25/11/2015	11
14/NW/1485/AM01	Clinical Study on POSS-PCU vascular grafts for vascular access v1.0	1	14/09/2015	3
14/NW/1491/AM01	Missed Diagnostic Opportunities	1	31/03/2015	15

14/NW/1491/AM02	Missed Diagnostic Opportunities	2	16/10/2015	4
14/NW/1499/AM01	Wii Fit and Cerebral Palsy Feasibility Study (CP-WiiO)	1	22/12/2015	5
14/NW/1499/AM02	Wii Fit and Cerebral Palsy Feasibility Study (CP-WiiO)	2	18/02/2016	6
14/NW/1510/AM01	Dry January - Healthy Volunteers 1 month Alcohol Abstinence	1	08/07/2015	9
15/NW/0044/AM01	Micro endpoints for new antifungal drugs in asthma, version 1	1	15/11/2015	17
15/NW/0049/AM02	Access to dementia diagnosis & support in ethnic community.	1	03/08/2015	0
15/NW/0049/AM03	Access to dementia diagnosis & support in ethnic community.	2	19/10/2015	10
15/NW/0125/AM01	Trial comparing Nutriseal nasogastric aspiration tube to standard NGT	1	02/04/2015	7
15/NW/0126/AM01	COOLHEAD 2	1.0	06/07/2015	13
15/NW/0126/AM02	COOLHEAD 2	2	25/11/2015	3
15/NW/0126/AM03	COOLHEAD 2	3	05/01/2015	6
15/NW/0162/AM01	Chair Based Exercise Proof of Concept Study Version 1.0	1	02/04/2015	8
15/NW/0162/AM02	Chair Based Exercise Proof of Concept Study Version 1.0	2	30/04/2015	4
15/NW/0162/AM03	Chair Based Exercise Proof of Concept Study Version 1.0	3	06/05/2015	2
15/NW/0162/AM04	Chair Based Exercise Proof of Concept Study Version 1.0	4	22/05/2015	1
15/NW/0180/AM01	Blindness registration in Scotland	1	08/04/2015	2
15/NW/0238/AM02	MBCT for people with Huntington's disease	1	22/06/2015	2
15/NW/0238/AM05	MBCT for people with Huntington's disease	3	02/10/2015	5
15/NW/0238/AM08	MBCT for people with Huntington's disease	5	18/02/2016	4
15/NW/0282/AM01	The function of genetic variants in immune cells	1	01/10/2015	13
15/NW/0282/AM02	The function of genetic variants in immune cells	2	14/01/2016	5
15/NW/0288/AM01	Psychological impact of macular degeneration management (POPPIES)	1	24/06/2015	19
15/NW/0366/AM01	The GP-Prompt study	1	24/09/2015	13
15/NW/0417/AM01	STARS project	1	29/10/2015	8
15/NW/0527/AM01	Canine Olfactory Detection of Human Urological Cancer	1	07/09/2015	3
15/NW/0527/AM02	Canine Olfactory Detection of Human Urological Cancer	2	05/01/2016	12
15/NW/0527/AM03	Canine Olfactory Detection of Human Urological Cancer	3	16/02/2016	2
15/NW/0553/AM01	The PROTECT study	5	20/01/2016	2
15/NW/0575/AM01	GiVE: external pilot randomised controlled trial	1	15/07/2015	2
15/NW/0732/AM01	REACT Trial	1	22/10/2015	4
15/NW/0732/AM03	REACT Trial	1.1	04/02/2016	5
15/NW/0733/AM01	Proportion of Endometrial Tumours Associated Lynch Syndrome (PETALS)	1	27/11/2015	4
15/NW/0784/AM01	205072 Occluding Dentifrice Efficacy for Dentinal	1	23/10/2015	1

	Hypersensitivity			
15/NW/0784/AM02	205072 Occluding Dentifrice Efficacy for Dentinal Hypersensitivity	2	09/12/2015	9
15/NW/0797/AM01	SMART Feasibility Study	1	17/11/2015	6

#### Unfavourable opinion

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
13/NW/0732/AM04	acoustic emission as a biomarker for knee osteoarthritis	3	14/12/2015	5
14/NW/0242/AM05	CFS/ME in the NHS: outcomes after treatment by NHS specialist services	3	15/01/2016	26
14/NW/1254/AM01	HPV, sexual behaviour and carcinoma of the mouth and throat		14/01/2015	16
15/NW/0292/AM01	School readiness in children with HIE	1	09/02/2016	5

**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
13/NW/0732/AM04/1	acoustic emission as a biomarker for knee osteoarthritis	3 modified	23/12/2015	7

#### 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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