

**London - Queen Square Research Ethics
Committee**

Annual Report

01 April 2017 - 31 March 2018



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:	Miss Kirstie Shearman (from 01/03/2018)
REC Manager:	Miss Katherine Ashley
REC Assistant:	Ms Harriet Wood
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:

This year the London Queen Square Research Ethics Committee reviewed a broad range of high quality applications from Researchers in a wide variety of fields. Each application presented the Committee with unique ethical challenges and nuances to tackle. This year especially has been a year of change regarding membership. Many valued and long-standing members stepped down having faithfully served their 10-year terms. Most of these have now moved on to serve on other Research Ethics Committees in the UK. Needless to say, this has been a big loss to us not only in terms of knowledge and experience, but also great colleagues. Fortunately, this loss has been more than offset by the arrival of new members to our Committee, each one of them bringing with them their own experience, perspectives, and a wealth of fresh ideas to complement the more established membership. We are proud to be a flagged Committee (Research Involving Adults Lacking Capacity) and continue to do our best to represent and protect participants who may never attend meetings, but who are always forefront in our minds. We are extremely fortunate as a Committee to have very capable Committee management and support. As we face the coming year, and the new challenges and changes it will surely bring, not to mention the 2018 General Data Protection Regulations, the Queen Square Research Ethics Committee will continue to strive to work with and advise Researchers in order to protect and promote the interests of patients and public alike in all the research we encounter.

London - Queen Square Research Ethics Committee Membership

Name	Profession	Expert or Lay	Dates	
			Appointed	Left
Miss Lisa Marie Doherty	Senior Nurse Practitioner	Expert	01/01/2017	
Dr Sabrina Germain	Lecturer in Law and Public Policy	Lay Plus	01/10/2017	
Miss Sarah Gregory	Clinical Research Officer	Lay	11/02/2014	31/08/2017
Dr Ciaran Scott Hill	Neurosurgery Speciality Registrar	Expert	08/03/2011	
Mrs Jenny Johnson	Charity Trustee	Lay Plus	18/03/2008	18/03/2018
Ms Eleanor Rose Lees-Millais	Clinical Standards Administration	Lay Plus	01/02/2016	
Dr Athena Lemesiou	Business Development Manager	Expert	01/09/2017	
Ms Karen Sanders	Senior Lecturer Nursing, Health Care Ethics & Law	Expert	01/06/2017	
Miss Kirstie Shearman	Doctoral Researcher	Lay	01/03/2017	
Mr Stephan Smith	Professional Development in Healthcare	Lay Plus	01/08/2017	
Miss Rosalyn Stanbury	Ophthalmologist (Retired)	Expert	10/11/2016	
Miss Sheetal Sumaria	Pharmacist	Expert	12/05/2009	
Dr Eamonn Walsh	Senior Lecturer and Programme Lead for MSc Neuroscience	Expert	19/04/2011	
Mr Jonathan Watkins	Social Worker	Expert	01/10/2015	20/02/2018
Ms Danielle Wilson	Clinical Trials Facility Manager	Expert	07/03/2013	

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

Name	Profession	Status	Meeting date attended
Miss Stephanie Ellis, BEM	Former Civil Servant	Lay Plus	21/09/2017
Mrs Marney Williams	Teacher	Lay Plus	21/09/2017
Mrs Sally Gordon-Boyd	Medical Ethicist	Lay Plus	17/08/2017

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

Name	Declaration of Interest	Date
Miss Lisa Marie Doherty	None	18/12/2017
Dr Sabrina Germain	None	16/11/2017
Dr Ciaran Scott Hill	None	26/11/2017
Mrs Jenny Johnson	Trustee of Kennedy Trust for Rheumatology Research	29/11/2017
Ms Eleanor Rose Lees-Millais	None	31/03/2018
Dr Athena Lemesiou	None	18/01/2018
Ms Karen Sanders	None	16/11/2017
Miss Kirstie Shearman	Doctoral researcher at the University of Warwick	22/01/2018
Mr Stephan Smith	None	15/07/2017
Miss Rosalyn Stanbury	None	02/12/2017
Miss Sheetal Sumaria	No declarations of interest have been recorded for this period.	18/12/2017
Dr Eamonn Walsh	Member of the Experimental Psychological Society (EPS). Also an employee of King's College London and performing research is part of his job requirements.	27/11/2017
Ms Danielle Wilson	Committee member is a consultant to MyCognition, which is a private company. In this role she monitors three on-going clinical studies in the Netherlands. Committee member also manages an NHS clinical trials facility which conducts commercial clinical research studies.	15/12/2017

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

Month	Date	Number of Members Present at Meeting
April	20/04/2017	8
May	18/05/2017	9
June	15/06/2017	10
August	17/08/2017	9
September	21/09/2017	9
October	19/10/2017	10
November	16/11/2017	7
January	18/01/2018	9
February	15/02/2018	8
March	15/03/2018	7

10 full committee meetings were held during the reporting period.

