

**London - Camberwell St Giles Research Ethics
Committee**

Annual Report

01 April 2016 - 31 March 2017



Part 1 – Committee Membership and Training

Name of REC:	London - Camberwell St Giles Research Ethics Committee
Type of REC:	Authorised
Type of Flag:	Research involving Adults Lacking Capacity Qualitative Social Care
Chair:	Mr John Richardson
Vice-Chair:	Dr Mark Tanner
Alternate Vice-Chair:	Vacant (01/01/2016 – 31/07/2016) Mrs Jennifer Bostock (01/08/2016 – present)
REC Manager:	Aliki Sifostratoudaki (until 11/01/2017) Vacant (12/01/2017 - 19/03/2017) Tina Cavaliere (20/03/2017 - present)
REC Assistant:	Vacant (until 13/06/2017) Alex Martin (14/06/2016 – 19/03/2017) Charlotte Ferris (20/03/2017 - present)
Committee Address:	Level 3, Block B Whitefriars Lewins Mead Bristol BS1 2NT
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Chair's overview of the past year:

I have now completed six years as Chair of the committee and I am as ever grateful for the privilege of being involved in such interesting work among such a fine group of people.

As in previous years, a wide range of applications has come to us for review. Naturally, most relate to mental health, many involving participants unable to consent for themselves. But sight loss, smoking cessation, weight management, rhinitis, orthodontics and many more subjects have been among the variety presented to us. I trust that we have reviewed each application rigorously, fairly and courteously, always mindful of our responsibilities to protect participants and promote good research. I hope too that researchers have appreciated our approach and on occasion have felt that their work has been strengthened by our consideration of the ethical aspects.

We were honored to be one of the first RECs to be invited to take on social care research and we look forward to the new challenges this type of research will bring.

We have had relative stability in our membership, losing nobody and welcoming Rob McDowall who brings great expertise in research procedures and, as a bonus, reduces our average age! I repeat the aim I mentioned last year, namely to recruit a couple more medically-qualified members and I hope I can omit this sentence in next year's review.

We have had good managerial consistency in that Aliko Sifostratoudaki stayed with us and brought great competence to her role. When she moved on to new responsibilities, it was a real joy to welcome back Tina Cavaliere and even more delightful to know that she actually chose to return to us. Her experience and knowledge have already made their mark and it is a strength to me as Chair to know that our organisation is in safe hands. The committee's relations with the Bristol office continue to work well and I am glad to note that our performance record is excellent.

I believe that this has been a year in which we have all worked together well to foster significant research and above all to protect those who participate in it. I look forward to more of the same in the coming months.

John Richardson
22 May 2017

London - Camberwell St Giles Research Ethics Committee Membership

Name	Profession	Expert or Lay	Dates	
			Appointed	Left
Ms Justine Antill	Deputy Director, Dept of Health Legal Adviser	Lay Plus	01/01/2016	
Dr Ana Bajo	Lecturer	Expert	07/03/2013	
Mrs Jennifer Bostock	Philosopher of Psychiatry	Lay Plus	01/12/2008	
Ms Biddy Gillman	Retired Biology Teacher/ Head of year 12	Lay Plus	11/03/2013	
Mrs Naomi Hare	Modern Matron for Research in Abdominal Medicine and Surgery	Expert	11/11/2015	
Ms Alison Higgs	Lecturer in Social Work	Lay	31/03/2011	31/03/2017
Ms Deborah Horney	Research Associate / Trial Manager	Expert	01/04/2016	
Dr Hilary Lavender	Retired General Practitioner (GP)	Expert	16/11/2015	
Dr Alison Macrae	Solicitor	Expert	07/06/2013	23/09/2016
Mr Robert McDowall	Research Coordinator	Lay	26/08/2016	
Mr John Richardson	Retired Director of COREC: former Ecumenical Officer for Churches Together in South London	Lay Plus	01/01/2011	
Dr Caroline Shackleton	Retired Clinical Psychologist	Lay	01/01/2016	
Dr Mark Tanner	Consultant Psychiatrist	Expert	07/02/2013	
Mr James Uwalaka	Regulatory Compliance Officer	Lay	11/04/2011	

