

**London - Queen Square Research Ethics
Committee**

Annual Report

01 April 2016 - 31 March 2017



Part 1 – Committee Membership and Training

Name of REC:	London - Queen Square Research Ethics Committee
Type of REC:	Authorised
Type of Flag:	Research Involving Adults Lacking Capacity
Chair:	Dr Eamonn Walsh
Vice-Chair:	Ms Danielle Wilson
Alternate Vice-Chair:	None
REC Manager:	Miss Amber Ecclestone Miss Katherine Ashley (From 03/04/17)
REC Assistant:	Jenna Wooburn (to January 2017) Miss Harriet Wood (From March 2017)
Committee Address:	HRA NRES Centre Manchester Barlow House 3rd Floor 4 Minshull Street Manchester M1 3DZ
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Chair's overview of the past year:

The Committee has continued to work well together this year. There have been many changes, most noticeably to the HRA processes and procedures and the committee has coped well with these challenges. We have also said goodbye to our excellent REC Manager Rachel Heron and have welcomed both Amber Ecclestone, who is now on maternity leave, and Katherine Ashley as our new REC managers.

We have had several experienced members come to the end of their 10 year term and therefore have been a small committee for a number of months. We are delighted to now have several new members Kirstie Shearman, Rosalyn Stanbury and Lisa Marie Doherty. Some are at the beginning of their role on the ethics committee and I look forward to them growing in confidence and reviewing applications independently, with the support of experienced members.

After Dr Yogi Amin completed his 10 year term of service we were delighted that Dr Eamonn Walsh has taken over as Chair with Danielle Wilson as Vice Chair of the Committee, we have the position of Alternative Vice Chair as currently vacant, which we hope to fill in the near future.

London - Queen Square Research Ethics Committee Membership

Name	Profession	Expert or Lay	Dates	
			Appointed	Left
Dr Yogi Amin	Consultant in Neuroanaesthesia & Neurocritical Care	Expert	28/07/2006	28/07/2016
Miss Miriamtha Dahdal	Teaching Assistant	Lay Plus	20/03/2014	07/10/2016
Miss Lisa Marie Doherty	Clinical Research Nurse	Expert	01/01/2017	
Dr Simon Eaton	Senior Lecturer in Paediatric Surgery and Metabolic Biochemistry	Expert	11/09/2006	04/09/2016
Miss Sarah Gregory	Clinical Research Officer	Lay	11/02/2014	
Dr Katie Harron	Statistician	Expert	01/02/2014	11/11/2016
Dr Khalil Hassanally	GP	Expert	01/09/2015	07/09/2016
Dr Ciaran Scott Hill	Neurosurgery Speciality Registrar	Expert	08/03/2011	
Mrs Jenny Johnson	Charity Trustee	Lay Plus	18/03/2008	
Ms Eleanor Rose Lees-Millais	Nurse	Lay Plus	01/02/2016	
Mrs Claire Reynolds	Radiotherapy Radiographer	Expert	26/06/2013	05/07/2016
Miss Kirstie Shearman	R&D Facilitator	Lay	01/03/2017	
Miss Rosalyn Stanbury	Ophthalmologist (Retired)	Expert	10/11/2016	
Miss Sheetal Sumaria	Pharmacist	Expert	12/05/2009	
Dr Eamonn Walsh	Senior Lecturer	Expert	19/04/2011	
Mr Jonathan Watkins	Social Worker	Expert	01/10/2015	
Ms Danielle Wilson	Clinical Trials Facility Manager	Expert	07/03/2013	
Miss Zalika Xavier	Vaccine Sales Representative	Lay	16/04/2015	20/10/2016
Dr Lorraine Ludman	Chartered Psychologist	Lay	18/05/2006	18/05/2016

