

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

Annual Report

01 April 2015 - 31 March 2016



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
Chair:	Mr John Richardson
Vice-Chair:	Mr Evan Stone QC (01/01/2011 – 16/10/2015) Vacant (10/02/2015 – 18/03/2016) Dr Mark Tanner (18/03/2016 – present).
Alternate Vice-Chair:	Ms Sally Gordon Boyd (17/02/2012 – 31/12/2015) Vacant from (01/01/2016 – present)
REC Manager:	Miss Tina Cavaliere (01/11/2014 – 01/09/2015) Miss Gemma Oakes (02/09/2015 – 01/11/2015) Miss Aliko Sifostratoudaki (01/12/2015 – present).
REC Assistant:	Miss Claudia Harrison (01/04/2015 – 01/09/2015) Miss Aliko Sifostratoudaki (01/10/2015 – 01/11/2015) Vacant from 01/12/2015 – present).
Committee Address:	Level 3, Block B Whitefriars Lewins Mead Bristol BS1 2NT
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Chair's overview of the past year:

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	Research Psychologist	Expert	07/03/2013	
Mrs Jennifer Bostock	Philosopher of Psychiatry	Lay Plus	01/12/2008	
Ms Bidy Gillman	Retired Biology Teacher/ Head of year 12	Lay Plus	11/03/2013	
Ms Sally Gordon Boyd	Medical Ethicist	Lay Plus	31/05/2011	31/12/2015
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	
Dr Hilary Lavender	Retired General Practitioner (GP)	Expert	16/11/2015	
Dr Alison Macrae	Solicitor	Expert	07/06/2013	
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	
Mr Evan Stone QC	Retired Queen's Counsel	Lay	08/10/2010	16/10/2015
Dr Mark Tanner	Consultant Psychiatrist	Expert	07/02/2013	
Mr James Uwalaka	Regulatory Compliance Officer	Lay	11/04/2011	
Mr Thomas Walters	Clinical Research Charge Nurse	Expert	20/03/2013	01/08/2015
Mr Jonathan Watkins	Independent Social Worker	Expert	17/08/2005	01/10/2015

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	15/04/2015, 17/07/2015
Dr Jan Downer	Consultant Anaesthetist	Expert	15/01/2016
Miss Stephanie Ellis	Former Civil Servant	Lay Plus	16/10/2015, 21/08/2015, 15/05/2015
Mrs Dinah Smith	Retired Head Teacher	Lay Plus	21/08/2015, 20/11/2015

Mrs Hemawtee Sreeneebus	Clinical Research Nurse	Expert	17/04/2015, 15/05/2015
Dr Michael Schachter	Clinical Pharmacologist	Expert	16/10/2015

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

Name	Declaration of Interest	Date
Ms Justine Antill	None	02/01/2016
Dr Ana Bajo	None	15/01/2016
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. I am a 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. I am also an 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>	14/01/2016
Ms Biddy Gillman	None	15/03/2016
Mrs Naomi Hare	Clinical Nurse at Guys & St Thomas' NHS Foundation Trust and has regular contact with their Local R&D	19/11/2015
Ms Alison Higgs	Lecturer, Open University. Peer reviewer for academic journal papers (social work, social care, ethics)	14/03/2016
Dr Hilary Lavender	None	15/01/2016
Dr Alison Macrae	None	02/11/2015
Mr John Richardson	None	15/01/2016
Dr Caroline Shackleton	None	18/03/2016
Dr Mark Tanner	Attends a research support group at his workplace, the Herefordshire Partnership University NHS Foundation Trust.	15/01/2016
Mr James Uwalaka	Owner and Director of OPJU LTD and Regulatory Compliance Officer at Roche Pharmaceuticals.	16/04/2015

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

Month	Date	Number of Members Present at Meeting
April	17/04/2015	10
May	15/05/2015	7
June	19/06/2015	10
July	17/07/2015	9
August	21/08/2015	8
October	16/10/2015	9
November	20/11/2015	8
December	11/12/2015	9
January	15/01/2016	11
March	18/03/2016	8

10 full committee meetings were held during the reporting period.