London - Camberwell St Giles Research Ethics Committee: Deputy Members

Name	Profession	Status	Meeting date attended
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London - Camberwell St Giles Research Ethics Committee: Co-opted Members

Name	Profession	Status	Meeting date attended
Dr Margaret Jones	Retired General Practitioner	Expert	15/04/2016
Dr Michael Schachter	Clinical Pharmacologist	Expert	27/06/2016 PRSC

London - Camberwell St Giles Research Ethics Committee: Members' Declarations of Interest:

Name	Declaration of Interest	Date
Ms Justine Antill	None	31/03/2017
Dr Ana Bajo	None	09/12/2016
Mrs Jennifer Bostock	<p>1. Independent Mental Health Act Manager at Oxleas NHS FT (this is an independent role not an employed role)</p> <p>2. Lay member at NICE sitting on the following panels: Quality Standards (QSAC1); Trauma (Spine) Guideline Development Group. Former lay member on a Public Health Committee at NICE and on a Surgical Site Infection Topic Expert Group.</p> <p>3. Former CQC Mental Health Act Commissioner.</p> <p>4. Lay member to the National Clinical Audit and Enquiries Advisory Group and to HQIP.</p> <p>5. Lay member to the National Institute of Health Research as a peer reviewer & a funding panel member sitting on the RfpB (London); PFgAR; HS&DR and TCC Fellowship interview panels. NIHR dissemination centre Rater & PPI advisor to the NIHR School of Pub Health.</p> <p>6. Lay member to Lewisham & Bexley CCG IFR & NHS England IFR.</p> <p>7. Lay member to a number of academic university health research groups based at Universities of Oxford, Cambridge, LSE, Kent, University of West London, KCL, Nottingham; Cardiff, UCL, Sussex & Leeds.</p> <p>8. Visiting academic/researcher to the of universities where I hold an honorary contract: Oxford, Cambridge, Kent, West London & UCL.</p> <p>9. PPI & Ethics advisor to the Research Design Service in London & PPI member of the North West & South London CLAHRC.</p>	09/12/2016
Ms Biddy Gillman	None	12/12/2016
Mrs Naomi Hare	None	09/12/2016
Ms Alison Higgs	None	31/03/2017
Ms Deborah Horney	Employed by Moorfield Eye Hospital and is sometimes involved with setting up trials for the consultants.	04/04/2016
Dr Hilary Lavender	None	09/12/2016
Mr Robert McDowall	Member of the Neurology Research Advisory Group at King's College Hospital	06/09/2016
Mr John Richardson	None	31/03/2017
Dr Caroline Shackleton	None	09/12/2016
Dr Mark Tanner	None	09/12/2016
Mr James Uwalaka	ISGC Manager at Novela Clinical and the director of OPJU limited.	09/12/2016

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

Month	Date	Number of Members Present at Meeting
April	15/04/2016	13
May	20/05/2016	12
July	15/07/2016	9
August	19/08/2016	7
October	21/10/2016	9
December	09/12/2016	11
January	20/01/2017	10
March	17/03/2017	11

8 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	20/04/2016	3
May	31/05/2016	3
June	27/06/2016	3
July	26/07/2016	3
August	08/08/2016	3
October	07/10/2016	3
November	07/11/2016	3
December	07/12/2016	3
January	19/01/2017	3
February	22/02/2017	3

10 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	01/04/2016	3
April	01/04/2016	3
April	08/04/2016	3
April	15/04/2016	3
May	06/05/2016	3
May	20/05/2016	3
May	27/05/2016	3
June	06/06/2016	2
June	10/06/2016	3
June	17/06/2016	2
July	01/07/2016	3
July	06/07/2016	2
July	08/07/2016	3

July	22/07/2016	3
July	29/07/2016	2
August	12/08/2016	3
August	19/08/2016	3
August	26/08/2016	3
September	07/09/2016	2
September	09/09/2016	2
September	23/09/2016	3
September	30/09/2016	3
October	14/10/2016	2
November	04/11/2016	2
December	02/12/2016	2
December	08/12/2016	2
December	09/12/2016	2
December	30/12/2016	2
January	06/01/2017	2
January	24/01/2017	2
January	27/01/2017	2
February	10/02/2017	2
February	24/02/2017	2
March	05/03/2017	3
March	08/03/2017	2
March	08/03/2017	3
March	09/03/2017	3
March	10/03/2017	3
March	10/03/2017	2
March	24/03/2017	2

