

London - Bromley Research Ethics Committee

Annual Report

01 April 2015 - 31 March 2016



Part 1 – Committee Membership and Training

Name of REC:	London - Bromley Research Ethics Committee
Type of REC:	Authorised REC
Type of Flag:	Research Involving Adults Lacking Capacity
Chair:	Ms Carol Jones
Vice-Chair:	Ms Jayne Steadman
Alternate Vice-Chair:	Mrs Heather Salzer
REC Manager:	Lauren Allen (01/04/2015 – 01/05/2015) Georgina Castledine (01/05/2015 - 01/10/2015) Maeve Ip Groot Bluemink (01/10/2015- ongoing)
REC Assistant:	Mark Dawson (01/01/2015 – 01/01/2015) Sadie McKeown-Keegan (01/10/2015-ongoing)
Committee Address:	Level 3, Block B Whitefriars Lewins Mead Bristol BS1 2NT
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Chair's overview of the past year:

This year has seen an increase in the number of studies reviewed. It has been a pleasure to see the increased attendance of supervisors of educational studies attending the meetings to support students. Following the closure of City Road and Hampstead REC we have reviewed Substantial Amendments for this Committee, which has been interesting.

The introduction of HARP the new online system for access to study documents, has been welcomed by some, and has led to the opportunity for paperless review of the studies which must help with costs and save trees! For others on the Committee they prefer to continue to use the tried and tested paper based system. The HRA is to be commended for their flexible policy with regard to this as it does mean that members have a choice for which system they use.

The Chair's conference this year looked at how we review the effectiveness of Chairs and following discussion at our Committee we are going to reintroduce our review process for all members in the coming year. We all feel it is important to have a feedback on how we are contributing as individuals as well as an opportunity to feedback to the HRA on how we feel the systems and processes are working for us.

We have had a change of personnel this year. Our Committee had been operating under strength for a number of years so we were delighted to welcome four new members: Dr Jackie Tavabie, Dr Anna Barnes, Miss Amber Collingwood and Mr Colin Allies. They have settled in really well and are adding value to our decision making process.

We also have new management team Maeve Ip Groot Bluemink and Sadie McKeown-Keegan. We have been so delighted with our new management team. We were most concerned but delighted when our previous manager got a promotion to a new post but were anxious about the change. We need not have been worried as the changeover was seamless and the new team is helping us go from strength to strength.

Our year ended with another very useful training day for the Committee and we remain grateful to the support we receive from the HRA to enable us to have these very specially designed events for our Committee.

London - Bromley Research Ethics Committee Membership

Name	Profession	Expert or Lay	Dates	
			Appointed	Left
Mr Munir Ahmed	Consultant Urologist	Expert	01/09/2009	
Mr Colin Allies	General Manager (Retired)	Lay	01/02/2016	
Dr Anna Barnes	Associate Director; Programme Office and Governance	Lay	12/02/2016	
Mrs Susan Beer	Retired Project Manager	Lay Plus	01/08/2009	
Dr Jo Brooke	Associate Professor in Dementia Care	Expert	21/02/2014	
Mrs Angela Clayton-Turner	Retired NHS Therapy Manager	Lay	01/08/2009	
Miss Amber Collingwood	Programme Manager, Epilepsy Research	Lay	01/02/2016	
Mr Abdulzahra Hussain	Upper GI Consultant Surgeon	Expert	21/02/2014	
Ms Carol Jones	Management Consultant	Lay	01/08/2009	
Mrs Kathryn Kinnear	Solicitor	Lay Plus	01/08/2009	
Mrs Fran McMillan	Retired	Lay Plus	01/08/2009	
Canon Tim Mercer	Hospital Chaplain	Lay Plus	01/08/2009	
Dr Angela Orunta	Consultant Anaesthetist	Expert	01/08/2009	
Mrs Heather Salzer	Ultrasound Clinical Specialist	Expert	17/07/2013	
Ms Jayne Steadman	Consultant Physiotherapist	Expert	01/08/2009	
Dr Jacqueline Tavabie	General Practitioner	Expert	01/09/2015	

