

**London - Bromley Research Ethics Committee**

**Annual Report**

**01 April 2016 - 31 March 2017**



## Part 1 – Committee Membership and Training

<b>Name of REC:</b>	London - Bromley Research Ethics Committee
<b>Type of REC:</b>	Authorised REC
<b>Type of Flag:</b>	Research Involving Adults Lacking Capacity
<b>Chair:</b>	Ms Carol Jones (01/04/2016 - 31/01/2017) Ms Jayne Steadman (01/02/2017 – present)
<b>Vice-Chair:</b>	Ms Jayne Steadman (01/04/2016 – 31/01/2017) Mrs Heather Salzer (01/02/2017 – present)
<b>Alternate Vice-Chair:</b>	Mrs Heather Salzer (01/04/2016 – 31/01/2017) Vacant (01/02/2017 – present)
<b>REC Manager:</b>	Mrs Maeve Ip Groot Bluemink (01/04/2016 – 08/01/2017) Ms Helen Sivey (09/01/2017 – present)
<b>REC Assistant:</b>	Ms Sadie McKeown-Keegan (01/04/2016 – 08/01/2017) Ms Amy Peters (09/01/2017 – present)
<b>Committee Address:</b>	Level 3, Block B Whitefriars Lewins Mead Bristol BS1 2NT
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## Chair's overview of the past year:

This year has continued the trend of an increasing number of studies, proportionate reviews and amendments reviewed. The committee reviewed 48 studies this year compared with 42 last year; 27 PR's compared with 25 last year and 96 amendments compared with 42 last year.

We are noticing an increasing number of researchers opting to attend via telephone which has largely been successful.

The Committee acknowledges the HRA's encouragement to use the HARP system and some members have made the transition well. Others still value the opportunity to have paper copies.

The Committee had a new REC Manager and Assistant in January 2017, who have provided valuable support. We said a sad goodbye to Carol Jones, our outgoing Chair. Myself as Vice Chair was interviewed and then appointed to the Chair role which has provided continuity.

The Chair participated in an HRA workshop earlier this year which explained the new Chair's appraisal system. This workshop also afforded a valuable opportunity for the Chair, Manager and Assistant to meet together and discuss the running of the REC.

Unfortunately our annual training day had to be postponed due to a number of operational reasons but has been rebooked for later in the year.

Jayne Steadman

## 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	16/05/2016
Professor Jo Brooke	Associate Professor in Dementia Care	Expert	21/02/2014	
Mrs Angela Clayton-Turner	NHS Therapy Manager (Retired)	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	31/01/2017
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 (Retired)	Lay	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
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## 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.	31/03/2017
Mr Colin Allies	None	23/05/2016
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 "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."	16/05/2016
Mrs Susan Beer	Patient representative on steering committees for two clinical trials at Moorfields Eye Hospital.	31/03/2017
Professor Jo Brooke	Member of the Oxford Institute of Nursing and Allied Health Research (OxINAHR) Occasional lay reviewer for NIHR Deputy Chair of the College of Nursing, Midwifery and Healthcare University Ethics Committee, University of West London	14/05/2016
Mrs Angela Clayton-Turner	Research network volunteer with the Alzheimer's Society	23/05/2016
Miss Amber Collingwood	Committee member of the King's College Hospital, Dept of Neurosciences, Neuroscience Research Advisory Group Committee (NeuroRag), which meets once a month to discuss new project proposal feasibility. Chair, Professor Ray Chaudhuri. Role involves representing the KCL academic department, Basic & Clinical Neuroscience as delegated by Professor Mark Richardson, Vice Dean – Division of Neuroscience.	31/03/2017
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	31/03/2017
Ms Carol Jones	None	27/01/2017
Mrs Kathryn Kinnear	None	23/05/2016
Mrs Fran McMillan	None	31/03/2017
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.	31/03/2017
Dr Angela Orunta	None	13/05/2016
Mrs Heather Salzer	None	23/05/2016
Ms Jayne Steadman	Staff shareholder in Bromley Healthcare Social Enterprise	31/03/2017
Dr Jacqueline Tavabie	None	23/05/2016

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

Month	Date	Number of Members Present at Meeting
April	21/04/2016	11
May	19/05/2016	14
June	16/06/2016	9
July	21/07/2016	8
August	18/08/2016	12
September	15/09/2016	10
October	20/10/2016	8
December	08/12/2016	14
February	16/02/2017	11
March	16/03/2017	9