40 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
Ms Justine Antill	6
Dr Ana Bajo	5
Mrs Jennifer Bostock	5
Ms Bidy Gillman	7
Mrs Naomi Hare	8
Ms Alison Higgs	2
Ms Deborah Horney	6
Dr Hilary Lavender	7
Dr Alison Macrae	2
Mr Robert McDowall	4
Mr John Richardson	8
Dr Caroline Shackleton	7
Dr Mark Tanner	7
Mr James Uwalaka	7

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

Name	Number of Meetings Attended
Ms Justine Antill	2
Dr Ana Bajo	3
Mrs Jennifer Bostock	3
Ms Bidy Gillman	2
Mrs Naomi Hare	2
Ms Alison Higgs	1
Ms Deborah Horney	1
Dr Hilary Lavender	2
Dr Alison Macrae	1
Mr John Richardson	7
Dr Mark Tanner	3
Mr James Uwalaka	2

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

Name	Number of Meetings Attended
Ms Justine Antill	1
Dr Ana Bajo	2
Mrs Jennifer Bostock	20
Ms Bidy Gillman	2

Mrs Naomi Hare	5
Ms Alison Higgs	3
Dr Hilary Lavender	1
Dr Alison Macrae	2
Mr Robert McDowall	3
Mr John Richardson	39
Dr Caroline Shackleton	1
Dr Mark Tanner	21

Training 01 April 2016 - 31 March 2017

Name of Member	Date	Event(s) attended
Ms Justine Antill	25/07/2016	Equality and Diversity
Dr Ana Bajo	18/11/2016	Local Training Day - London - Camberwell
Dr Ana Bajo	08/02/2017	Evaluated 12 undergraduate projects in terms of ethics
Mrs Jennifer Bostock	02/09/2016	'Buddy' for new member - Mr Robert McDowall
Ms Bidy Gillman	18/11/2016	Local Training Day - London - Camberwell
Mrs Naomi Hare	18/11/2016	Local Training Day - London - Camberwell
Mrs Naomi Hare	16/02/2017	National Members Training Day
Ms Alison Higgs	07/04/2016	E&D
Ms Deborah Horney	08/06/2016	Member's Induction Training
Ms Deborah Horney	27/07/2016	Equality and Diversity online module
Ms Deborah Horney	18/11/2016	Local Training Day - London - Camberwell
Dr Hilary Lavender	18/11/2016	Local Training Day - London - Camberwell
Mr Robert McDowall	14/07/2016	Training - Personal Data in Research - A Workshop
Mr Robert McDowall	05/09/2016	Equality and Diversity
Mr Robert McDowall	18/10/2016	Induction for new Research Ethics Service Committee members
Mr John Richardson	18/11/2016	Local Training Day - London - Camberwell
Mr John Richardson	01/12/2016	Training - National Training Day for Committee Chairs
Mr John Richardson	22/03/2017	National Members Training Day
Mr John Richardson	27/03/2017	Chairs Review Programme
Dr Caroline Shackleton	16/11/2016	Local Training Day - London REC Members' Training Day
Dr Caroline Shackleton	16/02/2017	National Members Training Day
Dr Mark Tanner	18/11/2016	Local Training Day - London - Camberwell
Mr James Uwalaka	18/11/2016	Local Training Day - London - Camberwell

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	45	100.00
Total Applications Reviewed	45	100

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

Number of applications made invalid by the REC Manager	1
Number of applications withdrawn prior to the meeting	0
Number of student applications reviewed	25
Number of paediatric applications reviewed	6
Number of device applications reviewed	1
Number of prisoner applications reviewed	0
Number of applications involving adults unable consent reviewed	7
Number of applications reviewed that are funded by the US DHHS	0
Number of qualitative applications reviewed	12

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	10	22.22
Unfavourable Opinion	3	6.67
Provisional Opinion	31	68.89
Provisional Opinion Pending Consultation with Referee	1	2.22
Total	45	100
Number of studies sent back to full committee meeting for final opinion	0	