London - Bromley Research Ethics Committee: Deputy Members

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

Name	Profession	Status	Meeting date attended
Mrs Sally Gordon-Boyd	Medical Ethicist	Lay Plus	22/10/2015

London - Bromley Research Ethics Committee: Members' Declarations of Interest:

Name	Declaration of Interest	Date
Mr Munir Ahmed	Urology and Healthcare director, NHS Consultant which may be involved in research.	31/03/2016
Mr Colin Allies	None	31/03/2016
Dr Anna Barnes	Chair of Seaview in Hastings – Day centre for people with complex needs including homelessness, mental illness and substance misuse Reviewer for Professor Charles Watters at University of Sussex Research Co-ordinator for: Original Study Title: Investigating outcomes for complex trauma patients using SF-36. A longitudinal study measuring outcomes pre and post the introduction of the Major Trauma Centre at Brighton and Sussex University Hospital Trust.	22/02/2016
Mrs Susan Beer	Patient representative on steering committees for two clinical trials at Moorfields Eye Hospital.	31/03/2016
Dr Jo Brooke	Member of the: Oxford Institute of Nursing and Allied Health Research (OxINAHR) Deputy Chair: College of Nursing, Midwifery and Healthcare University Ethics Committee, University of West London	31/03/2016
Mrs Angela Clayton-Turner	Member of Alzheimer's Society research network of volunteers. Occasional PPI reviews for NIHR. Member of Oxleas NHS Foundation Trust R&D for older people (as a volunteer).	31/03/2016
Miss Amber Collingwood	Member of the King's College Hospital (KCH) Internal Research Advisory Group. Committee to assess study feasibility with KCH.	31/03/2016
Mr Abdulzahra Hussain	Member of European Association of Endoscopic surgery, RCSI, IFSO, RCS England, BOMSS. Editorial board member of Journal of Gastroenterology and Hepatology. Reviewer for about 30 surgical and medical journals	31/03/2016
Ms Carol Jones	None	31/03/2016
Mrs Kathryn Kinnear	None	31/03/2016
Mrs Fran McMillan	None	31/03/2016
Canon Tim Mercer	Oakhill Trust Charity - re spiritual care, Rochester Diocesan Synod. Potential for research into chaplaincy or end of life care requiring some participation.	31/03/2016
Dr Angela Orunta	None	31/03/2016
Mrs Heather Salzer	None	31/03/2016
Ms Jayne Steadman	None	31/03/2016
Dr Jacqueline Tavabie	GP Education lead for Bromley Clinical Commissioning Group	27/08/2015

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

Month	Date	Number of Members Present at Meeting
May	21/05/2015	10
June	18/06/2015	7
July	23/07/2015	10
August	20/08/2015	10
September	17/09/2015	8
October	22/10/2015	7
December	10/12/2015	8
February	18/02/2016	9
March	17/03/2016	12

9 full committee meetings were held during the reporting period.

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

Month	Date	Number of Members Present at Meeting
April	01/04/2015	3
May	06/05/2015	3
June	03/06/2015	3
July	01/07/2015	3
August	05/08/2015	3
September	02/09/2015	3
November	04/11/2015	3
February	02/02/2016	3
March	01/03/2016	3

9 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	27/04/2015	2
May	20/05/2015	2
June	03/06/2015	2
June	16/06/2015	2
July	01/07/2015	2
July	14/07/2015	2
August	10/08/2015	2
September	23/09/2015	2
October	07/10/2015	2
October	21/10/2015	2
November	04/11/2015	3
November	10/11/2015	2
November	18/11/2015	2

December	02/12/2015	2
December	16/12/2015	2
December	28/12/2015	2
January	11/01/2016	2
January	25/01/2016	2
February	09/02/2016	2
February	24/02/2016	2
March	10/03/2016	2
March	25/03/2016	2
March	29/03/2016	2