Proportionate Review Sub-Committee Meetings held during 01 April 2017 - 31 March 2018:

Month	Date	Number of Members Present at Meeting
April	27/04/2017	3
May	25/05/2017	3
June	22/06/2017	3
August	17/08/2017	3
September	21/09/2017	3
October	19/10/2017	3
November	16/11/2017	3
December	21/12/2017	3
January	18/01/2018	3
February	15/02/2018	3
March	14/03/2018	3

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

Sub-Committee Meetings held during 01 April 2017 - 31 March 2018:

Month	Date	Number of Members Present at Meeting
April	04/04/2017	2
April	18/04/2017	2
May	02/05/2017	3
May	16/05/2017	3
May	30/05/2017	3
June	13/06/2017	2
June	26/06/2017	2
June	27/06/2017	2
June	29/06/2017	6
July	11/07/2017	3

July	25/07/2017	2
August	08/08/2017	2
August	22/08/2017	2
August	23/08/2017	2
September	05/09/2017	2
September	19/09/2017	4
October	03/10/2017	3
October	17/10/2017	2
October	31/10/2017	2
November	14/11/2017	3
November	28/11/2017	2
December	12/12/2017	2
December	28/12/2017	2
January	11/01/2018	2
January	25/01/2018	2
February	08/02/2018	2
February	22/02/2018	2
March	08/03/2018	3
March	22/03/2018	2

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

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

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

Name	Number of Meetings Attended
Miss Lisa Marie Doherty	8
Dr Sabrina Germain	4
Miss Sarah Gregory	3
Dr Ciaran Scott Hill	4
Mrs Jenny Johnson	6
Ms Eleanor Rose Lees-Millais	4
Dr Athena Lemesiou	3
Ms Karen Sanders	6
Miss Kirstie Shearman	6
Mr Stephan Smith	6
Miss Rosalyn Stanbury	9
Miss Sheetal Sumaria	5
Dr Eamonn Walsh	9
Mr Jonathan Watkins	3
Ms Danielle Wilson	7

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

Name	Number of Meetings Attended
Miss Lisa Marie Doherty	1
Dr Ciaran Scott Hill	2
Mrs Jenny Johnson	2
Ms Eleanor Rose Lees-Millais	4
Ms Karen Sanders	2
Miss Kirstie Shearman	3
Mr Stephan Smith	2
Miss Rosalyn Stanbury	1
Miss Sheetal Sumaria	3
Dr Eamonn Walsh	6
Mr Jonathan Watkins	2
Ms Danielle Wilson	5

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

Name	Number of Meetings Attended
Miss Sarah Gregory	2
Dr Ciaran Scott Hill	2
Mrs Jenny Johnson	4

Ms Eleanor Rose Lees-Millais	3
Ms Karen Sanders	3
Miss Kirstie Shearman	4
Miss Rosalyn Stanbury	9
Miss Sheetal Sumaria	4
Dr Eamonn Walsh	18
Mr Jonathan Watkins	4
Ms Danielle Wilson	18