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

Status of applications at date of generation of report	Number	%
Further Information Favourable Opinion with Standard Conditions	31	68.89
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	10	22.22
Unfavourable Opinion	3	6.67
Provisional Opinion	1	2.22
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	45	100

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

Total Applications Reviewed	20
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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	2
Number of student applications reviewed	9
Number of paediatric applications reviewed	3
Number of device applications reviewed	0
Number of qualitative applications reviewed	2

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

Decisions taken at proportionate review sub-committee meetings	Number	%
Favourable Opinion with Standard Conditions	4	20.00
Favourable Opinion with Additional Conditions	3	15.00
No Opinion transfer to full committee for review	5	25.00
Provisional Opinion	7	35.00
Unfavourable Opinion	1	5.00
Total	20	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	5.63
Number of completed applications for full ethical review	45
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	4.44%
Number of days taken to final decision – average (mean)	31
Number of completed proportionate review applications for ethical review	15
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)	3
Number of completed proportionate review applications for ethical review over 21 days	2
Number of completed proportionate review applications over 21 days as a % of total	13.33
Number of SSAs (non-Phase 1) reviewed	3
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	58
Number of completed substantial amendments over 35 days	3
Number of completed substantial amendments over 35 days as a % of total substantial amendments	5.17%
Number of completed substantial amendments over 28 days	7
Number of completed substantial amendments over 28 days as a % of total substantial amendments	12.07%
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 non substantial 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	39
Number of safety reports received	0
Number of Serious Adverse Events received	6
Number of final reports received	14

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

Further Information Favourable Opinion with Standard Conditions		
REC Reference	Title	Number of Days on Clock
16/LO/0492	My Story, Our Future: Early Intervention in Psychosis – Life Stories	34
16/LO/0514	InHALe: deep INspiration breath Hold setup Accuracy for LEft breast RT	32
16/LO/0528	MBRACE: Metabolic Biomarker Responses in Acute Cerebral Events	34
16/LO/0531	The effects of weight loss in people with cancer	30
16/LO/0540	IDEA Intervention for Depressive symptoms in EARly stage dementia	34
16/LO/0609	Acceptance and Commitment Therapy for Muscle Disease (ACTMUS)	36
16/LO/0820	Exploring the psychosocial needs of amputee patients during recovery	31
16/LO/0837	TEMPO Temporary Sight Loss in Young People	32
16/LO/0890	What do patients find helpful in psychological therapy for depression?	30
16/LO/0892	Psychotic symptoms in Borderline Personality Disorder V1	35
16/LO/0893	INcOSA (Version 1)	35
16/LO/1137	Carer Skills training for inpatients with anorexia nervosa	37
16/LO/1270	Increasing home practice in a group based intervention for LTC's	35
16/LO/1271	Oesophageal sensor for early detection of MODS	38
16/LO/1377	TRIANGLE: A novel patient and carer intervention for Anorexia Nervosa	36
16/LO/1439	Reviewing and modifying beliefs in people who hear voices	39
16/LO/1459	The EPIC Study	37
16/LO/1878	HDClarity	31
16/LO/1910	Impact of almond nut consumption on markers of CVD & metabolic disease	36
16/LO/1925	Timeliness of a dementia diagnosis during an acute hospital admission	38
16/LO/2048	IARE II: needs & preferences of recently hospitalised older people	32
16/LO/2143	Dietetic Assessment and Intervention in Lung Cancer	31
16/LO/2144	Exploring Anxiety in Parkinson's v1.0	31
16/LO/2149	Tensor Imaging in Paediatric Tumours for functional Outcome Prediction	40
16/LO/2154	Validation of BIA device in CF	31
17/LO/0006	Mental Snapp Pilot	41
17/LO/0091	Self-over-time and decision-making in Borderline Personality Disorder	44
17/LO/0133	THE AGEING BODY: DRESS, DEMENTIA AND IDENTITY	27
17/LO/0294	Retrospective Case-Control Study of Ictal Asystole	37
17/LO/0424	An exploration of coercion in a forensic inpatient unit. Version 0.1	33
17/LO/0426	Epigenetic Regulation of Muscle Wasting in End-Stage Renal Failure	39

