

**London - Queen Square Research Ethics
Committee**

Annual Report

01 April 2015 - 31 March 2016



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 Yogi Amin
Vice-Chair:	Dr Eamonn Walsh
Alternate Vice-Chair:	Mrs Jenny Johnson (16/04/2015 – 16/10/2015) Miss Danielle Wilson – 19/11/2015
REC Manager:	Ms Rachel Heron
REC Assistant:	Miss Jenna Woodburn (from December 2015)
Committee Address:	HRA NRES Centre Manchester Barlow House 3rd Floor 4 Minshull Street Manchester M1 3DZ
Telephone:	
Email:	nrescommittee.london-queensquare@nhs.net

Chair's overview of the past year:

The Committee has continued to work well together this year. The newer members have grown in confidence, and have been pleased to welcome another 3 new members – Miss Zalika Xavier, Dr Khalil Hassanally and Miss Rosie Millais. Danielle Wilson has taken on the position of Alternative Vice Chair and this has been much appreciated.

Dr Mark Barrett left in April and three more members are close to the end of their 10 year term of service, including Dr Yogi Amin, Chair. The Committee has been sad to see them go.

I am sure that the Committee will continue to grow in numbers, and continue to improve as members become more knowledgeable and confident in their role.

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	
Dr Mark Barrett	GP	Expert	19/04/2005	19/04/2015
Miriamtha Dahdal	Teaching Assistant	Lay Plus	20/03/2014	
Dr Simon Eaton	Senior Lecturer in Paediatric Surgery and Metabolic Biochemistry	Expert	11/09/2006	
Miss Sarah Gregory	Clinical Research Officer	Lay	11/02/2014	
Dr Katie Harron	Statistician	Expert	01/02/2014	
Dr Khalil Hassanally	GP	Expert	01/09/2015	
Dr Ciaran Scott Hill	Neurosurgery Speciality Registrar	Expert	08/03/2011	
Mrs Jenny Johnson	Charity Trustee	Lay Plus	18/03/2008	
Eleanor Rose Lee-Millais	Nurse	Lay Plus	01/02/2016	
Dr Lorraine Ludman	Chartered Psychologist	Lay	18/05/2006	
Mrs Claire Reynolds	Radiotherapy Radiographer	Expert	26/06/2013	
Dr Gella Richards	Psychologist	Expert	20/01/2005	20/01/2015
Miss Sheetal Sumaria	Pharmacist	Expert	12/05/2009	
Dr Eamonn Walsh	Lecturer	Expert	19/04/2011	
Mr Jonathan Watkins	Social Worker	Expert	01/10/2015	
Ms Danielle Wilson	Clinical Trials Facility Manager	Lay	07/03/2013	
Miss Zalika Xavier	Vaccine Sales Representative	Lay	16/04/2015	

London - Queen Square Research Ethics Committee: Deputy Members

Name	Profession	Status	Meeting date attended
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London - Queen Square Research Ethics Committee: Co-opted Members

Name	Profession	Status	Meeting date attended
Mr Ron Driver	Retired Statistician	Lay	16/07/2015 (Full REC meeting)
Mrs Julie Brinton	Speech and Language Therapist	Expert	16/07/2015 (Full REC meeting)
Dr Lorraine Lighton	Consultant in Communicable Diseases	Expert	20/08/2015 (PRSC)
Dr Lisa Booth	Senior Lecturer	Expert	18/02/2016 (PRSC)
Dr Yash Patel	Research Project Manager	Expert	16/04/2015 (PRSC)
Dr Simon Jones	Podiatrist	Expert	16/04/2015 (PRSC)

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

Name	Declaration of Interest	Date
Dr Simon Eaton	No interests were declared for this period	23/03/2016
Miss Sarah Gregory	Member declared that she is Senior Clinical Research Coordinator in a Clinical trials facility at West London Mental Health Trust.	22/02/2016
Dr Katie Harron	Member declared that she is employed by the London School of Hygiene and Tropical Medicine, and is a reviewer for Archives of Disease in Medicine and BMJ	24/02/2016
Dr Khalil Hassanally	No interests have been declared for this period.	23/12/2015
Mrs Jenny Johnson	Trustee of Kennedy Trust for Rheumatology Research	23/02/2016
Eleanor Rose Lee-Millais	No interests were declared for this period	21/01/2016
Miss Sheetal Sumaria	No interests were declared for this period	30/03/2016
Dr Eamonn Walsh	Member declared that he works in research at Birbeck and Kings College London, mainly with healthy volunteers.	23/02/2016
Mr Jonathan Watkins	Member stated that he is a consultant for Coram Children's Legal Centre and Health PROM, he is also a consultant for development charities in Central Asia and East Africa. He is a part time lecturer at London Metropolitan University.	23/02/2016
Ms Danielle Wilson	Member declared that she manages an NHS clinical trials unit and is employed by West London Mental Health Trust.	01/03/2016
Miss Zalika Xavier	No interests were declared for this period.	26/06/2015