10 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	05/04/2016	3
May	03/05/2016	3
July	05/07/2016	3
August	02/08/2016	3
September	06/09/2016	3
October	05/10/2016	3
December	14/12/2016	3
February	08/02/2017	3
March	08/03/2017	3

9 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	09/04/2016	2
April	09/04/2016	2
April	22/04/2016	2
April	22/04/2016	2
May	06/05/2016	2
May	06/05/2016	2
May	07/05/2016	2
May	11/05/2016	3
May	16/05/2016	2
May	18/05/2016	3
May	20/05/2016	2
June	01/06/2016	2

June	10/06/2016	2
June	20/06/2016	2
June	22/06/2016	2
June	25/06/2016	2
June	25/06/2016	2
July	10/07/2016	2
July	10/07/2016	2
July	25/07/2016	2
July	25/07/2016	2
August	18/08/2016	2
August	24/08/2016	2
August	24/08/2016	2
September	08/09/2016	2
September	08/09/2016	2
October	08/10/2016	2
October	23/10/2016	2
October	23/10/2016	2
October	28/10/2016	3
November	07/11/2016	2
November	07/11/2016	2
November	22/11/2016	2
December	07/12/2016	2
December	22/12/2016	3
January	21/01/2017	2
February	04/02/2017	2
February	18/02/2017	2
March	03/03/2017	2
March	03/03/2017	2
March	17/03/2017	2
March	31/03/2017	2

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

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

None.

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

Name	Number of Meetings Attended
Mr Munir Ahmed	6
Mr Colin Allies	9
Dr Anna Barnes	5
Professor Jo Brooke	5
Mrs Angela Clayton-Turner	10
Miss Amber Collingwood	7
Mr Abdulzahra Hussain	5
Ms Carol Jones	6
Mrs Kathryn Kinnear	5

Mrs Fran McMillan	7
Canon Tim Mercer	8
Dr Angela Orunta	9
Mrs Heather Salzer	8
Ms Jayne Steadman	8
Dr Jacqueline Tavabie	8

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

<b>Name</b>	<b>Number of Meetings Attended</b>
Professor Jo Brooke	5
Miss Amber Collingwood	3
Ms Carol Jones	4
Mrs Kathryn Kinnear	5
Dr Angela Orunta	2
Mrs Heather Salzer	3
Ms Jayne Steadman	5

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

<b>Name</b>	<b>Number of Meetings Attended</b>
Mr Colin Allies	6
Professor Jo Brooke	1
Mrs Angela Clayton-Turner	4
Miss Amber Collingwood	9
Ms Carol Jones	23
Mrs Kathryn Kinnear	4
Mrs Fran McMillan	5
Dr Angela Orunta	4
Mrs Heather Salzer	10
Ms Jayne Steadman	13
Dr Jacqueline Tavabie	9



**Training 01 April 2016 - 31 March 2017**

<b>Name of Member</b>	<b>Date</b>	<b>Event(s) attended</b>
Dr Anna Barnes	01/01/2017	Reviewer for Peer review Journal; International Journal of Migration, Health and Social Care
Professor Jo Brooke	31/03/2017	HRA Approval Study title: Enhancing dementia care services in prison populations: The PrisDem Project IRAS: 225329 REC: 18/HRA/0107
Miss Amber Collingwood	14/07/2016	Personal Data in Research - A Workshop
Mr Abdulzahra Hussain	31/03/2017	Publication of 11 research papers such as 1.Etiology of Leaks Following Sleeve Gastrectomy: Current Evidence.Hussain A, Vasas P, Kirk K, Finney J, Balchandra
Mr Abdulzahra Hussain	31/03/2017	Reviewer of studies in journals such as journal of Obesity • World Journal of Gastrointestinal Endoscopy WJGE • Journal of Gastroenterology and Hepatology Research
Ms Carol Jones	01/12/2016	National Training Day for Committee Chairs
Canon Tim Mercer	31/03/2017	Reading: 'Spiritual care in practical case studies' by George Fitchett and Steve Nolan
Mrs Heather Salzer	30/06/2016	Training for New REC Chairs
Ms Jayne Steadman	27/03/2017	Chairs Review Programme Workshop
Ms Jayne Steadman	29/03/2017	The Practicalities of Running a REC - a workshop for Chairs and REC Managers
Dr Jacqueline Tavabie	31/03/2017	Reading: "Ethics in General Practice - a practical handbook for personal development" by Ann Orme-Smith and John Spicer.