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		
REC Reference	Title	Number of Days on Clock

Favourable Opinion with Additional Conditions		
REC Reference	Title	Number of Days on Clock
16/LO/0686	Acceptability of sedation monitoring in palliative care	28
16/LO/1116	Multicenter Aggression subTyping Research in Conduct Syndromes	28
16/LO/1269	UK DR-TB management v1	28
16/LO/1422	A 2 arm feasibility trial to support postnatal weight management	28
16/LO/1862	SlowMo trial: a digital therapy for people who fear harm from others.	25
16/LO/1882	First Episode & Rapid Early Intervention for Eating Disorders Upscaled	28
17/LO/0009	The Relationship between Autobiographical Memory and Motivation	25
17/LO/0031	The perceived impact of art and design on patient experience	25
17/LO/0055	Unusual experiences and function in young people	25
17/LO/0414	LSHTM study into stop smoking services & e-cigarettes (v1)	26

Unfavourable Opinion		
REC Reference	Title	Number of Days on Clock
16/LO/1274	Meaning-making following group anger management.	28
16/LO/1289	The Impact of Training Nurses in PICC Care	27
16/LO/1790	THE AGEING BODY: DRESS, DEMENTIA AND IDENTITY	25

Provisional Opinion		
REC Reference	Title	Number of Days on Clock
17/LO/0421	National Evaluation of the Integrated Care & Support Pioneers Program	n/a

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

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

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

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

Further Information Favourable Opinion with Standard Conditions		
REC Reference	Title	Number of Days on Clock
16/LO/1496	COmputer Games for Amblyopia Study (COGAS), Version 1	9
16/LO/1500	Haemodynamics, haemodialysis and Adult CKD v1.0	14
16/LO/1503	Factors affecting uptake of orthodontic treatment among adults.	13
16/LO/1855	Visual function alterations in age-related macular degeneration V1.0	14
17/LO/0194	Rhinitis Prevalence & Omalizumab Impact Study (RHOS)	23
17/LO/0367	Evaluation of implicit-referential thoughts and cognitive fusion.	26

Further Information Favourable Opinion with Additional Conditions		
REC Reference	Title	Number of Days on Clock
16/LO/1067	Genotyping of patients with age related macular degeneration	10

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

Favourable Opinion with Standard Conditions		
REC Reference	Title	Number of Days on Clock
16/LO/1449	FACTS- Finding active Schistosoma infections by CAA detection	9
16/LO/1865	Non-invasive prenatal testing for sickle cell disease (SCIP study) v1	14
16/LO/2198	Exploring Lived Experiences of Females Receiving Autism Diagnosis	12
17/LO/0364	TWILIGHT	14

Favourable Opinion with Additional Conditions		
REC Reference	Title	Number of Days on Clock
16/LO/1095	Superficial skin responses in humans to local commensals	10
16/LO/1444	Evaluating the Implementation of Robust Vocabulary Intervention	9
17/LO/0370	Magnetic resonance imaging of Abdominal Lymph nodes (MAL) Version 1.0	16

Unfavourable Opinion		
REC Reference	Title	Number of Days on Clock
16/LO/1451	Optimising the Transition from Home to Hospital	9

Provisional Opinion		
REC Reference	Title	Number of Days on Clock

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

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

Table 10.1: Breakdown of current status of all substantial amendments reviewed within the reporting period