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

Month	Date	Number of Members Present at Meeting
April	16/04/2015	7
May	21/05/2015	8
July	16/07/2015	6
August	20/08/2015	7
September	17/09/2015	7
October	15/10/2015	9
November	19/11/2015	10
January	21/01/2016	7
February	18/02/2016	9
March	17/03/2016	8

10 full committee meetings were held during the reporting period.

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

Month	Date	Number of Members Present at Meeting
April	16/04/2015	4
July	16/07/2015	3
August	20/08/2015	3
September	17/09/2015	3
October	15/10/2015	3
November	19/11/2015	3
December	04/12/2015	3
January	21/01/2016	3
February	18/02/2016	3
March	17/03/2016	3

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

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

Month	Date	Number of Members Present at Meeting
April	02/04/2015	2
April	16/04/2015	2
May	07/05/2015	2
May	21/05/2015	2
June	15/06/2015	2
July	06/07/2015	2
July	16/07/2015	3
August	14/08/2015	6
August	20/08/2015	2
September	07/09/2015	3
September	14/09/2015	3

September	25/09/2015	2
October	19/10/2015	2
November	02/11/2015	2
November	19/11/2015	2
November	23/11/2015	2
December	14/12/2015	2
December	14/12/2015	3
December	15/12/2015	3
January	06/01/2016	3
January	06/01/2016	3
January	20/01/2016	3
January	21/01/2016	2
January	28/01/2016	2
February	01/02/2016	3
February	04/02/2016	2
February	10/02/2016	3
February	18/02/2016	2
March	03/03/2016	4
March	11/03/2016	3
March	17/03/2016	3

31 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

Name	Number of Meetings Attended
Dr Yogi Amin	5
Dr Simon Eaton	4
Miss Sarah Gregory	8
Dr Katie Harron	7
Dr Khalil Hassanally	5
Mrs Jenny Johnson	6
Dr Lorraine Ludman	7
Miss Sheetal Sumaria	6
Dr Eamonn Walsh	9
Mr Jonathan Watkins	4
Ms Danielle Wilson	8
Miss Zalika Xavier	9

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

Name	Number of Meetings Attended
Dr Yogi Amin	2
Dr Simon Eaton	4
Miss Sarah Gregory	4
Mrs Jenny Johnson	5
Dr Lorraine Ludman	5
Miss Sheetal Sumaria	1
Dr Eamonn Walsh	4
Ms Danielle Wilson	2

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

Name	Number of Meetings Attended
Dr Yogi Amin	16
Dr Simon Eaton	8
Miss Sarah Gregory	7
Mrs Jenny Johnson	8
Dr Lorraine Ludman	6
Miss Sheetal Sumaria	2
Dr Eamonn Walsh	21
Mr Jonathan Watkins	3
Ms Danielle Wilson	4
Miss Zalika Xavier	4

Training 01 April 2015 - 31 March 2016

Name of Member	Date	Event(s) attended
Dr Simon Eaton	11/03/2016	Introduction to Analysis of Hospital Episodes Statistics Course
Dr Simon Eaton	14/03/2016	HSCIC Data Applications and Approvals
Dr Katie Harron	13/01/2016	Assessing the Consequences (benefits and harms) of research
Dr Khalil Hassanally	04/11/2015	Members Induction
Mrs Jenny Johnson	13/01/2016	Assessing the Consequences (benefits and harms) of research
Dr Lorraine Ludman	12/10/2015	Complex Cases
Dr Eamonn Walsh	19/05/2015	NREAP Chairs Meeting
Dr Eamonn Walsh	02/11/2015	NREAP Chairs Meeting
Dr Eamonn Walsh	06/11/2015	Gave lecture to trainee psychiatry consultants on conducting research in the NHS
Dr Eamonn Walsh	01/12/2015	Read up on Caldicott Principles
Dr Eamonn Walsh	01/01/2016	Read up on Declaration of Helsinki
Dr Eamonn Walsh	18/01/2016	Online GCP refresher course
Ms Danielle Wilson	01/05/2015	Workplace experience Presentation at International Clinical Trials day on research ethics, namely ethical issues in research involving patients with dementia who might lack capacity
Ms Danielle Wilson	01/09/2015	Workplace experience - teaching consent process
Ms Danielle Wilson	01/10/2015	Workplace experience - teaching staff to assess capacity
Ms Danielle Wilson	30/03/2016	Workplace experience developing protocols and patient facing documentation