23 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
Mr Munir Ahmed	5
Mr Colin Allies	2
Dr Anna Barnes	1
Mrs Susan Beer	6
Dr Jo Brooke	6
Mrs Angela Clayton-Turner	6
Miss Amber Collingwood	2
Mr Abdulzahra Hussain	4
Ms Carol Jones	8
Mrs Kathryn Kinnear	6
Mrs Fran McMillan	7
Canon Tim Mercer	5
Dr Angela Orunta	6
Mrs Heather Salzer	9
Ms Jayne Steadman	4
Dr Jacqueline Tavabie	3

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

Name	Number of Meetings Attended
Mrs Susan Beer	1
Dr Jo Brooke	3
Ms Carol Jones	8
Mrs Kathryn Kinnear	5
Mrs Fran McMillan	2
Dr Angela Orunta	2
Mrs Heather Salzer	5
Ms Jayne Steadman	1

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

Name	Number of Meetings Attended
Mr Munir Ahmed	1
Mrs Susan Beer	1
Dr Jo Brooke	3
Mrs Angela Clayton-Turner	5
Ms Carol Jones	18
Mrs Kathryn Kinnear	4

Mrs Fran McMillan	4
Dr Angela Orunta	3
Mrs Heather Salzer	6
Ms Jayne Steadman	1
Dr Jacqueline Tavabie	1

Training 01 April 2015 - 31 March 2016

Name of Member	Date	Event(s) attended
Mr Munir Ahmed	17/03/2016	REC Local Training day
Mr Colin Allies	10/02/2016	Training - Committee Members Induction
Mr Colin Allies	17/03/2016	REC Local Training day
Dr Anna Barnes	10/02/2016	Training - Committee Members Induction
Dr Jo Brooke	17/03/2016	REC Local Training day
Mrs Angela Clayton-Turner	17/03/2016	REC Local Training day
Miss Amber Collingwood	10/02/2016	Training - Committee Members Induction
Miss Amber Collingwood	17/03/2016	REC Local Training day
Ms Carol Jones	17/03/2016	REC Local Training day
Mrs Kathryn Kinnear	17/03/2016	REC Local Training day
Mrs Fran McMillan	17/03/2016	REC Local Training day
Canon Tim Mercer	17/03/2016	REC Local Training day
Mrs Heather Salzer	17/03/2016	REC Local Training day
Ms Jayne Steadman	22/07/2015	Training - Qualitative Research and Ethical
Ms Jayne Steadman	17/03/2016	REC Local Training day
Dr Jacqueline Tavabie	04/11/2015	Training - Committee Members Induction
Dr Jacqueline Tavabie	17/03/2016	REC Local Training day

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	42	100.00
Total Applications Reviewed	42	100

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

Number of applications made invalid by the REC Manager	3
Number of applications withdrawn prior to the meeting	0
Number of student applications reviewed	16
Number of paediatric applications reviewed	5
Number of device applications reviewed	4
Number of prisoner applications reviewed	0
Number of applications involving adults unable consent reviewed	6
Number of applications reviewed that are funded by the US DHHS	0
Number of qualitative applications reviewed	9

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

Decisions taken at meetings following review of applications	Number	%
Favourable Opinion with Standard Conditions	0	0.00
Favourable Opinion with Additional Conditions	9	21.43
Unfavourable Opinion	4	9.52
Provisional Opinion	29	69.05
Provisional Opinion Pending Consultation with Referee	0	0.00
Total	42	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	29	69.05
Further Information Favourable Opinion with Additional Conditions	0	0.00
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	0	0.00
Favourable Opinion with Additional Conditions	9	21.43
Unfavourable Opinion	4	9.52
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	42	100

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

Total Applications Reviewed	25
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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	7
Number of studies withdrawn prior to the meeting	1
Number of student applications reviewed	10
Number of paediatric applications reviewed	2
Number of device applications reviewed	0
Number of qualitative applications reviewed	5

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	9	36.00
Favourable Opinion with Additional Conditions	7	28.00
No Opinion transfer to full committee for review	2	8.00
Provisional Opinion	7	28.00
Unfavourable Opinion	0	0.00
Total	25	100