London - Queen Square Research Ethics Committee: Co-opted Members

Name	Profession	Status	Meeting date attended
Professor David Caplin	Physicist	Lay	16/03/2017
Mrs Marion Cumbers	Retired Librarian	Lay Plus	16/02/2017
Mrs Sally Gordon Boyd	Medical Ethicist	Lay Plus	02/08/2016
Dr Margaret Jones	Retired General Practitioner	Expert	16/02/2017
Dr Edward Lavender	GP	Expert	16/06/2016
Dr Hilary Lavender	Retired General Practitioner (GP)	Expert	16/06/2016
Ms Karen Sanders	Senior Lecturer Nursing, Health Care Ethics & Law	Expert	16/03/2017
Miss Nabila Youssouf	Research Fellow in Clinical Trials	None	02/08/2016

Mr Robert Goldstein	Economist	Lay Plus	16/03/2017
Ms Stephanie Ellis	Civil Servant (Retired)	Lay Plus	15/09/2016 17/11/2016 19/01/2017 16/02/2017 Sub-Committee 21/07/2017

London - Queen Square Research Ethics Committee: Members' Declarations of Interest:

Name	Declaration of Interest	Date
Miss Sarah Gregory	Member declared that they are Deputy Manager of the West London Mental Health Trust Clinical Trials Facility, an active NHS research site specialising in ageing and dementia research	30/03/2017
Dr Ciaran Scott Hill	None	30/03/2017
Mrs Jenny Johnson	Trustee of Kennedy Trust for Rheumatology Research	30/03/2017
Dr Eamonn Walsh	Member declared he is a researcher at Kings College London	30/03/2017
Mr Jonathan Watkins	None in the UK or EU. Member takes part in some research in Central Asia as they manage an Early Child Development and deinstitutionalisation project funded by the EU and the Government of Canada. Employed by the UK-based charity:www.HealthProm.org	30/03/2017
Ms Danielle Wilson	Member declared that they are currently consulting for MyCognition who aim to bring to market an app which measures cognition. Manages a Clinical Research Facility in the NHS which conducts commercial clinical research studies.	30/03/2017
Miss Zalika Xavier	No interests were declared for this period	19/05/2016
Miss Sheetal Sumaria	No interests were declared for this period	16/03/2017
Miss Kirstie Shearman	R&D Governance Facilitator at GSTT	02/03/2017
Miss Rosalyn Stanbury	No interests were declared for this period	31/03/2017
Miss Lisa Marie Doherty	No interests were declared for this period	31/03/2017
Ms Eleanor Rose Lees-Millais	No interests were declared for this period	31/03/2017

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

Month	Date	Number of Members Present at Meeting
April	21/04/2016	8
May	19/05/2016	9
June	16/06/2016	7
August	02/08/2016	7
August	18/08/2016	9
September	15/09/2016	7
October	20/10/2016	8
November	17/11/2016	8
January	19/01/2017	9
February	16/02/2017	8
March	16/03/2017	9

11 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	21/04/2016	3
May	19/05/2016	5
June	16/06/2016	3
August	16/08/2016	3
September	15/09/2016	3
October	20/10/2016	3
November	17/11/2016	3
December	15/12/2016	4
January	26/01/2017	3
February	23/02/2017	3
March	23/03/2017	3

11 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	07/04/2016	2
April	29/04/2016	2
May	06/05/2016	2
June	06/06/2016	2
June	16/06/2016	2
July	21/07/2016	2
August	04/08/2016	2
September	02/09/2016	2
September	19/09/2016	2

October	06/10/2016	2
October	25/10/2016	2
November	08/11/2016	2
November	22/11/2016	2
December	06/12/2016	2
December	21/12/2016	2
January	06/01/2017	2
January	24/01/2017	2
February	07/02/2017	2
February	21/02/2017	2
March	07/03/2017	2
March	21/03/2017	2

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

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

0

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

Name	Number of Meetings Attended
Miss Lisa Marie Doherty	2
Dr Simon Eaton	3
Miss Sarah Gregory	7
Dr Katie Harron	4
Dr Ciaran Scott Hill	8
Mrs Jenny Johnson	8
Ms Eleanor Rose Lees-Millais	6
Dr Lorraine Ludman	2
Miss Kirstie Shearman	1
Miss Rosalyn Stanbury	3
Miss Sheetal Sumaria	7
Dr Eamonn Walsh	10
Mr Jonathan Watkins	2
Ms Danielle Wilson	8
Miss Zalika Xavier	5