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)	1	1.89
Others	52	98.11
Total Applications Reviewed	53	100

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	20
Number of paediatric applications reviewed	8
Number of device applications reviewed	3
Number of prisoner applications reviewed	0
Number of applications involving adults unable consent reviewed	13
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	2	3.77
Favourable Opinion with Additional Conditions	13	24.53
Unfavourable Opinion	1	1.89
Provisional Opinion	37	69.81
Provisional Opinion Pending Consultation with Referee	0	0.00
Total	53	100
Number of studies sent back to full committee meeting for final opinion	1	

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	8	14.81
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	2	3.70
Favourable Opinion with Additional Conditions	13	24.07
Unfavourable Opinion	1	1.85
Provisional Opinion	0	0.00
Provisional Opinion Pending Consultation with Referee	0	0.00
Further Information response not complete	0	0.00
No decision entered on system	0	0.00
Number of studies withdrawn after the meeting	0	0.00
Total	54	100

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

Total Applications Reviewed	18
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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	10
Number of studies withdrawn prior to the meeting	4
Number of student applications reviewed	7
Number of paediatric applications reviewed	2
Number of device applications reviewed	3
Number of qualitative applications reviewed	0

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	5	27.78
Favourable Opinion with Additional Conditions	11	61.11
No Opinion transfer to full committee for review	1	5.56
Provisional Opinion	1	5.56
Unfavourable Opinion	0	0
Total	18	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	5.30
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	6
Number of completed applications over 40 days as a % of total	11.32%
Number of days taken to final decision – average (mean)	28
Number of completed proportionate review applications for ethical review	17
Number of completed proportionate review applications for ethical review over 14 days	1
Number of completed proportionate review applications over 14 days as a % of total	5.88%
Number of SSAs (non-Phase 1) reviewed	3
Number of completed applications for SSA review over 25 days	1
Number of completed applications for SSA review over 25 days as % of all non- Phase 1 SSAs	33.33%
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%
Number of substantial amendments reviewed	100
Number of completed substantial amendments over 35 days	2
Number of completed substantial amendments over 35 days as a % of total substantial amendments	2%
Number of completed substantial amendments over 28 days	7
Number of completed substantial amendments over 28 days as a % of total substantial amendments	7%
Number of modified amendments reviewed	4
Number of completed modified amendments over 14 days	0
Number of completed modified amendments over 14 days as a % of total modified amendments	0%
Number of minor amendments received	56
Number of substantial amendments received for information	0
Number of substantial amendments received for new sites/PIs	0
Number of annual progress reports received	44
Number of safety reports received	0
Number of Serious Adverse Events received	0