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

Month	Date	Number of Members Present at Meeting
June	29/06/2015	3

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

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

Month	Date	Number of Members Present at Meeting
April	02/04/2015	3
April	09/04/2015	3
April	13/04/2015	3
May	01/05/2015	3
May	15/05/2015	3
May	22/05/2015	4
May	29/05/2015	3
June	05/06/2015	3
June	12/06/2015	4
June	19/06/2015	5
June	26/06/2015	3
July	03/07/2015	4
July	10/07/2015	3
July	17/07/2015	3
July	24/07/2015	3
July	31/07/2015	4
August	07/08/2015	3
August	14/08/2015	4
August	21/08/2015	3
August	28/08/2015	2

September	18/09/2015	2
September	18/09/2015	3
September	25/09/2015	3
October	16/10/2015	3
October	30/10/2015	3
November	20/11/2015	3
December	04/12/2015	2
December	11/12/2015	3
December	25/12/2015	2
December	31/12/2015	3
January	08/01/2016	2
January	15/01/2016	2
January	22/01/2016	2
February	05/02/2016	3
February	05/02/2016	2
February	12/02/2016	2
February	19/02/2016	2
February	26/02/2016	3
March	04/03/2016	2
March	11/03/2016	3
March	18/03/2016	3

41 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
Ms Justine Antill	2
Dr Ana Bajo	8
Mrs Jennifer Bostock	5
Ms Bidy Gillman	7
Ms Sally Gordon Boyd	8
Mrs Naomi Hare	3
Ms Alison Higgs	8
Dr Hilary Lavender	3
Dr Alison Macrae	5
Mr John Richardson	9
Dr Michael Schachter	1
Dr Caroline Shackleton	1
Mr Evan Stone QC	3
Dr Mark Tanner	5
Mr James Uwalaka	6
Mr Thomas Walters	3
Mr Jonathan Watkins	4

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

Name	Number of Meetings Attended
Ms Sally Gordon Boyd	1
Mr John Richardson	1
Mr Thomas Walters	1

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

Name	Number of Meetings Attended
Dr Ana Bajo	1
Mrs Jennifer Bostock	36
Ms Bidy Gillman	1
Ms Sally Gordon Boyd	28
Ms Alison Higgs	3
Dr Alison Macrae	2
Mr John Richardson	33
Mrs Hemawtee Sreeneebus	1
Mr Evan Stone QC	7
Dr Mark Tanner	6

Mr James Uwalaka	1
Mr Jonathan Watkins	4

Training 01 April 2015 - 31 March 2016

Name of Member	Date	Event(s) attended
Ms Justine Antill	15/01/2016	MCA Training with Dr Jan Downer
Ms Justine Antill	10/03/2016	Induction Day
Dr Ana Bajo	16/10/2015	MCA training with Ms Stephanie Ellis
Dr Ana Bajo	26/11/2015	London REC Member's Training Day
Dr Ana Bajo	15/01/2016	MCA Training with Dr Jan Downer
Mrs Jennifer Bostock	26/11/2015	London REC Member's Training Day
Ms Bidy Gillman	28/07/2015	E&D
Ms Bidy Gillman	17/11/2015	Buddy for Naomi Hare
Ms Bidy Gillman	15/01/2016	MCA Training with Dr Jan Downer
Ms Bidy Gillman	24/02/2016	Training - Human Tissue Act (Use of Human Samples in Research) - An Introductory Level
Ms Sally Gordon Boyd	14/05/2015	Cystic Fibrosis Trust - Clinical Trials Forum
Ms Sally Gordon Boyd	26/11/2015	Local Training Day - London REC Members' Training Day
Mrs Naomi Hare	16/10/2015	MCA training with Ms Stephanie Ellis
Mrs Naomi Hare	18/11/2015	Online E&D Training
Mrs Naomi Hare	15/01/2016	MCA Training with Dr Jan Downer
Mrs Naomi Hare	10/02/2016	Training - Committee Members Induction
Ms Alison Higgs	16/10/2015	MCA training with Ms Stephanie Ellis
Ms Alison Higgs	26/11/2015	London REC Member's Training Day
Ms Alison Higgs	15/01/2016	MCA Training with Dr Jan Downer
Dr Hilary Lavender	16/10/2015	MCA training with Ms Stephanie Ellis
Dr Hilary Lavender	15/01/2016	MCA Training with Dr Jan Downer
Dr Hilary Lavender	05/02/2016	Training - Committee Members Induction
Dr Hilary Lavender	18/02/2016	Training - National Members Training Day
Dr Hilary Lavender	10/03/2016	Training - Committee Members Induction
Dr Alison Macrae	16/10/2015	MCA training with Ms Stephanie Ellis
Dr Alison Macrae	15/01/2016	MCA Training with Dr Jan