Training 01 April 2017 - 31 March 2018

Name of Member	Date	Event(s) attended
Miss Lisa Marie Doherty	02/05/2017	RES Committee Members Induction
Miss Lisa Marie Doherty	12/12/2017	National Members Training Day
Dr Sabrina Germain	27/09/2017	Induction for new Research Ethics Service Committee members
Dr Sabrina Germain	12/12/2017	National Members Training Day
Dr Sabrina Germain	11/01/2018	RES Committee Members Induction
Dr Sabrina Germain	19/02/2018	Research involving participants lacking mental capacity
Dr Ciaran Scott Hill	01/06/2017	Active involvement in basic science research on traumatic brain injury and neurodegeneration
Dr Ciaran Scott Hill	01/06/2017	Mentoring of 2 committee members
Dr Ciaran Scott Hill	11/09/2017	Self directed study of document "Regulation and governance of health research: five years on. Nov 2016"
Dr Ciaran Scott Hill	11/09/2017	Delivered lecture 'understanding research ethics' to a group of scientists. This was related to Research governance in the UK
Dr Ciaran Scott Hill	28/11/2017	Equality, Diversity and Human Rights
Mrs Jenny Johnson	27/02/2018	Genetic and Genomic Research (previously HTA Advanced)
Dr Athena Lemesiou	17/02/2018	Equality Diversity and Human Rights
Ms Karen Sanders	01/09/2017	Equality & Diversity
Ms Karen Sanders	29/09/2017	East Midlands Member Training Day
Ms Karen Sanders	12/12/2017	National Members Training Day
Miss Kirstie Shearman	25/07/2017	Committee Members Induction Day Course
Miss Kirstie Shearman	07/02/2018	Research involving participants lacking mental capacity
Mr Stephan Smith	28/06/2017	Equality and Diversity
Mr Stephan Smith	17/07/2017	Induction for new Research Ethics Service Committee members
Mr Stephan Smith	25/07/2017	Committee Members Induction Day Course
Mr Stephan Smith	12/12/2017	National Members Training Day
Miss Rosalyn Stanbury	01/08/2017	Human Tissue Act
Miss Rosalyn Stanbury	03/12/2017	Equality, Diversity & Human Rights
Miss Rosalyn Stanbury	12/12/2017	National Members Training Day

Miss Rosalyn Stanbury	01/03/2018	Research involving participants lacking mental capacity
Miss Sheetal Sumaria	11/11/2017	MRC e-learning module on Human Tissue Act
Miss Sheetal Sumaria	28/12/2017	Self-Directed Learning – Read the NRES informed consent in CTIMPS to refresh knowledge of this process.
Dr Eamonn Walsh	03/05/2017	NREAP Chairs Meeting
Dr Eamonn Walsh	06/11/2017	NREAP Chairs Meeting
Dr Eamonn Walsh	27/11/2017	Equality, Diversity & Human Rights
Dr Eamonn Walsh	05/02/2018	Research involving participants lacking mental capacity
Ms Danielle Wilson	01/05/2017	Diversity, Equality & Dignity at Work
Ms Danielle Wilson	24/11/2017	HRA National Chairs' Day and Policy Event

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)	0	0.00
Others	50	100.00
Total Applications Reviewed	50	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	3
Number of student applications reviewed	18
Number of paediatric applications reviewed	5
Number of device applications reviewed	5
Number of prisoner applications reviewed	0
Number of applications involving adults unable consent reviewed	12
Number of applications reviewed that are funded by the US DHHS	0
Number of qualitative applications reviewed	4

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	5	10.00
Favourable Opinion with Additional Conditions	8	16.00
Unfavourable Opinion	1	2.00
Provisional Opinion	36	72.00
Provisional Opinion Pending Consultation with Referee	0	0.00
Total	50	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	33	64.71
Further Information Favourable Opinion with Additional Conditions	1	1.96
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	5	9.80
Favourable Opinion with Additional Conditions	8	15.69
Unfavourable Opinion	1	1.96
Provisional Opinion	2	3.92
Provisional Opinion Pending Consultation with Referee	0	0.00
Further Information response not complete	1	1.96
No decision entered on system	0	0.00
Number of studies withdrawn after the meeting	0	0.00
Total	51	100

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

Total Applications Reviewed	26
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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	2
My Number of student applications reviewed	9
Number of paediatric applications reviewed	3
Number of device applications reviewed	0
Number of qualitative applications reviewed	2

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	6	23.08
Favourable Opinion with Additional Conditions	5	19.23
No Opinion transfer to full committee for review	2	7.69
Provisional Opinion	13	50.00
Unfavourable Opinion	0	0.00
Total	26	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	5.00
Number of completed applications for full ethical review	51
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 days taken to final decision – average (mean)	34
Number of completed proportionate review applications for ethical review	24
Number of completed proportionate review applications for ethical review over 21 days	0
Number of completed proportionate review applications over 21 days as a % of total	0.00%
Number of SSAs (non-Phase 1) reviewed	19
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	108
Number of completed substantial amendments over 35 days	0
Number of completed substantial amendments over 35 days as a % of total substantial amendments	0.00%
Number of modified amendments reviewed	2
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	115
Number of substantial amendments received for information	0
Number of substantial amendments received for new sites/PIs	0
Number of annual progress reports received	46
Number of safety reports received	0
Number of Serious Adverse Events received	2
Number of final reports received	11