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

Name	Number of Meetings Attended
Dr Simon Eaton	1
Miss Sarah Gregory	5
Dr Katie Harron	2
Dr Ciaran Scott Hill	4
Mrs Jenny Johnson	4
Ms Eleanor Rose Lees-Millais	1
Miss Rosalyn Stanbury	1
Miss Sheetal Sumaria	1
Dr Eamonn Walsh	10
Mr Jonathan Watkins	2
Ms Danielle Wilson	3
Miss Zalika Xavier	2

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

Name	Number of Meetings Attended
Miss Sarah Gregory	3
Dr Ciaran Scott Hill	2
Mrs Jenny Johnson	6

Ms Eleanor Rose Lees-Millais	2
Miss Rosalyn Stanbury	1
Miss Sheetal Sumaria	2
Dr Eamonn Walsh	17
Mr Jonathan Watkins	2
Ms Danielle Wilson	5
Miss Zalika Xavier	1

Training 01 April 2016 - 31 March 2017

Name of Member	Date	Event(s) attended
Miss Kirstie Shearman	08/03/2017	Equality and Diversity
Miss Kirstie Shearman	08/03/2017	Induction Training
Miss Kirstie Shearman	08/03/2017	Induction of new Research Ethics Service Committee Member
Miss Kirstie Shearman	08/03/2017	Equality Diversity and Human Rights
Miss Danielle Wilson	16/02/2017	National Members Training Day
Miss Jenny Johnson	01/02/2017	Governance Arrangements for Research Ethics Committees (SDL) Revision and greater understanding of details to make sure member was up to date.
Miss Jenny Johnson	02/02/2017	NRES DOC MCA Q&A (SDL) - Revision regarding MCA studies which the Committee is flagged for
Miss Sheetal Sumaria	10/10/2016	Self-directed Learning - Medicines for human use (clinical trial regulations) 2004
Sarah Gregory	16/02/2017	National Members Training Day
Ms Eleanor Rose Lees-Millais	30/11/2016	Induction of new Research Ethics Service Committee Member
Dr Eamonn Walsh	11/05/2016	Assessing the consequences (benefits and harm) of Research: A Health Research Authority Workshop

PART 2: REC WORKLOAD AND ACTIVITY DURING THE REPORTING PERIOD

Table 1: Applications assigned to a full committee meeting held within the reporting period:

Applications for full ethical review – Study Type	Number	%
Clinical Trial of Investigational Medicinal Product	0	0.00
Phase 1	0	0.00
Gene Therapy	0	0.00
Research Tissue Bank (including renewals)	0	0.00
Research Database (including renewals)	2	3.70
Others	52	96.30
Total Applications Reviewed	54	100

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

Number of applications made invalid by the REC Manager	1
Number of applications withdrawn prior to the meeting	0
Number of student applications reviewed	16
Number of paediatric applications reviewed	6
Number of device applications reviewed	3
Number of prisoner applications reviewed	0
Number of applications involving adults unable consent reviewed	15
Number of applications reviewed that are funded by the US DHHS	0
Number of qualitative applications reviewed	5

Table 3: Decisions given at meetings held within the reporting period

Decisions taken at meetings following review of applications	Number	%
Favourable Opinion with Standard Conditions	3	5.56
Favourable Opinion with Additional Conditions	11	20.37
Unfavourable Opinion	2	3.70
Provisional Opinion	38	70.37
Provisional Opinion Pending Consultation with Referee	0	0.00
Total	54	100
Number of studies sent back to full committee meeting for final opinion	0	

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

Status of applications at date of generation of report	Number	%
Further Information Favourable Opinion with Standard Conditions	30	55.56
Further Information Favourable Opinion with Additional Conditions	6	11.11
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	3	5.56
Favourable Opinion with Additional Conditions	11	20.37
Unfavourable Opinion	2	3.70
Provisional Opinion	2	3.70
Provisional Opinion Pending Consultation with Referee	0	0.00
Further Information response not complete	0	0.00
No decision entered on system	0	0.00
Number of studies withdrawn after the meeting	0	0.00
Total	54	100