## PART 2: REC WORKLOAD AND ACTIVITY DURING THE REPORTING PERIOD

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

<b>Applications for full ethical review – Study Type</b>	<b>Number</b>	<b>%</b>
Clinical Trial of Investigational Medicinal Product	0	0.00
Phase 1	0	0.00
Gene Therapy	0	0.00
Research Tissue Bank (including renewals)	1	2.08
Research Database (including renewals)	0	0.00
Others	47	97.92
<b>Total Applications Reviewed</b>	<b>48</b>	<b>100</b>

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

Number of applications made invalid by the REC Manager	3
Number of applications withdrawn prior to the meeting	1
Number of student applications reviewed	23
Number of paediatric applications reviewed	3
Number of device applications reviewed	1
Number of prisoner applications reviewed	1
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	6

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

<b>Decisions taken at meetings following review of applications</b>	<b>Number</b>	<b>%</b>
Favourable Opinion with Standard Conditions	0	0.00
Favourable Opinion with Additional Conditions	13	27.08
Unfavourable Opinion	5	10.42
Provisional Opinion	28	58.33
Provisional Opinion Pending Consultation with Referee	2	4.17
<b>Total</b>	<b>48</b>	<b>100</b>
Number of studies sent back to full committee meeting for final opinion	0	

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

<b>Status of applications at date of generation of report</b>	<b>Number</b>	<b>%</b>
Further Information Favourable Opinion with Standard Conditions	28	58.33
Further Information Favourable Opinion with Additional Conditions	1	2.08
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	0	0.00
Favourable Opinion with Additional Conditions	13	27.08
Unfavourable Opinion	5	10.42
Provisional Opinion	0	0.00
Provisional Opinion Pending Consultation with Referee	1	2.08
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
<b>Total</b>	<b>48</b>	<b>100</b>

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

<b>Total Applications Reviewed</b>	<b>27</b>
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**Table 6: Breakdown of PRS applications and other activity during reporting period:**

Number of applications made invalid by the REC Manager	2
Number of studies withdrawn prior to the meeting	0
Number of student applications reviewed	15
Number of paediatric applications reviewed	3
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**

<b>Decisions taken at proportionate review sub-committee meetings</b>	<b>Number</b>	<b>%</b>
Favourable Opinion with Standard Conditions	12	44.44
Favourable Opinion with Additional Conditions	7	25.93
No Opinion transfer to full committee for review	5	18.52
Provisional Opinion	3	11.11
Unfavourable Opinion	0	0.00
<b>Total</b>	<b>27</b>	<b>100</b>

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

<b>Average number of applications reviewed per full meeting</b>	4.80
<b>Number of completed applications for full ethical review</b>	48
<b>Number of completed applications for full ethical review over 60 days</b>	0
<b>Number of completed applications over 60 days as a % of total</b>	0.00%
<b>Number of completed applications for full ethical review over 40 days</b>	10
<b>Number of completed applications over 40 days as a % of total</b>	20.83%
<b>Number of days taken to final decision – average (mean)</b>	33
<b>Number of completed proportionate review applications for ethical review</b>	22
<b>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 to 21 calendar days in December 2016)</b>	4
<b>Number of completed proportionate review applications for ethical review over 21 days</b>	3
<b>Number of completed proportionate review applications over 21 days as a % of total</b>	13.64%
<b>Number of SSAs (non-Phase 1) reviewed</b>	8
<b>Number of completed applications for SSA review over 25 days</b>	0
<b>Number of completed applications for SSA review over 25 days as % of all non- Phase 1 SSAs</b>	0.00%
<b>Number of SSAs (Phase 1) reviewed</b>	0
<b>Number of completed applications for SSA review over 14 days</b>	0
<b>Number of completed applications for SSA review over 14 days as % of all Phase 1 SSAs</b>	0.00%
<b>Number of substantial amendments reviewed</b>	96
<b>Number of completed substantial amendments over 35 days</b>	6
<b>Number of completed substantial amendments over 35 days as a % of total substantial amendments</b>	6.25%
<b>Number of completed substantial amendments over 28 days</b>	22
<b>Number of completed substantial amendments over 28 days as a % of total substantial amendments</b>	22.92%
<b>Number of modified amendments reviewed</b>	3
<b>Number of completed modified amendments over 14 days</b>	2
<b>Number of completed modified amendments over 14 days as a % of total modified amendments</b>	66.67%
<b>Number of non substantial amendments received</b>	92