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
17/LO/0485	MRI of brain immune cells	35
17/LO/0586	Multimodal Monitoring Directed Management of Subarachnoid Haemorrhage	32
17/LO/0587	Multimodality Monitoring Directed Management of Traumatic Brain Injury	34
17/LO/0613	Impact of the Glycaemic Load of Meals on Mood in Older Adults	47
17/LO/0686	The Role of Dopamine in Reward and Punishment Processing in Depression	40
17/LO/0738	STROKE ODYSSEYS Version 1	52
17/LO/0766	Mindfulness meditation to treat insomnia	55
17/LO/0840	A non-invasive tool to diagnose ACM/DCM in asymptomatic children	41
17/LO/0841	Understanding the medical features of Norrie disease	29
17/LO/0936	Imaging effects of Minocycline on Microglia	34
17/LO/1025	Precision Genetic Counselling and Reproduction (PREGCARE)	37
17/LO/1037	VASCULARUM	54
17/LO/1243	Investigating physical rehabilitation in severe stroke	30
17/LO/1329	Family adjustment when a member is in Forensic Mental Health setting ²	34
17/LO/1393	Social isolation and loneliness in people aged 60 and above	47
17/LO/1400	Managing agitation in severe dementia	28
17/LO/1542	BHiRCH Pilot cluster randomised trial	34
17/LO/1740	31P Validation Study	56
17/LO/1741	EMmY - Preventing Gestational Diabetes with myo-inositol supplement	45
17/LO/1805	ULRAS Study: Upper Limb Rehabilitation After Stroke	28
17/LO/1820	Change in MND	43
17/LO/1846	Digital Interventions in Neuro-Rehabilitation (DINR)	27
17/LO/1857	Does the Clinical Frailty Score predict functional decline?	29
18/LO/0072	DONATE-GI	37
18/LO/0088	KidGut: Effect of Fibre on Gut Microbes and Kidney disease v1	34
18/LO/0091	Brain Microcirculation in Head Injuries and Brain Tumours	39
18/LO/0092	IRLM-TOF	38
18/LO/0134	Patient-reported outcomes of CKD and diabetes treatments (version 1.1)	54
18/LO/0145	Macustar UK	34
18/LO/0228	RHINE™ Cervical Disc Study	33
18/LO/0234	GEN-AFRICA	46
18/LO/0376	Investigating physiological effects of weight loss on male fertility	31

18/LO/0408	Supporting family carers of people with dementia at the end of life	28
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Further Information Favourable Opinion with Additional Conditions		
REC Reference	Title	Number of Days on Clock
17/LO/0934	ROSProx	32

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
17/LO/0646	UROBIOME study	28
17/LO/0880	OPEL H@H - phase 2	22
17/LO/0916	CMV in Transplants	22
17/LO/1936	Testing alternatives for Psychiatric Nursing Observation at night v1	21
18/LO/0440	Aqueous Dynamics and MicroPulse Laser	22

Favourable Opinion with Additional Conditions		
REC Reference	Title	Number of Days on Clock
17/LO/0996	DEMCOM: National Evaluation of Dementia Friendly Communities	18
17/LO/1254	ARISE - BCG	22
17/LO/1880	Rectal balloon inflation during the push manoeuvre	21
17/LO/1924	Fathers' Experiences of Their Partner's Perinatal OCD	20
17/LO/1935	Use of blue blocking glasses in mania: a feasibility study	21
18/LO/0084	Cognitive function study Version 0.3	28
18/LO/0248	Efficiency of Presurgical Basal Cell Carcinoma margin mapping V02	21
18/LO/0265	Multiple Sclerosis, Executive Function and Employment	26

Unfavourable Opinion		
REC Reference	Title	Number of Days on Clock
17/LO/1351	Molecular Profiling of Patients with CUP and Rare Cancers	26

Provisional Opinion		
REC Reference	Title	Number of Days on Clock
18/LO/0250	Aspects of Auditory Processing Disorder (APD) in children	n/a
18/LO/0443	Ex-BodyComp-Hb study Version 1	n/a