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

Total Applications Reviewed	19
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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	3
Number of studies withdrawn prior to the meeting	0
Number of student applications reviewed	6
Number of paediatric applications reviewed	4
Number of device applications reviewed	1
Number of qualitative applications reviewed	3

Table 7: Decisions given at proportionate review sub-committee meetings held within the reporting period

Decisions taken at proportionate review sub-committee meetings	Number	%
Favourable Opinion with Standard Conditions	2	10.53
Favourable Opinion with Additional Conditions	2	10.53
No Opinion transfer to full committee for review	3	15.79
Provisional Opinion	12	63.16
Unfavourable Opinion	0	0.00
Total	19	100

Table 8: Other Management Information based on the number of completed applications for the reporting period:

Average number of applications reviewed per full meeting	4.91
Number of completed applications for full ethical review	54
Number of completed applications for full ethical review over 60 days	0
Number of completed applications over 60 days as a % of total	0.00%
Number of completed applications for full ethical review over 40 days	5
Number of completed applications over 40 days as a % of total	9.26%
Number of days taken to final decision – average (mean)	30
Number of completed proportionate review applications for ethical review	16
Number of completed proportionate review applications for ethical review over 14 days (Please note the timeline for the review of PR applications was extended from 14 – 21 calendar days in December 2016)	1
Number of completed proportionate review applications for ethical review over 21 days.	0
Number of completed proportionate review applications over 14 days as a % of total	6.25%
Number of SSAs (non-Phase 1) reviewed	6
Number of completed applications for SSA review over 25 days	0
Number of completed applications for SSA review over 25 days as % of all non- Phase 1 SSAs	0.00%
Number of SSAs (Phase 1) reviewed	0
Number of completed applications for SSA review over 14 days	0
Number of completed applications for SSA review over 14 days as % of all Phase 1 SSAs	0.00%
Number of substantial amendments reviewed	83
Number of completed substantial amendments over 35 days	3
Number of completed substantial amendments over 35 days as a % of total substantial amendments	3.61%
Number of completed substantial amendments over 28 days	21
Number of completed substantial amendments over 28 days as a % of total substantial amendments	25.30%
Number of modified amendments reviewed	3
Number of completed modified amendments over 14 days	0
Number of completed modified amendments over 14 days as a % of total modified amendments	0.00%
Number of non substantial amendments received	102
Number of substantial amendments received for information	0
Number of substantial amendments received for new	0

sites/PIs	
Number of annual progress reports received	29
Number of safety reports received	0
Number of Serious Adverse Events received	4
Number of final reports received	3

Table 9.1: Breakdown of current status of all full applications reviewed within the reporting period