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

Average number of applications reviewed per full meeting	4.67
Number of completed applications for full ethical review	42
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	2
Number of completed applications over 40 days as a % of total	4.76%
Number of days taken to final decision – average (mean)	29
Number of completed proportionate review applications for ethical review	23
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	4.35%
Number of SSAs (non-Phase 1) reviewed	1
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	42
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 completed substantial amendments over 28 days	0
Number of completed substantial amendments over 28 days as a % of total substantial amendments	0.00%
Number of modified amendments reviewed	1
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 minor amendments received	21
Number of substantial amendments received for information	0
Number of substantial amendments received for new sites/Pis	0
Number of annual progress reports received	33

Number of safety reports received	0
Number of Serious Adverse Events received	0
Number of final reports received	13

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/0870	Self-Disgust & Visual Perspective Taking	28
15/LO/0889	Mental health promotion groups for people with intellectual disability	39
15/LO/0899	Hopeful and included: Domain-specific hope and social inclusion	28
15/LO/0902	Thrombin generation in older adults with dementia	28
15/LO/0934	LAL-CSS01: STUDY OF FREQUENCY OF LYSOSOMAL ACID LIPASE DEFICIENCY	30
15/LO/0992	Proactive Health Coaching in the English NHS	29
15/LO/1005	Experiences of transition between secure services from ASC patients.	35
15/LO/1014	The effect of an aromatherapy intervention on sleep in the ICU	43
15/LO/1023	Empathy/altruism in sex offenders with ID/ASC	41
15/LO/1170	Human Rights and Psychiatric Intensive Care Units	33
15/LO/1231	'Service users and staff views and experiences of Community Treatment Orders'.	32
15/LO/1233	A comparison of body composition techniques in COPD patients	34
15/LO/1241	Mechanisms of Increased Susceptibility to Rhinovirus Infection in COPD	30
15/LO/1291	Effect of Copper on Healing of Obstetric wounds (ECHO trial)	31
15/LO/1320	Exploring the role of bilingualism in Dementia.	30
15/LO/1335	Mathematical modelling to improve pathways to cancer diagnosis v1	26
15/LO/1350	A Pilot Randomised Trial of Light Therapy in People with Dementia	22
15/LO/1494	Diagnostic approaches in gestational diabetes and impact of ethnicity	25
15/LO/1506	IMRiS	21
15/LO/1542	MMARDS: Molecular Mechanisms of Acute Respiratory Distress Syndrome	25
15/LO/1767	[11C]CFN PET and fMRI in interictal depression	28
15/LO/1778	Social Inclusion in Mental Health	23
15/LO/2024	FCT with young children with ID in the UK: A feasibility project V.1	31
15/LO/2110	All Polyethylene Vs Metal Backed Tibial Components in Knee Replacement	28
15/LO/2123	Labour Epidural Top-up with Warmed Ropivacaine [1]	35
16/LO/0105	Adapted Sex Offender Treatment Programmes for Individuals with Autism	31
16/LO/0139	Reasons why patients do not wait to be seen in Emergency Department	35
16/LO/0243	AIPACa	38
16/LO/0290	AlcoChange	36

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
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Favourable Opinion with Standard Conditions

REC Reference	Title	Number of Days on Clock
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Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
15/LO/1073	Telomere shortening in renal disease	28
15/LO/1218	Illumien III	29
15/LO/1311	Disgust and mental health in palliative care patients	26
15/LO/1624	CoRe Study v1.0	20
15/LO/1772	Development and Validation of the TRIALÂ® database for Rett Syndrome	22
15/LO/1786	Acute effect of Donepezil on transcranial magnetic stimulation parameters in Alzheimer's disease	22
15/LO/1790	PET/MR in Radiotherapy for Head and Neck Cancer Pilot V.1.0	22
15/LO/1929	"Test n Treat": a feasibility trial of rapid STI testing and treatment	25
15/LO/2042	Expectations of transitioning to adult services from CAMHS	26