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
17/LO/1743	Bluedop	n/a

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
17/LO/0755	Autonomic stimulation	12
17/LO/1063	Predicting risk in thoracic aortic aneurysm	15
17/LO/1076	Enabling women from BME groups to access NHS cervical screening	16
17/LO/1640	The use of breathing patterns as a potential marker in asthma	18
17/LO/1654	Biomarkers of knee osteoarthritis progression: VIDEO trial	17
17/LO/1817	Change in muscle strength in frail older hospitalised patients	18
17/LO/1823	Health intelligence in the West Midlands (the HILL study)	12
17/LO/1825	MEAN-IT v.1.0	19
17/LO/1996	ORAMMA	16
18/LO/0148	CEP – UK (Clinical Experience of Patiromer in UK)	11

18/LO/0291	Implementation of the IOSN within the Oral Surgery department	17
18/LO/0449	Predicting the long term outcomes of spinal cord stimulation.	17

Further Information Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
17/LO/1418	International Ovarian Tumour Analysis (IOTA) Phase 7: UK Study	13

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
17/LO/0733	Sleep easy with OI	15
17/LO/0908	Emotion recognition, set-shifting and anorexia nervosa	15
17/LO/1414	The Relationship Between Research and the Clinic in Cardiac Genetics	14
17/LO/1420	Whole-genome sequencing-based rapid diagnostics	14
17/LO/2139	LAMMA study - Lung and Mesothelioma Study	13
18/LO/0290	RIB Trans Study	11

Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
17/LO/0539	Cognitive functioning and adherence to treatment in ESRD	10
17/LO/0750	Carpel Tunnel Syndrome (CTS) Grading Tool Study	13
17/LO/1082	Bio-ceramics as a novel treatment of the Charcot foot – in vitro study	14
18/LO/0147	A combination of double staining to aid in grading follicular lymphoma	12
18/LO/0344	MOA study	19

Unfavourable Opinion

REC Reference	Title	Number of Days on Clock
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Provisional Opinion		
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 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
03/N008/AM08	HD Biomarkers	Amendment 18, 26 June 2017	12/07/2017	15
03/N008/AM09	HD Biomarkers	Amendment 19, 29 August 2017	07/09/2017	27
05/Q0512/74/AM21	Structural plasticity in Huntington`s disease	Amendment Number: 20, dated 3rd May 2017	26/05/2017	14
05/Q0512/74/AM23	Structural plasticity in Huntington`s disease	21, 20 August 2017	01/09/2017	7
06/Q0512/106/AM04	Transbil Version 4.0	3 05/11/2017	16/11/2017	31
07/H0716/90/AM03	The role of SOD-1 in ALS pathogenesis.	Version 2, July 2017	26/10/2017	22
07/Q0512/26/AM21	Investigation of human neurological ion channel disorders	AMD#9 26/07/2017	05/09/2017	8
09/H0716/51/AM03	Functional Imaging & DBS in Parkinson's disease	Amendment 3, 9th May 2017	13/06/2017	20
09/H0716/53/AM03	Understanding the role of interruptions in polyQ diseases (Pilot) v1	Amendment 2 (Protocol V3 09.12.16)	27/03/2017	9
09/H0716/61/AM22	CMT: A Natural History Study	# 15 22/06/2017	26/06/2017	8
09/H0716/61/AM24	CMT: A Natural History Study	#16 30/10/2017	30/11/2017	16
09/H0716/64/AM12	A novel cell model for the dementias - Version 1	Amendment 9.0 (Amended): 22/06/2017	23/06/2017	14
09/H0716/76/AM06	Molecular mechanisms in mitochondrial disease (version 1.4)	AMD#4 28/03/2017	18/05/2017	15
09/H0716/76/AM07	Molecular mechanisms in mitochondrial disease (version 1.4)	Sub AM # 5 12.09.2017	16/10/2017	23
10/H0716/51/AM08	European Friedreich's Ataxia Consortium for Translational Studies v1	Amendment - 6	12/07/2017	23
10/H0716/64/AM09	Clinical Relevance Of Microbleeds In Stroke -Intracerebral	Amendment 8, 28	18/10/2017	24