Further Information Favourable Opinion with Standard Conditions		
REC Reference	Title	Number of Days on Clock
16/LO/0620	The Microcirculation in Liver Cirrhosis	24
16/LO/0697	Negotiating Identity: Young People, ADHD and Medication	37
16/LO/0847	Collection and characterisation of human olfactory ensheathing cells.	26
16/LO/0848	Lock and Key	28
16/LO/0901	Mechanisms underlying spoken language production	29
16/LO/0904	Multisensory Integration in Aging and Parkinson's disease	43
16/LO/1096	Comparative analysis of the use of three breath sampling devices	21
16/LO/1101	Colorectal oncology patients' attitudes towards pre-operative exercise	23
16/LO/1125	Patient Reported Outcomes - patients and caregivers (PROACT) study 3	27
16/LO/1251	Sleep as a Predictive and Precipitating Factor for Delirium	26
16/LO/1350	OPTIC - Optical Polyp Testing for In vivo Classification	27
16/LO/1361	BHiRCH feasibility study Version 1.0	46
16/LO/1366	The demenTia Research And Care Clinic (TRACC)	26
16/LO/1417	Attentional and inhibitory mechanisms in Tourette's syndrome	28
16/LO/1520	IFN-alpha and neuroinflammation in healthy men	28
16/LO/1565	PASS Safety Study for Delamanid in Routine Medical Practise for MDRTB	27
16/LO/1642	Very old ICU Patients (VIP study)	30
16/LO/1646	Musculoskeletal Modelling to Analyse and Treat ACL deficiency Version1	31
16/LO/1912	Tendyne Expanded Clinical Study	29
16/LO/1968	Validating Music Therapy Assessment Tool	34
17/LO/0004	Psychosexual health after banking sperm following a cancer diagnosis	26
17/LO/0027	Modelling cognition in schizophrenia (version 1)	27
17/LO/0095	TANDEM COPD Trial	43
17/LO/0099	Created Out of Mind: Shaping perceptions of the dementias	30
17/LO/0134	Suicide and crisis care: How Crisis Houses influenced recovery	36
17/LO/0182	FORTIFY Clinical Trial	48
17/LO/0291	Longitudinal language mapping in surgical LGG patients	32
17/LO/0407	Acceptance and Commitment Therapy for Dementia Carers version 1.0	33
17/LO/0449	ECCI cCMV Database V2.0	35
17/LO/0475	CABRIO proof of concept study V1.1 020217	35

Further Information Favourable Opinion with Additional Conditions		
REC Reference	Title	Number of Days on Clock
16/LO/0544	Understanding and managing everyday task performance in dementia	23
16/LO/1711	Localised Neuropathic Pain in primary care	26
16/LO/1870	Changes in male and female fertility using wearable fitness technology	23
16/LO/1979	STATEC	34
16/LO/2015	Sub-talar Joint Motion –Where is the centre of rotation?	34
17/LO/0056	SCD-WELL	28

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

Favourable Opinion with Standard Conditions		
REC Reference	Title	Number of Days on Clock
16/LO/0687	RECOVER - TAVR	21
16/LO/1093	A National Neonatal Research Database - 5 year REC renewal	57
16/LO/1098	Experiences of Health-related Quality of Life in Bangladeshi patients	20

Favourable Opinion with Additional Conditions		
REC Reference	Title	Number of Days on Clock
16/LO/0633	Brain connectivity, functional decline & neuropsychiatric symptoms AD	22
16/LO/0670	DREAMS (Dementia Related Manual for Sleep) START	22
16/LO/0891	A feasibility trial of Power Up	26
16/LO/0907	Ultrasound Elastography of fascia of lower leg muscle compartment.	26
16/LO/0965	The CUSSP study	20
16/LO/1649	Effects of food intake on the univentricular circulation	26
16/LO/1852	Single molecule biomarker discovery in inflammatory neuropathy	22
16/LO/1945	Clinical characteristics and immunopathology of PACNS	32
16/LO/1987	CLIMB-CF	32
17/LO/0079	CARDIUM	25
17/LO/0430	OPPD Orofacial Pain in People with Dementia Version 1.0	27

Unfavourable Opinion		
REC Reference	Title	Number of Days on Clock
16/LO/2017	Created Out of Mind	32
17/LO/0476	CST for people with LD and Dementia	29

Provisional Opinion		
REC Reference	Title	Number of Days on Clock

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

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

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

Table 9.2: Breakdown of current status of all PRS applications reviewed within the reporting period

Further Information Favourable Opinion with Standard Conditions		
REC Reference	Title	Number of Days on Clock
16/LO/0780	What do parents think about their children's dental decay?	12
16/LO/0786	Impact of reduced visual acuity on lesion detection in mammography	11
16/LO/1578	BMX Alpha Registry	7
16/LO/1597	Reclaiming words - App based word retraining for people with SD	5
16/LO/1961	Integrated Health: Optimising Strength and Resilience	13
16/LO/2090	Review: Auto-titrating Protocol for Nocturnal NIV	10
16/LO/2097	Accuracy of Clinical Examination Techniques for Knee Effusion	12
16/LO/2104	AdVance	7
16/LO/2254	3% oxygen desaturation indices (ODI) in healthy children-normal values	15
17/LO/0218	Mothers' experiences of feeding their child jejunally/via gastrostomy.	11