<b>Number of substantial amendments received for information</b>	0
<b>Number of substantial amendments received for new sites/PIs</b>	0
<b>Number of annual progress reports received</b>	34
<b>Number of safety reports received</b>	0
<b>Number of Serious Adverse Events received</b>	2
<b>Number of final reports received</b>	8

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

<b>Further Information Favourable Opinion with Standard Conditions</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
16/LO/0464	Validating an extended scale on the HCR-20 V3.	39
16/LO/0714	tDCS in post-stroke fatigue (TIPS)	23
16/LO/0720	Effect of home based balance training in peripheral neuropathy	24
16/LO/0727	The CAPAPAF Study	37
16/LO/0923	Differences in outcome: Face to face v internet enabled CBT	32
16/LO/1102	The NOC Study. Version 1	16
16/LO/1311	Imaginator - functional imagery training for self harm in young people	43
16/LO/1313	The Prevalence and Clinical Features of Epilepsy in Dementia and MCI	44
16/LO/1344	Management of sleep disturbance in care homes: Feasibility study	35
16/LO/1463	The pathophysiology of functional neurological disorders - version 1	31
16/LO/1470	DOLORisk	32
16/LO/1472	Gender Differences in Autism Spectrum Disorders	32
16/LO/1486	Gastrointestinal tolerance of an upgraded peptide feed in ICU patients	26
16/LO/1542	Cardiovascular and gut health effects of oat (poly)phenols_v1	31
16/LO/1584	Spectroscopy for blood perfusion monitoring	40
16/LO/1695	Treatment Responder Experiences in the Addiction Recovery Clinic Trial	54
16/LO/1702	Does prehabilitation improve CPX results in OG cancer patients	44
16/LO/1872	Therapeutic group for women on the autism spectrum	31
16/LO/1877	RESCUE (version 1.0)	51
16/LO/1901	HCN-pain	58
16/LO/2168	Characterisation of microglia after an acute brain injury	32
16/LO/2179	Beta-lactam pharmacometrics in secondary care	35
17/LO/0329	Effect of salpingectomy for tubal ectopic pregnancy on ovarian reserve	58
17/LO/0334	FLO-ELA	51
17/LO/0335	Self-criticism pilot study	36
17/LO/0348	Experiences of People with Cystic Fibrosis and their Families	49
17/LO/0452	SASAC: Skin ageing signatures and cancer	39
17/LO/0479	Effects of service user involvement on personal recovery from ABI	28

<b>Further Information Favourable Opinion with Additional Conditions</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>

16/LO/1053	Not So Grim Up North	40
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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
16/LO/0667	CFASII Dementia Diagnosis Study (CADDY)	51
16/LO/0762	Exercise training in patients awaiting liver transplantation	22
16/LO/0935	Monitoring the transition from smoking to e-cigarettes	40
16/LO/0937	Physical Activity in Chronic Kidney Disease	33
16/LO/1021	Testing a case-mix classification in palliative care	18
16/LO/1127	Clinical value of stress echocardiography in moderate aortic stenosis	18
16/LO/1129	The role of SV2A in PD and PD Dementia	15
16/LO/1294	Molecular toolkit for severe community acquired pneumonia	29
16/LO/1303	Tissue Stresses of Cancer	28
16/LO/1479	IGFBP7 and TIMP2 as Biomarkers of Acute Kidney Injury	19
16/LO/1636	POEM vs Dilatation	28
16/LO/1683	Cardiac-rehabilitation decliners: perceptions and coping strategies	28
16/LO/2182	SPM regulation by Fish Oil Supplements in Healthy Volunteers V003	24

### Unfavourable Opinion

REC Reference	Title	Number of Days on Clock
16/LO/0969	Experience of patients breaching cancer waiting times	32
16/LO/1139	STEPP: Safety and tolerance of a peptide tube feed in ICU patients	19
16/LO/1756	Barriers to developing proactive support for people with autism	28
16/LO/2181	Evaluation of Whole Systems Integrated Care	27
17/LO/0388	BIOPS	23



<b>Provisional Opinion</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>

<b>Provisional Opinion Pending Consultation with Referee</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
17/LO/0220	TIN-TIN Biobank	n/a