Unfavourable Opinion

REC Reference	Title	Number of Days on Clock
15/LO/0832	A Pilot Randomised Trial of Light Therapy in People with Dementia	26
15/LO/1318	NHS Transition	26
15/LO/1337	SBoCK	26
16/LO/0235	An exploration of the attachment process in dementia	28

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

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
15/LO/0865	MDMW Communication Platform Study	12
15/LO/0866	Predictors of late adverse affects after radiotherapy	15
15/LO/1064	Stem Cell Therapy for the Treatment of Congenital Heart Disease	11
15/LO/1220	Sarcasm and aggression after traumatic brain injury	9
15/LO/1411	Using PatientView in self-care.	14
15/LO/1962	Acoustic analysis of snoring	13
16/LO/0276	Development of novel MR and PET/MR imaging techniques	10

Further Information Favourable Opinion with Additional Conditions		
REC Reference	Title	Number of Days on Clock

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

Favourable Opinion with Standard Conditions		
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REC Reference	Title	Number of Days on Clock
15/LO/0619	Image analysis using customised computer software	11
15/LO/1053	The acceptability of an affective cognition tool for new mothers	8
15/LO/1056	Socioeconomic variation and hip fracture	8
15/LO/1397	How does the meaning of cancer progress post-treatment? (v1)	12
15/LO/1413	Impact of sepsis on oropharyngeal function (London-Bromley 15/LO/1413)	7
15/LO/1584	Metabonomic analysis of cART efficacy in urine from HIV patients	8
15/LO/1590	Evaluation of Physical Inactivity Intervention	8
15/LO/1976	LUNG SOLVE version 3	11
16/LO/0275	Infective endocarditis after prosthetic valve replacement	7

Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
15/LO/0613	Use of frequency compression in severe-profound hearing loss adults	6
15/LO/0614	MSc Advanced Practice: Research Project: 23 hour pathway (Version 1)	7
15/LO/0617	The DISCLOSE study	11
15/LO/0872	Staphylococcal bacteraemia in substance misuse	11
15/LO/1052	Sleep and Psoriasis survey	7
15/LO/1221	The importance of informational items in a PIL for RCTs	7
15/LO/1586	Discharge from Acute Medicine: Patients' and Carers' Views	9

Unfavourable Opinion

REC Reference	Title	Number of Days on Clock
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Provisional Opinion

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

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

REC Reference	Title	Number of Days on Clock
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Table 10.1: Breakdown of current status of all substantial amendments reviewed within the reporting period

Favourable opinion				
Amendment REC Reference	Title	Version	Date	Number of Days on Clock
07/H0809/49/AM18	Patient contributions to the evidence base	14 (AM18)	17/02/2016	6
08/H0805/14/AM15	T cell studies in type 1 diabetes	AM10	13/10/2015	2
10/H0805/48/AM07	Global Anticoagulant Registry in the FIELD (GARFIELD)	5	22/05/2015	5
10/H0805/50/AM04	Plasma DNA as a surrogate for breast cancer phenotype	Protocol v7.2, 30-Mar-2015	30/03/2015	7
10/H0805/51/AM07	Expression of muscle repair factors in bladder detrusor muscle	5 (AM07)	15/01/2016	2
11/LO/0583/AM05	laryngeal reinnervation versus type I thyroplasty	7	25/06/2015	14
11/LO/0583/AM06	laryngeal reinnervation versus type I thyroplasty	Amendment 08 (AM06)	15/12/2015	16
12/LO/0442/AM04	Outcome Measures In Duchenne Muscular Dystrophy	AM04 - Substantial Amendment 2	09/11/2015	22
12/LO/1610/AM02	The genetic control and predictive value of HbF in sickle cell disease	4	08/05/2015	6
13/LO/0640/AM02	(May) The Addiction Recovery Clinic (ARC)	1 (AM02)	28/01/2016	9
13/LO/1347/AM06	PROMPT	4 (AM06)	10/12/2015	3
13/LO/1569/AM01	Usefulness of patient-specific 3D models during clinical consultations	1	14/05/2015	11
13/LO/1738/AM02	Novel biomarkers in cooled newborns (Oct 2013)	3	14/01/2016	2
13/LO/1745/AM03	STRATEGIC	Amendment 2 (AM03)	01/12/2015	2
13/LO/1748/AM06	UK national platform for Spinal Muscular Atrophy (SMA)	Amendment 4	20/11/2015	26
13/LO/1748/AM07	UK national platform for Spinal Muscular Atrophy (SMA)	5 (AM07)	22/03/2016	21
13/LO/1907/AM03	Determining physical activity levels in young cystic fibrosis patients	4	25/10/2015	28
14/LO/0090/AM04	Mascot v12	Amendment 3 (AM04)	13/01/2016	4
14/LO/0193/AM02	Brain Networks in Focal Epilepsy	AM02	15/10/2015	13
14/LO/0424/AM02	Online CBT for Type 1 diabetes	2	18/05/2015	8
14/LO/0424/AM03	Online CBT for Type 1 diabetes	3	07/09/2015	1
14/LO/0445/AM02	Study of [11C]PBR28 TSPO PET as a disease marker in MS patients	2	27/07/2015	10