17/LO/0543	Establishing an intergenerational falls prevention gardening programme	9
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Further Information Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
16/LO/2251	HAPII Impact and prevalence study	11

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/LO/0974	UK surveillance of Ophthalmic Behcet's Disease	14
17/LO/0221	Investigation of novel immunomodulatory agents on immune cell function	7

Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
16/LO/0980	ADAPT-CKD	9
16/LO/2257	Metabolomic study of urine samples in ALSPAC study	8

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

Favourable opinion				
Amendment REC Reference	Title	Version	Date	Number of Days on Clock
05/Q0512/112/AM05	MRI Data Bank	3	01/11/2016	22
05/Q0512/74/AM20	Structural plasticity in Huntington`s disease	19	19/04/2016	21
06/Q0512/107/AM10	Periodontal Therapy and Vascular Function	009 8th February 2017	16/02/2017	22
06/Q0512/52/AM11	Brain Signatures of Auditory Processing in Dementia	Amendment 9.0: 13-December-201	15/12/2016	28
06/Q0512/81/AM09	Neuropsychology of posterior cortical atrophy (Version 1)	Amendment 8; 22-December-2016	16/02/2017	29
07/H0716/78/AM03	Structural and Haemodynamic Imaging of carotid Plaque (SHIP)	2	05/04/2016	27
07/Q0512/26/AM18	Investigation of human neurological ion channel disorders	7	30/03/2016	27
07/Q0512/26/AM19	Investigation of human neurological ion channel disorders	8	24/01/2017	7
08/H0716/16/AM01	Genomic and expression profiling of brain tumours	1	17/10/2014	27
09/H0716/6/AM02	Cognitive functions in ciliopathy syndromes - version 1	Substantial Amendment 1.2	08/07/2016	5
09/H0716/61/AM20	CMT: A Natural History Study	#13 22/06/2016	29/06/2016	21
09/H0716/61/AM21	CMT: A Natural History Study	#14: 13/01/2017	13/01/2017	23
09/H0716/64/AM11	A novel cell model for the dementias - Version 1	Amendment 8.0: 23-January-2017	24/01/2017	33
10/H0716/51/AM06	European Friedreich's Ataxia Consortium for Translational Studies v1	4	22/03/2016	31
10/H0716/64/AM08	Clinical Relevance Of Microbleeds In Stroke -Intracerebral Haemorrhage	AM 7, March 2016	05/05/2016	22
10/H0716/72/AM03	VEP and OCT in Uhthoff's phenomenon	2	14/09/2016	14
10/H0716/85/AM09	Predict PD - the 1000/100/100 pilot study	Amendment 7 27th June 2016	11/07/2016	26
10/H0716/85/AM10	Predict PD - the 1000/100/100 pilot study	8	14/12/2016	19
11/LO/0396/AM05	The Metabolic Profile in Obstetric Cholestasis	3 - 28/09/16	28/09/2016	15
11/LO/1425/AM05	MRI in Motor Neuropathies V1	3	03/06/2016	5
11/LO/1846/AM04	The Effects of Ageing on the Cutaneous Immune System,	4	18/04/2016	25