Number of final reports received	5
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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
15/LO/0442	TTR V122I allele in Afro-Caribbeans and Cardiovascular Disease V1.2	54
15/LO/0468	BASIS Human Genomics	25
15/LO/0585	Goal Setting in Neurological Rehabilitation	29
15/LO/0601	Patient Decision Aid for Antidepressant Use In Pregnancy	28
15/LO/0685	Glycosade® v UCCS in Hepatic GSD (Glyde). Version 2	25
15/LO/0686	Self-Esteem and Aggression in Forensic Psychiatric Patients	23
15/LO/0867	Users' and carers' views of stratified medicine: phase 2	36
15/LO/0876	PSYCHLOPS VASC V1.0	32
15/LO/0938	How do family caregivers maintain their relative's personhood?	27
15/LO/1150	Decisions and judgements in OCD	14
15/LO/1167	Pain management in people with dementia in care homes: feasibility	32
15/LO/1211	RIVER Registry – Rivaroxaban Evaluation in Real life setting	39
15/LO/1475	Whole body magnetic resonance imaging in juvenile idiopathic arthritis	27
15/LO/1486	Developing a brief clinical screening tool for trauma and its impact	29
15/LO/1501	Immune mechanisms of alcoholic hepatitis	24
15/LO/1531	Study of Parkinson's disease and impulsive compulsive behaviours	20
15/LO/1704	Evaluating patient knowledge and competence in CBT for OCD	28
15/LO/1783	High frequency activity in epilepsy patients	27
15/LO/1853	PRO-14023	38
15/LO/1899	Low radiation dose Computer Tomography (CT) assessment of TSA	44
15/LO/1914	The feasibility of an RCT for stroke mimics in a stroke setting	56
16/LO/0076	ENERGY-ICU REHAB	19
16/LO/0077	Major Depressive Disorder (MDD)- a computational neuroscience approach	20
16/LO/0164	Neuromodulation for Reducing Neurogenic Detrusor Overactivity in SCI	20
16/LO/0178	Fatigue in people with musculoskeletal problems.	29
16/LO/0238	NECTARINE -Neonate Childrens study of Anaesthesia Practice in Europe	35
16/LO/0264	Hemianopia in posterior cortical atrophy	31
16/LO/0269	Vascular changes in CKD	34
16/LO/0458	Natural history in mucopolysaccharidosis type IIIA	34
16/LO/0460	Social media: understandings and experiences in eating disorders	23

Further Information Favourable Opinion with Additional Conditions		
REC Reference	Title	Number of Days on Clock
15/LO/1248	An exploration of the enactment of midwifery led care version 1	51
15/LO/1288	Using technology to improve the care of adolescents with arthritis	30
15/LO/1647	Realtime fMRI neurofeedback training of SMA in pre-op DBS-STN patients	20
15/LO/1726	Time and motion study: point of tear ABG sampling	35
16/LO/0044	Determinants of prognosis in stroke	20
16/LO/0265	NOPRODUCTHPB0003	41
16/LO/0326	Effect of standing, lying and stockings on blood bio-markers (v.1)	55
16/LO/0461	Causes of Acute Coronary Syndrome in People with SCAD or CAE	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
15/LO/0650	Clinically isolated syndrome 30 year follow up study	21
16/LO/0450	Cancer survival in the United Kingdom (Wales)	21

Favourable Opinion with Additional Conditions		
REC Reference	Title	Number of Days on Clock
15/LO/0864	Service provision in end of life dementia care (version 1:0)	25
15/LO/0875	Having Spinal Tuberculosis.	25
15/LO/1155	RAPSODI GD	26
15/LO/1224	Oxytocin in healthy relatives of frontotemporal dementia (Version 1)	26
15/LO/1323	Patient Reported Outcomes - patients and caregivers (PROACT)	27
15/LO/1412	A study of brain amyloid and tau deposition using Florbetapir and T807	20
15/LO/1459	Genetics of Severe Personality Disorder and Mental Illness	20
15/LO/1464	DARS	20
15/LO/1720	Serial CrCl in AKI	19
15/LO/1741	Telomere biology and acute kidney injury in cardiac surgery	19

15/LO/1845	Serial mpMRI scanning in prostate cancer post ADT and RT	22
15/LO/1909	Parent Led Articulation Therapy in Cleft Palate Speech-PLAT	22
16/LO/0011	BESPOKE	19

Unfavourable Opinion

REC Reference	Title	Number of Days on Clock
15/LO/1321	AEGLE	26

Provisional Opinion

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

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

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

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

Further Information Favourable Opinion with Standard Conditions

REC Reference	Title	Number of Days on Clock
15/LO/1463	Dietary patterns analysis in PKU	12

Further Information Favourable Opinion with Additional Conditions

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

Favourable Opinion with Standard Conditions		
REC Reference	Title	Number of Days on Clock
15/LO/1307	Knee Arthroplasty Patients Predicted versus Actual recovery (KAPPA)	7
15/LO/1662	AMR 2 Trial - Reducing Antibiotic Prescribing in Primary Care	6
15/LO/2143	Biomarker assessment in bladder cancer V1.0	6
16/LO/0402	Rhinoclediella antibody study v1.0	10
16/LO/0539	A phylogenetic analysis of the Brighton HIV cohort	8