Favourable opinion				
Amendment REC Reference	Title	Version	Date	Number of Days on Clock
09/H0807/12/AM07	Nutrition, Eating and Stress in Pregnancy: a study of risk mechanisms	6 20/06/2016	20/06/2016	8
09/H0807/12/AM09	Nutrition, Eating and Stress in Pregnancy: a study of risk mechanisms	Substantial 7 dated 17.11.2016	17/11/2016	28
10/H0807/101/AM08	Gait Analysis Using An Instrumented Treadmill	SA6 - 17.07.16	17/07/2016	15
10/H0807/93/AM06	Brain Function in Rolandic Epilepsy	Substantial Amendment 3	26/09/2016	26
11/LO/0927/AM22	World Hip Trauma Evaluation (WHiTE study)	Substantial Amendment 11	22/03/2016	18
11/LO/0927/AM25	World Hip Trauma Evaluation (WHiTE study)	Substantial Amendment 12	22/11/2016	23
11/LO/0927/AM27	World Hip Trauma Evaluation (WHiTE study)	Substantial amendment - AM13;	09/01/2017	11
11/LO/1274/AM03	Immunology of the intestine; features associated with autoimmunity	SA - dated 3rd February 2017 ¹ ₃ / ₄	01/03/2017	26
12/LO/1023/AM15	The PREVENT Research Programme - Pilot and Feasibility Stage	Substantial Amendment 8	29/11/2016	28
13/LO/1370/AM01	Version 1.0 - Investigating neonatal opiate abstinence syndrome (NAS).	Substantial Amendment 1	26/04/2016	9
13/LO/1481/AM03	MARS 2	Substantial Amendment 3	04/05/2016	15
13/LO/1481/AM04	MARS 2	Substantial Amendment 4	29/09/2016	17
13/LO/1494/AM01	Optimisation of paediatric PM imaging	Amendment #1, 16/09/2016	24/01/2017	18
13/LO/1595/AM09	CBT vs Standardised Medical Care to treat Dissociative Seizures	6	30/03/2016	15
13/LO/1595/AM10	CBT vs Standardised Medical Care to treat Dissociative Seizures	Substantial Amendment 7.0 24th	24/02/2017	28

13/LO/1855/AM03	Stakeholders' views and experiences of perinatal mental health care	SA3 - 25.07.16	25/07/2016	15
13/LO/1855/AM04	Stakeholders' views and experiences of perinatal mental health care	Substantial Amendment 4	04/09/2016	12
13/LO/1896/AM01	Abundances of enzyme and transporters in kidney tissue v1	Substantial Amendment 1	18/03/2016	16
14/LO/0075/AM07	Well-being in pregnancy	SA5 - 09.09.16	09/06/2016	11
14/LO/0112/AM03	Living Together with Dementia: a Psychosocial Intervention for Couples	3	18/11/2016	29
14/LO/0477/AM04	Long term neurobiological impact of early deprivation	Substantial Amendment 3	05/07/2016	25
14/LO/0556/AM04	Frame Fit - falls prevention for frame users.	Substantial Amendment 2	01/03/2016	14
14/LO/0578/AM02	Social anxiety in autism-spectrum disorder: a mixed-methods study	Substantial Amendment 2	11/12/2016	28
14/LO/0736/AM14	VALID WPs 3/4: Pilot trial and RCT of COTiD-UK	Amendment 17	26/01/2017	39
14/LO/0765/AM04	The effectiveness of perinatal mental health services	Substantial Amendment 4	24/05/2016	28
14/LO/1477/AM10	Evaluation of internet-based STI testing in Lambeth and Southwark	8	25/04/2016	22
14/LO/2085/AM01	(duplicate) Enhanced surveillance for resistant Gram-negative bacteria v1.0	SA001 08_12_16	24/01/2017	26
14/LO/2115/AM02	The influence of oxytocin on eating behaviours and stress	3	28/03/2016	17
15/LO/0057/AM09	Persistent Physical Symptoms - waiting list cluster RCT	Substantial Amendment 5	06/05/2016	15
15/LO/0058/AM11	PRINCE Secondary (version 1)	SA6 - 17.08.16	17/08/2016	11
15/LO/0100/AM02	Brain network structures in Idiopathic Generalised Epilepsy (IGE)	2	24/11/2016	27
15/LO/0577/AM02	Neuromodulation in Depression (NeuroMooD)	Substantial Amendment 2	05/05/2016	22
15/LO/0827/AM01	C-PLACID:Assessing cognition in dementia using adapted/novel paradigms	Amendment 1	22/01/2016	25
15/LO/0827/AM02	C-PLACID:Assessing cognition in dementia using adapted/novel paradigms	2	23/05/2016	46
15/LO/0887/AM03	Understanding complexity and care needs	Substantial Amendment 1	12/07/2016	8