<b>Further information response not complete</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>

<b>Withdrawn after the meeting</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>

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

<b>Further Information Favourable Opinion with Standard Conditions</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
16/LO/1672	Novel Methods for Epidermal BioMarker Measurements (Student Study)	22
16/LO/2193	3D Models in Scoliosis surgery	27
16/LO/2228	Assessment of high density lipoprotein in coronary artery disease	24

<b>Further Information Favourable Opinion with Additional Conditions</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>

<b>Further Information Unfavourable Opinion</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>

**Favourable Opinion with Standard Conditions**

REC Reference	Title	Number of Days on Clock
16/LO/0812	Impact of bariatric surgery on resolution of type 2 diabetes mellitus	8
16/LO/0865	CIMPRES-COPD	2
16/LO/1290	Cellular/gene therapy: haematological disorders and immunodeficiency	7
16/LO/1473	Biomarkers for diagnosis of joint disease	8
16/LO/1474	Ambulatory measurements of FEV1 in moderate Asthma	9
16/LO/1481	The Bowel Scope Screening Experience: A qualitative study	9
16/LO/1663	Monitoring compliance with TB medication from a fingerprint	14
16/LO/1665	Focus groups on patient perspectives of precision cancer medicine	9
16/LO/1834	Relationship between ankylosing spondylitis and periodontal disease	12
17/LO/0261	Consultation Guide for Young People with AIS	19
17/LO/0268	Self-reported mental disorders in pregnancy in Northern Ireland	10
17/LO/0429	DARC Phase 1 Extension Study	7

**Favourable Opinion with Additional Conditions**

REC Reference	Title	Number of Days on Clock
16/LO/0627	Fibromyalgia and employment	13
16/LO/0695	The Molecular Basis of Cardiac Arrhythmias in the Elderly.	9
16/LO/1296	PASIP	8
16/LO/1833	Consultation-based reassurance for people with low back pain	14
16/LO/1851	Quality of life associated with provision of complete dentures	12
16/LO/2244	Testing Food for Oral Immunotherapy	12
17/LO/0433	Haemodynamic changes in lower limb free tissue transfer	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**

<b>Favourable opinion</b>				
<b>Amendment REC Reference</b>	<b>Title</b>	<b>Version</b>	<b>Date</b>	<b>Number of Days on Clock</b>
05/Q0504/101/AM17	The MacTel Study	Protocol Version 5 (AM17)	21/06/2016	17
05/Q0504/101/AM18	The MacTel Study	Protocol Version 5.1 (AM18)	12/07/2016	33
05/Q0504/101/AM19	The MacTel Study	Protocol Version 5.2 (AM19)	01/09/2016	30
10/H0721/28/AM02	The Natural History of Inclusion Body Myositis	AMD2 (AM02)	25/02/2016	14
10/H0721/51/AM03	Identifying genetic and environmental interactions in psychosis	NOSA-3 (AM03)	14/06/2016	4
10/H0721/79/AM06	Evaluation of Integrated Cardiac Imaging (EVINCI)	Substantial Amendment 6 (AM06)	27/06/2016	28
10/H0721/87/AM07	Using Genetics to Understand Parkinson's Disease	Amendment 5, 1st of November 2	05/12/2016	32
11/LO/0583/AM07	laryngeal reinnervation versus type I thyroplasty	Amendment 9 16 January 2017	01/02/2017	12
11/LO/0583/AM08	laryngeal reinnervation versus type I thyroplasty	Amendment 10, 20 February 2017	20/02/2017	32
11/LO/1433/AM03	Immune regulation in autoimmune rheumatic disease	Amendment 3_November 2016	18/01/2017	14
11/LO/1653/AM03	Protocol to Collect Volunteer Blood Samples for T-cell Research	SA003 (AM03)	18/07/2016	9
12/LO/0442/AM05	Outcome Measures In Duchenne Muscular Dystrophy	Amendment 3 (AM05)	05/07/2016	25
12/LO/0442/AM06	Outcome Measures In Duchenne Muscular Dystrophy	Amendment 4.0 - 12/01/2017	30/01/2017	13
12/LO/0940/AM10	LiGHT: Laser-1st vs Drops-1st for Glaucoma and Ocular Hypertension 1.0	4.0 (AM10)	12/02/2016	9
12/LO/1463/AM04	Different Surgical Modalities in the Treatment of Periodontitis	Substantial Amendment 4 dated	13/09/2016	47
13/LO/0981/AM30	The SCIN (Skin Care intervention in Nurses) Trial	Substantial	04/05/2016	8