14/LO/0725/AM01	APUS eCig	1	16/06/2015	8
14/LO/1333/AM01	Hepatic lipogenesis, inflammation, fibrosis, omega-3 and vitamin D	AM01 - SA1 7th October 2015	12/11/2015	12
14/LO/1334/AM01	ESMiD	1	20/07/2015	16
14/LO/1489/AM04	Lipid Metabolism and Acute Fatty Liver in Pregnancy (V1)	5	02/06/2015	27
14/LO/1489/AM05	Lipid Metabolism and Acute Fatty Liver in Pregnancy (V1)	5	01/01/2016	6
14/LO/2025/AM02	TIMeLi: Towards Improving diagnosis of Memory Loss in general practice	1	04/05/2015	20
14/LO/2229/AM02	Rare Diseases Translational Research - DMD	Amendment 1 (AM02)	12/01/2016	15
15/LO/0252/AM01	Hedonic Touch in Neurological Conditions	1	11/06/2015	5
15/LO/0258/AM01	Immune Response and Pathogen-Fertility Interface (pilot study)	1	10/08/2015	5
15/LO/0258/AM02	Immune Response and Pathogen-Fertility Interface (pilot study)	AM02	29/02/2016	1
15/LO/0499/AM01	TATME database	1.1	26/10/2015	13
15/LO/0502/AM01	Home visits in stroke rehabilitation (version 1)	1	14/05/2015	8
15/LO/0617/AM01	The DISCLOSE study	1 (AM01)	01/02/2016	8
15/LO/0865/AM01	MDMW Communication Platform Study	1	30/07/2015	13
15/LO/0866/AM01	Predictors of late adverse affects after radiotherapy	1.0 (AM01)	02/11/2015	5
15/LO/1494/AM01	Diagnostic approaches in gestational diabetes and impact of ethnicity	Amendment 1 (AM01)	22/02/2016	2
15/LO/1624/AM01	CoRe Study v1.0	1 (AM01)	12/01/2016	18
15/LO/1778/AM01	Social Inclusion in Mental Health	1 (AM01)	04/02/2016	14
15/LO/1790/AM01	PET/MR in Radiotherapy for Head and Neck Cancer Pilot V.1.0	1st (AM01)	12/02/2016	4
15/LO/1976/AM01	LUNG SOLVE version 3	1	02/12/2015	13

Unfavourable opinion

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
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Table 10.2: Breakdown of current status of all modified amendments reviewed within the reporting period

Favourable opinion timeline				
Amendment REC Reference	Title	Version	Date	Number of Days on Clock
13/LO/0715/AM01/1	A prospective case series of patients with functional visual loss	2	08/05/2015	11

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 14 day timeline

REC Reference	Title	Number of Days on Clock
15/LO/0866	Predictors of late adverse affects after radiotherapy	15

SSAs (non Phase 1) over 25 day timeline

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

REC Reference	Title	Number of Days on Clock
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Substantial Amendments over 35 day timeline

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

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
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