15/LO/0939/AM02	Thinking and Social Skills in Functional Neurological Symptoms	Substantial Amendment 2	25/04/2016	18
15/LO/1618/AM01	The Pathways Project (v.1)	Substantial Amendment 1	20/09/2016	21
15/LO/2006/AM01	Health Relationships: Healthy Baby programme	1	10/03/2016	22
15/LO/2006/AM02	Health Relationships: Healthy Baby programme	Substantial Amendment 2 -	13/09/2016	14
15/LO/2006/AM03	Health Relationships: Healthy Baby programme	Substantial Amendment 3	18/11/2016	47
16/LO/0106/AM01	Visual Field Algorithm Study (vFAST)	Substantial Amendment 2	22/06/2016	15
16/LO/0106/AM03	Visual Field Algorithm Study (vFAST)	SA3 dated 20.10.2016	20/10/2016	15
16/LO/0466/AM01	Vitamin D in AKI Version 1	Substantial Amendment 1 - 10 J	10/01/2017	28
16/LO/0528/AM01	MBRACE: Metabolic Biomarker Responses in Acute Cerebral Events	Substantial Amendment 1	28/09/2016	28
16/LO/0609/AM01	Acceptance and Commitment Therapy for Muscle Disease (ACTMUS)	Amendment 1 21.06.2016	21/06/2016	9
16/LO/0609/AM03	Acceptance and Commitment Therapy for Muscle Disease (ACTMUS)	Substantial Amendment 2	02/09/2016	16
16/LO/0609/AM05	Acceptance and Commitment Therapy for Muscle Disease (ACTMUS)	Amendment 3, 21.02.2017	21/02/2017	24
16/LO/0890/AM01	What do patients find helpful in psychological therapy for depression?	Substantial Amendment 1 25.08.	25/08/2016	22
16/LO/1067/AM01	Genotyping of patients with age related macular degeneration	Substantial Amendment 1	26/08/2016	15
16/LO/1137/AM01	Carer Skills training for inpatients with anorexia nervosa	Substantial Amendment 1,	07/03/2017	17
16/LO/1269/AM02	UK DR-TB management v1	Substantial Amendment 1	24/11/2016	30
16/LO/1377/AM01	TRIANGLE: A novel patient and carer intervention for Anorexia Nervosa	Amendment n.1, 10/02/2017	10/02/2017	32
16/LO/1444/AM01	Evaluating the Implementation of Robust Vocabulary	Substantial	15/01/2017	23

	Intervention	Amendment 1		
16/LO/1496/AM01	COmputer Games for Amblyopia Study (COGAS), Version 1	Substantial Amendment 2	02/12/2016	29
16/LO/1855/AM01	Visual function alterations in age-related macular degeneration V1.0	Substantial Amendment 1	20/01/2017	16
16/LO/1882/AM01	First Episode & Rapid Early Intervention for Eating Disorders Upscaled	Substantial Amendment 1	07/12/2016	22
16/LO/1910/AM01	Impact of almond nut consumption on markers of CVD & metabolic disease	1	20/02/2017	6

Unfavourable opinion

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
16/LO/0382/AM02	The Wiedemann-Steiner Syndrome and Hypertrichosis Study	Substantial Amendment 1	20/07/2016	13

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
16/LO/0382/AM02/1	The Wiedemann-Steiner Syndrome and Hypertrichosis Study	Modified NoSA 1, 2nd August 20	02/08/2016	11

Unfavourable opinion timeline

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
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Table 11: Items exceeding timelines**Full applications for ethical review over 60 day timeline**

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

REC Reference	Title	Number of Days on Clock
17/LO/0194	Rhinitis Prevalence & Omalizumab Impact Study (RHOS)	23
17/LO/0367	Evaluation of implicit-referential thoughts and cognitive fusion.	26

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
14/LO/0736/AM14	VALID WPs 3/4: Pilot trial and RCT of COTiD-UK	Amendment 17	26/01/2017	39
15/LO/0827/AM02	C-PLACID:Assessing cognition in dementia using adapted/novel paradigms	2	23/05/2016	46
15/LO/2006/AM03	Health Relationships: Healthy Baby programme	Substantial Amendment 3	18/11/2016	47

Modified Amendments over 14 day timeline

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
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