Favourable Opinion with Additional Conditions		
REC Reference	Title	Number of Days on Clock
15/LO/0737	Medication uptake in difficult asthma – qualitative analysis	10
15/LO/0741	Time since last screen and breast cancer stage	15
15/LO/1497	Shaping a vision for implementing Recovery in Hull: a Delphi Study	7
15/LO/1507	FACE-Q KIDS PROM Study	13
15/LO/1522	Prevalence of Pompe's disease in respiratory clinics	4
15/LO/1660	Does cropping lateral cephalograms affect CVM staging reliability?	5
15/LO/1869	PhNR Repeatability Project	14
15/LO/2067	BIND	5
15/LO/2144	A feasibility study into the objective assessment of low back pain	11
16/LO/0219	Wound Infection Detection Test	12
16/LO/0234	Investigation of Visual Acuity with Near-Intermediate Monovision	10

Unfavourable Opinion		
REC Reference	Title	Number of Days on Clock

Provisional Opinion		
REC Reference	Title	Number of Days on Clock

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
03/N049/AM04	Genetic Analysis of Early Onset of Dementia	10	01/04/2015	14
05/Q0512/74/AM19	Structural plasticity in Huntington's disease	18	04/12/2015	6
06/Q0512/107/AM09	Periodontal Therapy and Vascular Function	8	21/04/2015	28
06/Q0512/81/AM08	Neuropsychology of posterior cortical atrophy (Version 1)	7	20/01/2016	10
07/Q0512/26/AM14	Investigation of human neurological ion channel disorders	6	20/10/2015	24
09/H0716/18/AM01	Magnetic resonance method development with healthy volunteers	1	17/12/2015	28
09/H0716/48/AM02	Validation of Web-Based BRAIN Test	2	03/12/2015	46
09/H0716/61/AM14	CMT: A Natural History Study	AMD#10	17/03/2015	18
09/H0716/61/AM16	CMT: A Natural History Study	AMD#11	07/07/2015	27
09/H0716/61/AM18	CMT: A Natural History Study	12	09/12/2015	27
09/H0716/75/AM04	Equilibrium phase CT to assess disease of the liver and heart	3	20/03/2015	18
09/H0716/75/AM05	Equilibrium phase CT to assess disease of the liver and heart	4	22/09/2015	47
09/H0716/76/AM05	Molecular mechanisms in mitochondrial disease (version 1.4)	3	13/12/2015	28
09/H0716/77/AM07	The Effects of Multiple Sclerosis on Brain Grey Matter	3	17/02/2016	28
10/H0716/2/AM04	Reward and punishment in depression	3	30/11/2015	23
10/H0716/51/AM04	European Friedreich's Ataxia Consortium for Translational Studies v1	Protocol v3	09/03/2015	8
10/H0716/51/AM05	European Friedreich's Ataxia Consortium for Translational Studies v1	3	20/01/2015	20

10/H0716/72/AM02	VEP and OCT in Uhthoff's phenomenon	1	26/11/2015	2
10/H0716/85/AM08	Predict PD - the 1000/100/100 pilot study	6	12/11/2015	10
11/LO/0396/AM02	The Metabolic Profile in Obstetric Cholestasis	1	23/04/2015	13
11/LO/0396/AM03	The Metabolic Profile in Obstetric Cholestasis	2:8	01/06/2015	11
11/LO/0753/AM02	Longitudinal Research into Alzheimer's Disease and other Dementias	2	14/12/2015	18
11/LO/1425/AM03	MRI in Motor Neuropathies V1	2	23/09/2015	14
11/LO/1675/AM04	Hearing Evaluation And Rehabilitation after Stroke-HEARS	4	13/03/2015	12
12/LO/1109/AM04	PROMPTS	5	10/02/2015	21
12/LO/1109/AM05	PROMPTS	6	22/04/2015	12
12/LO/1109/AM07	PROMPTS	7	02/03/2016	13
12/LO/1504/AM02	CSF collection in patients with neurodegenerative diseases	2	17/02/2016	6
13/LO/0269/AM03	Acute kidney injury and immune function	2	09/11/2015	14
13/LO/1015/AM01	Intra-tumoural Heterogeneity in Primary Breast cancer	1	11/03/2015	13
13/LO/1028/AM02	Non-invasive brain stimulation and cognitive processing in depression	One	08/04/2015	25
13/LO/1105/AM01	Multiple myeloma lifestyle study	1	10/07/2015	29
13/LO/1131/AM01	Genes for CMV; v1.0	1	11/03/2015	20
13/LO/1156/AM02	EU-AIMS Accelerated Longitudinal Study	2	23/04/2015	22
13/LO/1304/AM06	Optimising palliative care for older people; phases 1b and 2 (OPTCare)	3	04/12/2015	25
13/LO/1512/AM02	A RCT comparing twin block wear for varying durations	One	12/11/2015	26
13/LO/1515/AM07	PLORAS version 1	5	08/01/2016	15
13/LO/1515/AM10	PLORAS version 1	6	16/02/2016	29
13/LO/1762/AM01	A new prospective Study in Clinically Isolated Syndrome	1	13/01/2016	7
14/LO/0055/AM11	Epilepsy Nurse Trial for adults with ID (01)	4	22/05/2015	16
14/LO/0055/AM15	Epilepsy Nurse Trial for adults with ID (01)	5	17/08/2015	27
14/LO/0055/AM16	Epilepsy Nurse Trial for adults with ID (01)	6	13/11/2015	18
14/LO/0061/AM01	GlucoCEST	1	18/11/2015	17
14/LO/0288/AM02	Ketone levels in healthy individuals following a ketone drink.	2	07/01/2016	19
14/LO/0697/AM01	MARQUE: Improving agitation in people with dementia in care homes	1	09/09/2015	23
14/LO/0697/AM02	MARQUE: Improving agitation in people with dementia in care homes	2	22/02/2016	14
14/LO/0748/AM02	Evaluating a rehabilitation protocol following lumbar fusion surgery.	2	26/01/2015	21