		Amendment 5 (AM30)		
13/LO/0981/AM31	The SCIN (Skin Care intervention in Nurses) Trial	Substantial Amendment 6 (AM31)	27/05/2016	14
13/LO/1434/AM05	Hyperthermia for Intermediate risk bladder cancer(HIVEC-II)	Amendment number 4 (AM05)	10/02/2016	20
13/LO/1434/AM07	Hyperthermia for Intermediate risk bladder cancer(HIVEC-II)	Amendment Number 5 (AM07)	04/08/2016	28
13/LO/1442/AM08	Morbidity after paediatric cardiac surgery	SA7 (AM08)	25/05/2016	2
13/LO/1543/AM03	Prevention of Type 2 Diabetes in HIV - Version 1	3	25/10/2016	17
14/LO/0193/AM03	Brain Networks in Focal Epilepsy	AM03	23/05/2016	11
14/LO/0193/AM04	Brain Networks in Focal Epilepsy	14/02/2017 AM04	28/02/2017	20
14/LO/0279/AM01	CAPRELSA	AM01 - protocol amendment 01 (	22/11/2016	20
14/LO/1335/AM02	Steroid therapy and adrenal insufficiency in patients with RA v1	1 (AM02)	07/06/2016	28
14/LO/1489/AM06	Lipid Metabolism and Acute Fatty Liver in Pregnancy (V1)	V6 (AM06)	04/04/2016	11
14/LO/1515/AM01	Evaluation of SPECAL approach for carers of people with dementia	1 (AM01)	26/02/2016	12
14/LO/1515/AM02	Evaluation of SPECAL approach for carers of people with dementia	2 (25th January 2017)	25/01/2017	32
14/LO/1577/AM01	Facilitating Reading in Posterior Cortical Atrophy	1.0	13/10/2016	41
14/LO/1616/AM01	Acute Mild Psychological Stress and Immunity Version 1	Amendment 1 (AM01)	24/03/2016	1
14/LO/1636/AM04	Central neural control of lower urinary tract function - V1.00	2.0	30/11/2016	29
14/LO/1883/AM03	VOCAL - Virtual Online Consultations: Advantages and Limitations	2, 1 Dec 2016	01/12/2016	19
14/LO/1937/AM05	FACT	Amendment 3	27/09/2016	35
14/LO/2025/AM04	TIMeLi: Towards Improving diagnosis of Memory Loss in general practice	Number 2 (AM04)	10/06/2016	11
15/LO/0060/AM04	Look at food and lose your fear	Amendment 2, 01.11.2016	23/01/2017	20
15/LO/0490/AM01	Peritoneal inflammatory responses in the injured abdomen	Amendment number 1 (AM01)	16/05/2016	4
15/LO/1014/AM01	The effect of an aromatherapy intervention on sleep in the ICU	4 (AM01)	01/04/2016	31
15/LO/1033/AM01	Predictors of treatment response in late-onset depression 1.0	Amendment 1	29/03/2016	7