	Version 1			
11/LO/1846/AM06	The Effects of Ageing on the Cutaneous Immune System, Version 1	5	31/08/2016	28
12/LO/1109/AM10	PROMPTS	Amendment no.8 dated 29 November 2016	03/01/2017	20
12/LO/1437/AM01	Cough in bronchiectasis: severity, mechanisms & quality of life	Version SA01, date 08/07/2016	29/07/2016	14
12/LO/1816/AM02	ATTILA	Amendment 2 29/02/2016	03/03/2016	26
13/LO/0269/AM05	Acute kidney injury and immune function	Substantial amendment 3 09 February 2016	09/02/2016	36
13/LO/0269/AM06	Acute kidney injury and immune function	4	15/07/2016	13
13/LO/1028/AM03	Non-invasive brain stimulation and cognitive processing in depression	2	26/04/2016	31
13/LO/1156/AM04	EU-AIMS Accelerated Longitudinal Study	Amendment no 3, 25 May 2016	07/06/2016	7
14/LO/0055/AM17	Epilepsy Nurse Trial for adults with ID (01)	7	26/02/2016	26
14/LO/1069/AM09	IMAGINE	5.0 13 December 2016	28/02/2017	30
14/LO/1073/AM05	Life course pathways to ageing in the MRC NSHD	2	12/10/2016	28
14/LO/1146/AM08	Evaluation of Memory Assessment Services: Main Study (phase 2) v1	2.0	07/09/2016	18
14/LO/1575/AM12	PSP CBD MSA Longitudinal Study - UK (PROSPECT-M-UK)	4	06/09/2016	17
14/LO/1575/AM15	PSP CBD MSA Longitudinal Study - UK (PROSPECT-M-UK)	5	12/10/2016	30
14/LO/1758/AM06	Genetic Frontotemporal dementia Initiative (GENFI)	5	09/06/2016	29
14/LO/1792/AM07	Intermittent versus Continuous Feeding on the Intensive Care Unit v3	Amendment 3, 16/12/16	16/12/2016	28
14/LO/1833/AM02	WB-DW-MRI at 3T in relapsed multiple myeloma:early response assessment	23.6.2016 amendment 01	23/06/2016	14
14/LO/2028/AM04	GENFI - IMPETus Tau PET imaging pilot study	3	08/02/2016	33
14/LO/2028/AM05	GENFI - IMPETus Tau PET imaging pilot study	4	19/05/2016	18
14/LO/2301/AM02	Tissue collection for radiobiological research	AM1611/71, 28.11.2016	28/11/2016	26
15/LO/0086/AM04	Training-induced increased left ventricular trabeculation	4 - 29/07/2016	11/08/2016	30

15/LO/0086/AM05	Training-induced increased left ventricular trabeculation	5 - 13/08/16	13/08/2016	29
15/LO/0086/AM06	Training-induced increased left ventricular trabeculation	6	20/10/2016	4
15/LO/0685/AM02	Glycosade® v UCCS in Hepatic GSD (Glyde). Version 2	Substantial Amendment 2 16th May 2016	31/05/2016	7
15/LO/0685/AM03	Glycosade® v UCCS in Hepatic GSD (Glyde). Version 2	Substantial Amendment 3, 06/03/2017	13/03/2017	29
15/LO/1155/AM04	RAPSODI GD	Am02 dated 15 02 2016	04/03/2016	12
15/LO/1211/AM02	RIVER Registry – RIVaroxaban Evaluation in Real life setting	Substantial Amendment 02 - 14-	30/06/2016	15
15/LO/1248/AM01	An exploration of the enactment of midwifery led care version 1	4	10/06/2016	17
15/LO/1288/AM01	Using technology to improve the care of adolescents with arthritis	1.0	09/06/2016	34
15/LO/1507/AM03	FACE-Q KIDS PROM Study	3, 22/11/2016	06/01/2017	20
15/LO/1522/AM01	Prevalence of Pompe's disease in respiratory clinics	1	04/01/2017	24
15/LO/1647/AM01	Realtime fMRI neurofeedback training of SMA in pre-op DBS-STN patients	1	07/09/2016	25
15/LO/1662/AM04	AMR 2 Trial - Reducing Antibiotic Prescribing in Primary Care	4	06/05/2016	28
15/LO/1741/AM02	Telomere biology and acute kidney injury in cardiac surgery	1	29/03/2016	27
15/LO/1783/AM01	High frequency activity in epilepsy patients	1	18/11/2016	29
15/LO/2067/AM02	BIND	1.0	30/11/2016	32
15/LO/2144/AM02	A feasibility study into the objective assessment of low back pain	1	27/07/2016	12
16/LO/0011/AM03	BESPOKE	amendment 1, 14/09/2016	15/09/2016	18
16/LO/0044/AM17	Determinants of prognosis in stroke	Current amendment 17/02/2017 D	23/02/2017	27
16/LO/0265/AM01	NOPRODUCTHPB0003	Protocol amendment 1	29/06/2016	18
16/LO/0265/AM03	NOPRODUCTHPB0003	Substantial Amendment 2 dated	20/01/2017	25