14/LO/1069/AM02	IMAGINE	1.1	03/03/2015	24
14/LO/1069/AM03	IMAGINE	2	12/05/2015	17
14/LO/1069/AM04	IMAGINE	1.2.1	15/05/2015	14
14/LO/1069/AM06	IMAGINE	4.0	22/02/2016	27
14/LO/1073/AM04	Life course pathways to ageing in the MRC NSHD	1	06/01/2016	12
14/LO/1146/AM06	Evaluation of Memory Assessment Services: Main Study (phase 2) v1	1.0	19/06/2015	14
14/LO/1170/AM04	Understanding personal recovery experiences in Bipolar Disorder	2	29/03/2015	23
14/LO/1170/AM05	Understanding personal recovery experiences in Bipolar Disorder	3	30/07/2015	29
14/LO/1411/AM03	EEG measures of aging and Alzheimer's disease in Down's Syndrome	3	31/03/2015	17
14/LO/1479/AM01	Understanding and improving healthcare experiences of people with HIV	1	05/06/2015	28
14/LO/1575/AM01	PSP CBD MSA Longitudinal Study - UK (PROSPECT-M-UK)	1	07/08/2015	27
14/LO/1575/AM05	PSP CBD MSA Longitudinal Study - UK (PROSPECT-M-UK)	2	14/03/2016	15
14/LO/1758/AM02	Genetic Frontotemporal dementia Initiative (GENFI)	2	01/04/2015	15
14/LO/1758/AM03	Genetic Frontotemporal dementia Initiative (GENFI)	3	21/07/2015	21
14/LO/1758/AM04	Genetic Frontotemporal dementia Initiative (GENFI)	4	08/09/2015	24
14/LO/1792/AM01	Intermittent versus Continuous Feeding on the Intensive Care Unit v3	1	26/02/2015	23
14/LO/1830/AM01	LPS and neuroinflammation in healthy men	Version 2	20/04/2015	14
14/LO/1903/AM02	Fear of CHILDbirth and physiological stress (CHILL)	Protocol version 2.0	13/04/2015	10
14/LO/2028/AM02	GENFI - IMPETus Tau PET imaging pilot study	1	04/03/2015	23
14/LO/2028/AM03	GENFI - IMPETus Tau PET imaging pilot study	2	07/07/2015	27
14/LO/2045/AM01	The COGENT Study (version 1)	1	16/12/2015	23
14/LO/2270/AM01	Assessing the psychological impact of hyperemesis gravidarum	1	11/02/2016	28
15/LO/0046/AM01	Time for Dementia	4.6	30/05/2015	4
15/LO/0086/AM01	Training-induced increased left ventricular trabeculation	Protocol v8	07/06/2015	22
15/LO/0086/AM02	Training-induced increased left ventricular trabeculation	2	08/07/2015	7
15/LO/0086/AM03	Training-induced increased left ventricular trabeculation	3	15/09/2015	11
15/LO/0308/AM01	Understanding Mental Health in the Emergency Department	1	10/08/2015	7
15/LO/0324/AM01	Improving sexual function after treatment for gynaecological cancer	1	29/09/2015	21