		(AM01)		
15/LO/1038/AM02	Step Home Trial: Physical Activity in the Post-operative Setting	1 (AM02)	12/05/2016	6
15/LO/1038/AM03	Step Home Trial: Physical Activity in the Post-operative Setting	2	06/10/2016	24
15/LO/1038/AM04	Step Home Trial: Physical Activity in the Post-operative Setting	Amendment 3: 27/02/2017	02/03/2017	26
15/LO/1064/AM02	Stem Cell Therapy for the Treatment of Congenital Heart Disease	1-0	10/11/2016	11
15/LO/1186/AM02	Lung Screen Uptake Trial v1.0	AM02	28/06/2016	29
15/LO/1186/AM03	Lung Screen Uptake Trial v1.0	version 5.0, 10/02/2017	10/02/2017	18
15/LO/1188/AM02	Pilot walking intervention for people with severe mental illness	Amendment number 1 (AM02)	27/05/2016	27
15/LO/1413/AM01	Impact of sepsis on oropharyngeal function (London-Bromley 15/LO/1413)	Amended protocol version 2 (AM	03/05/2016	17
15/LO/1539/AM01	ARISE - Losmapimod	Version 3 (AM01)	29/06/2016	27
15/LO/1539/AM02	ARISE - Losmapimod	2	17/10/2016	12
15/LO/1539/AM03	ARISE - Losmapimod	15/03/2017	17/03/2017	16
15/LO/1549/AM01	Preventing Preterm Birth with Probiotics - Pilot Randomised Trial	Substantial Amendment 01 (AM01	04/04/2016	16
15/LO/1557/AM04	The Cognitive Remediation in Bipolar (CRiB) Study: A Feasibility Trial	4 (AM04)	03/06/2016	14
15/LO/1557/AM05	The Cognitive Remediation in Bipolar (CRiB) Study: A Feasibility Trial	4 (AM05)	04/10/2016	27
15/LO/1557/AM07	The Cognitive Remediation in Bipolar (CRiB) Study: A Feasibility Trial	6 16/03/2017	17/03/2017	20
15/LO/1624/AM02	CoRe Study v1.0	Amendment 2 (AM02)	02/08/2016	21
15/LO/1624/AM03	CoRe Study v1.0	Amendment 3.0, 05/01/2017	13/01/2017	10
15/LO/1624/AM04	CoRe Study v1.0	v4.0, 03-03-2017	03/03/2017	17
15/LO/1624/AM05	CoRe Study v1.0	v5.0, 17-03-2017	17/03/2017	20
15/LO/1767/AM02	[11C]CFN PET and fMRI in interictal depression	Amendment number 1 (AM02)	19/08/2016	17
15/LO/1778/AM02	Social Inclusion in Mental Health	2 (AM02)	08/08/2016	12
15/LO/1778/AM03	Social Inclusion in Mental Health	3	08/11/2016	21

15/LO/1786/AM01	Acute effect of Donepezil on transcranial magnetic stimulation parameters in Alzheimer's disease	S. Am 01 (AM01)	10/06/2016	6
15/LO/1786/AM02	Acute effect of Donepezil on transcranial magnetic stimulation parameters in Alzheimer's disease	Substantial Amendment 2.0: 07-	20/02/2017	10
15/LO/1840/AM02	Salivary cortisol and cortisone in healthy children	3	17/11/2016	20
15/LO/1904/AM01	MROC: MR in Ovarian Cancer	Substantial Amendment 01 (AM01)	12/08/2016	11
15/LO/1929/AM01	"Test n Treat": a feasibility trial of rapid STI testing and treatment	1 (AM01)	08/04/2016	2
15/LO/1929/AM02	"Test n Treat": a feasibility trial of rapid STI testing and treatment	2 (AM02)	01/06/2016	17
15/LO/1929/AM03	"Test n Treat": a feasibility trial of rapid STI testing and treatment	3 (AM03)	01/12/2016	27
15/LO/2024/AM02	FCT with young children with ID in the UK: A feasibility project V.1	Subst 1 (AM02)	11/07/2016	35
15/LO/2024/AM03	FCT with young children with ID in the UK: A feasibility project V.1	Subst 2 (AM03)	20/10/2016	28
15/LO/2110/AM01	All Polyethylene Vs Metal Backed Tibial Components in Knee Replacement	01	07/12/2016	21
15/LO/2134/AM01	Predictors 5.1	Amendment 1 (AM01)	07/04/2016	21
15/LO/2158/AM03	IPS Mental Health & Employment Support Evaluation v2.0	1, 22nd February 2017	02/03/2017	24
16/LO/0015/AM03	GAPS - Graduated compression as an Adjunct to Pharmacoprophylaxis in S	Amendment 2 (AM03)	12/07/2016	29
16/LO/0071/AM01	Cognitive Bias Modification for Paranoia	1 (AM01)	23/05/2016	16
16/LO/0071/AM03	Cognitive Bias Modification for Paranoia	Amendment number 2 Date:06/02/	27/02/2017	20
16/LO/0073/AM02	5-2 Study	Substantial amendment 1 (AM02)	18/05/2016	5
16/LO/0105/AM02	Adapted Sex Offender Treatment Programmes for Individuals with Autism	Amendment 1 (AM01)	08/07/2016	31