	Haemorrhage	September 2017		
10/H0716/85/AM11	Predict PD - the 1000/100/100 pilot study	Amendment 9 26th September 2017	23/11/2017	34
11/LO/1425/AM07	MRI in Motor Neuropathies V1	#4 20 December 2017	30/01/2018	14
11/LO/1846/AM07	The Effects of Ageing on the Cutaneous Immune System, Version 1	6 (21/12/2017)	16/02/2018	12
12/LO/1504/AM03	CSF collection in patients with neurodegenerative diseases	3.0	27/08/2017	10
13/LO/0731/AM03	PET imaging in MCI following ADT for PCa	3. dated 05 April 2017	10/04/2017	18
13/LO/0898/AM01	Endometriosis and ovarian reserve	1.0, 21/9/17	25/01/2018	23
13/LO/1156/AM05	EU-AIMS Accelerated Longitudinal Study	Amendment no 4, 27 March 2017	29/03/2017	19
13/LO/1156/AM06	EU-AIMS Accelerated Longitudinal Study	Amendment no 5, 21 August 2017	13/09/2017	34
13/LO/1457/AM02	PREDICT PD: Imaging Arm	Amendment 2 3rd October 2017	25/10/2017	10
13/LO/1457/AM03	PREDICT PD: Imaging Arm	Amendment 3 30th January 2018	16/02/2018	22
13/LO/1515/AM19	PLORAS version 1	7 12/12/2017	25/01/2018	23
14/LO/0061/AM03	GlucoCEST	version 1.11, April 2017	31/05/2017	26
14/LO/1069/AM10	IMAGINE	6.1 5 July 2017	05/07/2017	22
14/LO/1073/AM07	Life course pathways to ageing in the MRC NSHD	3 15/09/2017	23/10/2017	34
14/LO/1173/AM04	MRC National Survey of Health and Development Neuroimaging sub-study	Amendment 2: 14-Aug-2017	06/09/2017	15
14/LO/1575/AM17	PSP CBD MSA Longitudinal Study - UK (PROSPECT-M-UK)	Amendment 6, 10/03/2017	16/03/2017	31
14/LO/1575/AM20	PSP CBD MSA Longitudinal Study - UK (PROSPECT-M-UK)	Substantial amendment 7	25/05/2017	21
14/LO/1593/AM02	The effect of oxytocin on social processing in Anorexia V1 01.07.2014	V4 08.05.2017	11/05/2017	11
14/LO/1648/AM03	Minimal volume for a fluid challenge in septic patients	1 09/02/2017	07/04/2017	17
14/LO/1650/AM01	MAGENTA - v1.2	1 - 9/05/2017	12/06/2017	7
14/LO/1758/AM07	Genetic Frontotemporal dementia Initiative (GENFI)	Amendment 6: 22-March-2017	05/05/2017	10

14/LO/2028/AM06	GENFI - IMPETus Tau PET imaging pilot study	Amendment 5: 25-April-17	05/05/2017	10
14/LO/2045/AM02	The COGENT Study (version 1)	V2 14/04/2017	25/05/2017	10
15/LO/0046/AM04	Time for Dementia	3 06.10.17	07/11/2017	35
15/LO/0305/AM05	EU-AIMS synaptic gene deficit project	Substantial Amendment 4, 4th August 2017	17/08/2017	6
15/LO/0476/AM08	Vision in Parkinson's Disease	Amendment 4, 28th March 2017	31/03/2017	17
15/LO/0600/AM01	Non-Viral Liver Disease Service In HIV Positive Individuals	1 4th July 2017	06/07/2017	19
15/LO/1155/AM05	RAPSODI GD	3: 21.09.2017	19/10/2017	26
15/LO/1288/AM04	Using technology to improve the care of adolescents with arthritis	Amendment 2, 26/07/2017	16/08/2017	14
15/LO/1412/AM04	A study of brain amyloid and tau deposition using Florbetapir and T807	Substantial Amendment 2: 30-May-2017	19/06/2017	11
15/LO/1412/AM05	A study of brain amyloid and tau deposition using Florbetapir and T807	Substantial Amendment 3: 27-July-2017	09/08/2017	21
15/LO/1412/AM06	A study of brain amyloid and tau deposition using Florbetapir and T807	Substantial Amendment 4.0: 17-August-2017	22/08/2017	6
15/LO/1463/AM02	Dietary patterns analysis in PKU	Amendment 2 14/2/18	15/02/2018	19
15/LO/1464/AM04	DARS	Substantial amendment 02, 05/05/2017	08/05/2017	10
16/LO/0044/AM35	Determinants of prognosis in stroke	Amendment Number:2 Date of Amendment: 29/01/2018	23/02/2018	29
16/LO/0077/AM02	Major Depressive Disorder (MDD)- a computational neuroscience approach	Amendment 2 (Substantial), 25/10/2017	30/10/2017	34
16/LO/0264/AM01	Hemianopia in posterior cortical atrophy	Amendment 1	06/04/2017	12
16/LO/0265/AM05	NOPRODUCTHPB0003	Substantial Amendment 3	24/05/2017	13