15/LO/0416/AM01	Quantitative MRI techniques to detect occult lesions in epilepsy	1	26/06/2015	27
15/LO/0439/AM01	An RCT of a patient-initiated treatment service for BEB and HFS	One	13/10/2015	23
15/LO/0439/AM02	An RCT of a patient-initiated treatment service for BEB and HFS	Two	01/11/2015	27
15/LO/0476/AM03	Vision in Parkinson's Disease	1	10/06/2015	14
15/LO/0601/AM02	Patient Decision Aid for Antidepressant Use In Pregnancy	2	28/01/2016	27
15/LO/0685/AM01	Glycosade® v UCCS in Hepatic GSD (Glyde). Version 2	1	19/10/2015	10
15/LO/0686/AM01	Self-Esteem and Aggression in Forensic Psychiatric Patients	1	01/10/2015	14
15/LO/0875/AM01	Having Spinal Tuberculosis.	1	11/06/2015	16
15/LO/1150/AM01	Decisions and judgements in OCD	One	20/10/2015	15
15/LO/1155/AM02	RAPSODI GD	One	27/09/2015	21
15/LO/1224/AM01	Oxytocin in healthy relatives of frontotemporal dementia (Version 1)	1	09/11/2015	27
15/LO/1323/AM01	Patient Reported Outcomes - patients and caregivers (PROACT)	1	04/01/2016	14
15/LO/1464/AM02	DARS	01	12/02/2016	28
15/LO/1507/AM01	FACE-Q KIDS PROM Study	1	01/09/2015	32
15/LO/1507/AM02	FACE-Q KIDS PROM Study	2	07/12/2015	24
15/LO/1662/AM01	AMR 2 Trial - Reducing Antibiotic Prescribing in Primary Care	1	02/10/2015	24
15/LO/1662/AM02	AMR 2 Trial - Reducing Antibiotic Prescribing in Primary Care	2	20/11/2015	3
15/LO/1662/AM03	AMR 2 Trial - Reducing Antibiotic Prescribing in Primary Care	3	25/01/2016	3
15/LO/1726/AM01	Time and motion study: point of tear ABG sampling	4	21/12/2015	12

Unfavourable opinion				
Amendment REC Reference	Title	Version	Date	Number of Days on Clock
02/N099/AM04	Familial and sporadic non-Alzheimer degenerative dementia, longitudina	14	28/10/2015	27
06/Q0512/81/AM07	Neuropsychology of posterior cortical atrophy (Version 1)	6	04/08/2015	19
14/LO/1411/AM04	EEG measures of aging and Alzheimer's disease in Down's Syndrome	Four	17/11/2015	22
14/LO/1792/AM02	Intermittent versus Continuous Feeding on the Intensive Care Unit v3	2	13/08/2015	32
15/LO/0011/AM03	Investigating the role of D2 receptors in cognition	3	18/08/2015	27
15/LO/0476/AM06	Vision in Parkinson's Disease	2	24/09/2015	28

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
02/N099/AM04/1	Familial and sporadic non-Alzheimer degenerative dementia, longitudina	14 (modified)	07/12/2015	7
14/LO/1411/AM04/1	EEG measures of aging and Alzheimer's disease in Down's Syndrome	5	13/01/2016	9
15/LO/0011/AM03/1	Investigating the role of D2 receptors in cognition	3	22/09/2015	6
15/LO/0476/AM06/1	Vision in Parkinson's Disease	3	16/12/2015	8

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
15/LO/1167	Pain management in people with dementia in care homes: feasibility	75

Proportionate review applications for ethical review over 14 day timeline

REC Reference	Title	Number of Days on Clock
15/LO/0741	Time since last screen and breast cancer stage	15

SSAs (non Phase 1) over 25 day timeline

REC Reference	Title	Number of Days on Clock
15/LO/1156	Disruption of visual processing	26

Substantial Amendments over 35 day timeline

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
09/H0716/48/AM02	Validation of Web-Based BRAIN Test	2	03/12/2015	46
09/H0716/75/AM05	Equilibrium phase CT to assess disease of the liver and heart	4	22/09/2015	47