16/LO/0243/AM01	AIPACa	3.0 (AM01)	23/03/2016	17
16/LO/0243/AM02	AIPACa	4.0	11/07/2016	35
16/LO/0275/AM01	Infective endocarditis after prosthetic valve replacement	1.0	31/10/2016	24
16/LO/0275/AM02	Infective endocarditis after prosthetic valve replacement	2 20/2/17	22/02/2017	31
16/LO/0290/AM01	AlcoChange	AlcoChange_Amen dment (AM01)	18/07/2016	28
16/LO/0290/AM02	AlcoChange	AlcoChange_Amen dment_291216	29/12/2016	22
16/LO/0464/AM01	Validating an extended scale on the HCR-20 V3.	1 (AM01)	30/06/2016	36
16/LO/0720/AM01	Effect of home based balance training in peripheral neuropathy	1	31/08/2016	18
16/LO/1021/AM01	Testing a case-mix classification in palliative care	Amendment number 1 (AM01)	21/07/2016	41
16/LO/1021/AM03	Testing a case-mix classification in palliative care	2	28/10/2016	21
16/LO/1102/AM01	The NOC Study. Version 1	Version 2, 13/12/2016	21/12/2016	20
16/LO/1129/AM01	The role of SV2A in PD and PD Dementia	2.0, 07/02/2017	10/02/2017	30
16/LO/1303/AM01	Tissue Stresses of Cancer	Amendment 1.0 (AM01)	16/08/2016	26
16/LO/1472/AM01	Gender Differences in Autism Spectrum Disorders	1 26.01.17	09/02/2017	30
16/LO/1542/AM01	Cardiovascular and gut health effects of oat (poly)phenols_v1	Amendment 1	13/12/2016	20
16/LO/1834/AM01	Relationship between ankylosing spondylitis and periodontal disease	One (24.02.2017)	28/02/2017	15

### Unfavourable opinion

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
14/LO/0532/AM03	Characterising & contrasting paranoia in schizophrenia and schizotypy	2 (AM03)	22/02/2016	17
15/LO/1862/AM01	VEST™ Long term FU clinical protocol	CD0120 Rev 02 September 2016	02/09/2016	58
16/LO/0714/AM01	tDCS in post-stroke fatigue (TIPS)	1, 03/02/2017	07/02/2017	42

**Table 10.2: Breakdown of current status of all modified amendments reviewed within the reporting period**



<b>Favourable opinion timeline</b>				
<b>Amendment REC Reference</b>	<b>Title</b>	<b>Version</b>	<b>Date</b>	<b>Number of Days on Clock</b>
14/LO/0532/AM03/1	Characterising & contrasting paranoia in schizophrenia and schizotypy	3 (AM03b)	11/05/2016	20
15/LO/1862/AM01/2	VEST™ Long term FU clinical protocol	modified amendment December 20	19/12/2016	30

<b>Unfavourable opinion timeline</b>				
<b>Amendment REC Reference</b>	<b>Title</b>	<b>Version</b>	<b>Date</b>	<b>Number of Days on Clock</b>
15/LO/1862/AM01/1	VEST™ Long term FU clinical protocol	modified amendment (AM01/1)	01/11/2016	13

**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 days**

REC Reference	Title	Number of Days on Clock
16/LO/1672	Novel Methods for Epidermal BioMarker Measurements (Student Study)	22
16/LO/2193	3D Models in Scoliosis surgery	27
16/LO/2228	Assessment of high density lipoprotein in coronary artery disease	24

**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
12/LO/1463/AM04	Different Surgical Modalities in the Treatment of Periodontitis	Substantial Amendment 4 dated	13/09/2016	47
14/LO/1577/AM01	Facilitating Reading in Posterior Cortical Atrophy	1.0	13/10/2016	41
15/LO/1862/AM01	VEST™ Long term FU clinical protocol	CD0120 Rev 02 September 2016	02/09/2016	58
16/LO/0464/AM01	Validating an extended scale on the HCR-20 V3.	1 (AM01)	30/06/2016	36
16/LO/0714/AM01	tDCS in post-stroke fatigue (TIPS)	1, 03/02/2017	07/02/2017	42
16/LO/1021/AM01	Testing a case-mix classification in palliative care	Amendment number 1 (AM01)	21/07/2016	41

<b>Modified Amendments over 14 day timeline</b>				
<b>Amendment REC Reference</b>	<b>Title</b>	<b>Version</b>	<b>Date</b>	<b>Number of Days on Clock</b>
14/LO/0532/AM03/1	Characterising & contrasting paranoia in schizophrenia and schizotypy	3 (AM03b)	11/05/2016	20
15/LO/1862/AM01/2	VEST™ Long term FU clinical protocol	modified amendment December 20	19/12/2016	30