		Downer
Mr John Richardson	19/05/2015	London Chair's meeting
Mr John Richardson	12/06/2015	Training - Equality and Diversity (eLearning module)
Mr John Richardson	12/06/2015	E&D Training
Mr John Richardson	21/09/2015	Researcher Training Day
Mr John Richardson	16/10/2015	MCA training with Ms Stephanie Ellis
Mr John Richardson	19/10/2015	Training - The Ethical Issues of Research Involving Children.
Mr John Richardson	15/01/2016	MCA Training with Dr Jan Downer
Dr Michael Schachter	09/12/2015	Training - National Training Day for Committee Chairs
Dr Michael Schachter	11/01/2016	Local Training Day
Dr Caroline Shackleton	18/02/2016	National Member's Day
Dr Caroline Shackleton	10/03/2016	Induction Day
Dr Mark Tanner	16/10/2015	MCA Training with Ms Stephanie Ellis
Dr Mark Tanner	26/11/2015	London REC Member's Training Day
Dr Mark Tanner	15/01/2016	MCA Training with Dr Jan Downer
Dr Mark Tanner	24/03/2016	E&D
Mr James Uwalaka	22/10/2015	Good Clinical Practice KCL Training for the GW Pharma job role - essential guidelines and legislation
Mr James Uwalaka	19/11/2015	Serious breaches, Good Clinical Practice
Mr James Uwalaka	19/11/2015	Essential Document management - Standard Operating Procedure for the GW Pharma job role
Mr James Uwalaka	15/01/2016	MCA Training with Dr Downer
Mr James Uwalaka	31/03/2016	E&D on-line module

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	40	100.00
Total Applications Reviewed	40	100

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

Number of applications made invalid by the REC Manager	5
Number of applications withdrawn prior to the meeting	0
Number of student applications reviewed	19
Number of paediatric applications reviewed	5
Number of device applications reviewed	1
Number of prisoner applications reviewed	0
Number of applications involving adults unable consent reviewed	10
Number of applications reviewed that are funded by the US DHHS	0
Number of qualitative applications reviewed	13

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	1	2.50
Favourable Opinion with Additional Conditions	13	32.50
Unfavourable Opinion	0	0.00
Provisional Opinion	24	60.00
Provisional Opinion Pending Consultation with Referee	2	5.00
Total	40	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	23	57.50
Further Information Favourable Opinion with Additional Conditions	0	0.00
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	1	2.50
Favourable Opinion with Additional Conditions	13	32.50
Unfavourable Opinion	1	2.50
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	1	2.50
Total	40	100

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

Total Applications Reviewed	1
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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	6
Number of studies withdrawn prior to the meeting	0
Number of student applications reviewed	0
Number of paediatric applications reviewed	0
Number of device applications reviewed	0
Number of qualitative applications reviewed	0

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

Decisions taken at proportionate review sub-committee meetings	Number	%
Favourable Opinion with Standard Conditions	0	0.00
Favourable Opinion with Additional Conditions	0	0.00
No Opinion transfer to full committee for review	0	0.00
Provisional Opinion	1	100.00
Unfavourable Opinion	0	0.00
Total	1	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	4.00
Number of completed applications for full ethical review	39
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	1
Number of completed applications over 40 days as a % of total	2.50%
Number of days taken to final decision – average (mean)	31
Number of completed proportionate review applications for ethical review	1
Number of completed proportionate review applications for ethical review over 14 days	0
Number of completed proportionate review applications over 14 days as a % of total	0.00%
Number of SSAs (non-Phase 1) reviewed	8
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	76
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	1
Number of completed substantial amendments over 28 days as a % of total substantial amendments	1.32%
Number of modified amendments reviewed	2
Number of completed modified amendments over 14 days	0
Number of completed modified amendments over 14 days as a % of total modified amendments	0.00%
Number of minor amendments received	53
Number of substantial amendments received for information	0
Number of substantial amendments received for new sites/PIs	0
Number of annual progress reports received	80

Number of safety reports received	0
Number of Serious Adverse Events received	5
Number of final reports received	10