16/LO/0458/AM01	Natural history in mucopolysaccharidosis type IIIA	Amendment # 01 dated 27 Jun 20	28/06/2016	20
16/LO/0461/AM01	Causes of Acute Coronary Syndrome in People with SCAD or CAE	1	18/07/2016	19
16/LO/0697/AM01	Negotiating Identity: Young People, ADHD and Medication	Amendment 1 20/01/2017	20/01/2017	15
16/LO/0847/AM01	Collection and characterisation of human olfactory ensheathing cells.	SA01	19/07/2016	13
16/LO/0891/AM01	A feasibility trial of Power Up	1	06/06/2016	21
16/LO/0891/AM02	A feasibility trial of Power Up	Amendment 2	26/07/2016	10
16/LO/0891/AM06	A feasibility trial of Power Up	3	27/10/2016	10
16/LO/0974/AM01	UK surveillance of Ophthalmic Behcet's Disease	1	21/07/2016	18
16/LO/1101/AM01	Colorectal oncology patients' attitudes towards pre-operative exercise	Version 3.0 ; dated 6th November 2016	06/11/2016	20
16/LO/1125/AM01	Patient Reported Outcomes - patients and caregivers (PROACT) study 3	Amendment number 1, 27th September 2016	27/09/2016	11
16/LO/1251/AM02	Sleep as a Predictive and Precipitating Factor for Delirium	1, 20/02/2017	20/02/2017	10
16/LO/1520/AM01	IFN-alpha and neuroinflammation in healthy men	Amendment 1 28/02/2017	28/02/2017	32
16/LO/1912/AM01	Tendyne Expanded Clinical Study	1, 06Dec2016	29/12/2016	18
16/LO/2251/AM01	HAPII Impact and prevalence study	1.2, 22 February 2017	01/03/2017	15

Unfavourable opinion				
Amendment REC Reference	Title	Version	Date	Number of Days on Clock
10/H0716/51/AM07	European Friedreich's Ataxia Consortium for Translational Studies v1	5	14/05/2016	34
14/LO/1575/AM07	PSP CBD MSA Longitudinal Study - UK (PROSPECT-M-UK)	3	05/04/2016	20
14/LO/1648/AM02	Minimal volume for a fluid challenge in septic patients	1	26/02/2016	38
15/LO/0468/AM01	BASIS Human Genomics	1	24/02/2016	34
15/LO/1412/AM01	A study of brain amyloid and tau deposition using Florbetapir and T807	1	07/12/2015	36

16/LO/0076/AM01	ENERGY-ICU REHAB	1	12/04/2016	35
16/LO/0164/AM01	Neuromodulation for Reducing Neurogenic Detrusor Overactivity in SCI	1	28/11/2016	15

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
10/H0716/51/AM07/1	European Friedreich's Ataxia Consortium for Translational Studies v1	Modified Amendment - 5	28/06/2016	11
15/LO/0468/AM01/1	BASIS Human Genomics	Modification of Am1	17/06/2016	4
15/LO/1412/AM01/1	A study of brain amyloid and tau deposition using Florbetapir and T807	Modified Amendment 1	25/04/2016	1

Unfavourable opinion timeline				
Amendment REC Reference	Title	Version	Date	Number of Days on Clock

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
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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
13/LO/0269/AM05	Acute kidney injury and immune function	Substantial amendment 3 09 February 2016	09/02/2016	36
14/LO/1648/AM02	Minimal volume for a fluid challenge in septic patients	1	26/02/2016	38
15/LO/1412/AM01	A study of brain amyloid and tau deposition using Florbetapir and T807	1	07/12/2015	36

Modified Amendments over 14 day timeline

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
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