		dated 23 May 2017		
16/LO/0265/AM06	NOPRODUCTHPB0003	Substantial Amendment 4 dated 22 June 2017	22/06/2017	15
16/LO/0265/AM07	NOPRODUCTHPB0003	Substantial Amendment 4 dated 16 Aug 2017	17/08/2017	22
16/LO/0458/AM02	Natural history in mucopolysaccharidosis type IIIA	Protocol Amendment 1, v.2.0 dated 03 Apr 2017	21/06/2017	16
16/LO/0544/AM04	Understanding and managing everyday task performance in dementia	Substantial Amendment #1	24/10/2017	20
16/LO/0697/AM03	Negotiating Identity: Young People, ADHD and Medication	Amendment 3 12/10/2017	12/10/2017	15
16/LO/0847/AM02	Collection and characterisation of human olfactory ensheathing cells.	SA02 28/09/2017	03/10/2017	21
16/LO/0847/AM03	Collection and characterisation of human olfactory ensheathing cells.	SA03 22/11/2017	24/11/2017	10
16/LO/0907/AM01	Ultrasound Elastography of fascia of lower leg muscle compartment.	1.3 25/10/16	16/01/2017	29
16/LO/0907/AM02	Ultrasound Elastography of fascia of lower leg muscle compartment.	06.11.2017	04/12/2017	5
16/LO/1366/AM02	The demenTia Research And Care Clinic (TRACC)	2, 7th March 2017	06/04/2017	21
16/LO/1366/AM03	The demenTia Research And Care Clinic (TRACC)	3, 12th June 2017	20/06/2017	35
16/LO/1366/AM04	The demenTia Research And Care Clinic (TRACC)	4, 25th October 2017	26/10/2017	32
16/LO/1520/AM02	IFN-alpha and neuroinflammation in healthy men	Amendment 2 14/07/2017	28/07/2017	14
16/LO/1520/AM03	IFN-alpha and neuroinflammation in healthy men	Amendment 3 18/08/2017	18/08/2017	8
16/LO/1852/AM02	Single molecule biomarker discovery in inflammatory neuropathy	AM01 29/8/17	06/09/2017	23
16/LO/1912/AM02	Tendyne Expanded Clinical Study	2, 12 December 2017	12/12/2017	35

16/LO/1979/AM02	STATEC	STATEC: 01-17/07/2017	19/07/2017	28
16/LO/1987/AM02	CLIMB-CF	1 01/06/2017	09/06/2017	8
16/LO/2251/AM04	HAPII Impact and prevalence study	1.3 19th May 2017	01/06/2017	7
17/LO/0056/AM01	SCD-WELL	1 22.08.2017	22/09/2017	18
17/LO/0056/AM02	SCD-WELL	2. 02.11.2017	02/11/2017	29
17/LO/0056/AM03	SCD-WELL	3 14.12.17	14/12/2017	25
17/LO/0079/AM01	CARDIUM	Amendment 1 Date: 29/01/2018	23/02/2018	12
17/LO/0095/AM01	TANDEM COPD Trial	v2.0 4 April 2017	20/04/2017	13
17/LO/0095/AM02	TANDEM COPD Trial	Amendment number 2. Date 13-6-17	27/06/2017	30
17/LO/0095/AM03	TANDEM COPD Trial	Amendment number 3 dated 17-8-17	23/08/2017	34
17/LO/0107/AM02	COAGULUM	Amendment 1 Date 29/01/2018	23/02/2018	12
17/LO/0114/AM01	ATRIUM	Amendment 1 Date: 29/01/2018	23/02/2018	12
17/LO/0134/AM01	Suicide and crisis care: How Crisis Houses influenced recovery	Amendment 1, date: 19.04.17	19/04/2017	14
17/LO/0218/AM01	Mothers' experiences of feeding their child jejunally/via gastrostomy.	Amendment 1 05/04/2017	21/04/2017	9
17/LO/0291/AM01	Longitudinal language mapping in surgical LGG patients	No 1, Date: 07.08.2017	09/08/2017	20
17/LO/0407/AM02	Acceptance and Commitment Therapy for Dementia Carers version 1.0	ver 1.3, 08 August 2017	11/08/2017	22
17/LO/0449/AM01	ECCL cCMV Database V2.0	1.0 10 July 2017	18/07/2017	15
17/LO/0475/AM01	CABRIO proof of concept study V1.1 020217	Amendment number 1 dated 19/06/2017	28/06/2017	20
17/LO/0586/AM01	Multimodal Monitoring Directed Management of Subarachnoid Haemorrhage	Amendment #1, 13th March 2018	13/03/2018	29
17/LO/0587/AM01	Multimodality Monitoring Directed Management of Traumatic Brain Injury	Amendment #1, 07-03-2018	13/03/2018	29

17/LO/0686/AM01	The Role of Dopamine in Reward and Punishment Processing in Depression	first amendment, 31/08/17	04/09/2017	16
17/LO/0686/AM02	The Role of Dopamine in Reward and Punishment Processing in Depression	second amendment, 11/09/17	14/09/2017	26
17/LO/0766/AM01	Mindfulness meditation to treat insomnia	One 12/07/2017	28/07/2017	18
17/LO/0880/AM01	OPEL H@H - phase 2	Substantial Amendment 1, October 2017	09/11/2017	15
17/LO/0934/AM01	ROSProx	01, 18/09/2017	26/09/2017	15
17/LO/0934/AM02	ROSProx	02,12/02/2018	09/03/2018	34
17/LO/0936/AM01	Imaging effects of Minocycline on Microglia	Amendment 1: 20th October 2017	10/11/2017	19
17/LO/0996/AM02	DEMCOM: National Evaluation of Dementia Friendly Communities	Substantial Amendment 1 - Dec 17	07/12/2017	7
17/LO/1025/AM01	Precision Genetic Counselling and Reproduction (PREGCARE)	1, 16/08/2017	25/08/2017	24
17/LO/1037/AM01	VASCULARUM	Amendment 1 Date 29/01/2018	23/02/2018	31
17/LO/1400/AM01	Managing agitation in severe dementia	v4 10-NOV-2017	23/11/2017	22
17/LO/1805/AM01	ULRAS Study: Upper Limb Rehabilitation After Stroke	Substantial Amendment 01	11/12/2017	30
17/LO/1805/AM02	ULRAS Study: Upper Limb Rehabilitation After Stroke	Substantial Amendment 02	13/12/2017	30
17/LO/1805/AM03	ULRAS Study: Upper Limb Rehabilitation After Stroke	Substantial Amendment 03	23/01/2018	28
17/LO/1846/AM01	Digital Interventions in Neuro-Rehabilitation (DINR)	1 Date 13/11/17	16/11/2017	22

Unfavourable opinion				
Amendment REC Reference	Title	Version	Date	Number of Days on Clock
09/H0716/61/AM25	CMT: A Natural History Study	#17 22.01.2018	02/03/2018	27
15/LO/0305/AM04	EU-AIMS synaptic gene deficit project	Amendment 2, 6th April 2017	24/04/2017	14
16/LO/1711/AM01	Localised Neuropathic Pain in primary care	01 - 08th May 2017	17/05/2017	35

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
15/LO/0305/AM04/1	EU-AIMS synaptic gene deficit project	Amendment 2.2, 5th June 2017	21/06/2017	14
17/LO/0182/AM04/1	FORTIFY Clinical Trial	4, 5-March-2018	10/03/2018	3

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

Proportionate review applications for ethical review over 21 day timeline		
REC Reference	Title	Number of Days on Clock

SSAs (non Phase 1) over 25 day timeline		
REC Reference	Title	Number of Days on Clock

SSAs (Phase 1) over 14 day timeline		
REC Reference	Title	Number of Days on Clock

Substantial Amendments over 35 day timeline				
Amendment REC	Title	Version	Date	Number of Days on

Reference				Clock
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Modified Amendments over 14 day timeline				
Amendment REC Reference	Title	Version	Date	Number of Days on Clock