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/0427	The DECIDE Study	38
15/LO/0577	Neuromodulation in Depression (NeuroMooD)	40
15/LO/0734	Transforming End of Life Care - Cognitive Interview Study	33
15/LO/0784	Experience of crisis and recovery in BPD: an exploratory study	28
15/LO/0820	PRAM'OH Study: Patient-Reported and Assessment of Mothers' Oral Health	37
15/LO/0827	C-PLACID:Assessing cognition in dementia using adapted/novel paradigms	34
15/LO/0887	Understanding complexity and care needs	25
15/LO/0939	Thinking and Social Skills in Functional Neurological Symptoms	31
15/LO/1171	Experiences of Orthodox Jewish parents accessing community CAMHS.	28
15/LO/1197	Using Virtual Reality to Investigate Psychological Factors in Paranoia	28
15/LO/1205	Experiences of hip fracture version 1	35
15/LO/1328	Antenatal information for pregnant women with LD (phase 4) version2	27
15/LO/1336	Imagery, Appraisals and Emotional Regulation in Bipolar Disorder	26
15/LO/1618	The Pathways Project (v.1)	31
15/LO/1645	How do paramedics manage patients with mental health issues	30
15/LO/1915	Women's experiences of having a postnatal mental health assessment 1	34
15/LO/1917	HD-CSF version 1	40
15/LO/2006	Health Relationships: Healthy Baby programme	30
15/LO/2105	Evaluation of a Violence Reduction Programme in Acute Mental Health	28
15/LO/2130	Immune surveillance in the skin	38
16/LO/0030	Men's Attitudes to Intimate Life (MAIL)	40
16/LO/0106	Visual Field Algorithm Study (vFAST)	37
16/LO/0382	The Wiedemann-Steiner Syndrome and Hypertrichosis Study	36

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
15/LO/1650	Bacteria in stool from IBD patients	24

Favourable Opinion with Additional Conditions		
REC Reference	Title	Number of Days on Clock
15/LO/0592	Spasticity and Contractures at the ankle after head injury	35
15/LO/0747	Exploring barriers to compassionate imagery (Version 2)	32
15/LO/1183	Information following surgery for lung cancer	24
15/LO/1194	Changes after Seeing a Psychologist at Great Ormond Street Hospital	24
15/LO/1322	WBC collection for CAR T-Cells for Immunotherapies research.	25
15/LO/1338	Brief Talking therapies ON wards (amBITION study) v.1	25
15/LO/1866	Experiences of help-seeking among UK veterans	31
15/LO/1918	INVASIVE VS NON INVASIVE ICP MONITORING	26
15/LO/2015	The Feasibility and Acceptability of an Internet-based EC Service v.1	25
15/LO/2032	REBinD v 1.0	25
16/LO/0237	Migration and Perinatal Mental Health	26
16/LO/0375	ENABLE - NGS	26
16/LO/0466	Vitamin D in AKI Version 1	26

Unfavourable Opinion		
REC Reference	Title	Number of Days on Clock
15/LO/1934	Multicenter Aggression subTyping Research in Conduct Syndromes	47

Provisional Opinion		
REC Reference	Title	Number of Days on Clock

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
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Withdrawn after the meeting

REC Reference	Title	Number of Days on Clock
15/LO/0568	OAB treated with antibiotics	18

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/1209	LTC and depression: Barriers and facilitators to integrated care	10

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
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Unfavourable Opinion

REC Reference	Title	Number of Days on Clock
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Provisional Opinion		
REC Reference	Title	Number of Days on Clock

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

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

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

Favourable opinion				
Amendment REC Reference	Title	Version	Date	Number of Days on Clock
05/Q0706/128/AM01	EFFECTS OF DEPRESSION ON PAIN AND PERFORMANCE: A MOOD INDUCTION STUDY	Substantial Amendment - Protocol V8 28.1.15	28/01/2015	10
06/Q0706/50/AM12	AddNeuroMed	Substantial Amendment 12, 13/03/2015	27/04/2015	9
08/H0807/84/AM01	Development of Computerised Analysis Methods for Brain Imaging 1.0	Substantial Amendment 1	01/02/2016	19
08/H0807/95/AM05	Dopaminergic function and treatment response	Substantial Amendment 5 - 28.07.15	28/07/2015	19
10/H0807/14/AM06	Risk factors of perinatal mental disorders _ Version 1	Substantial Amendment 4	20/10/2016	12
10/H0807/23/AM07	Injured Spinal Cord Pressure Evaluation (ISCoPE) [v.1]	Substantial Amendment 6 - 2.06.2015	10/06/2015	11
10/H0807/23/AM08	Injured Spinal Cord Pressure Evaluation (ISCoPE) [v.1]	Amendment 7	07/02/2016	19
10/H0807/97/AM02	Investigation of genetic and epigenetic defects in humans	Substantial Amendment 2	19/11/2014	8
11/LO/0376/AM07	CanTalk V3	Substantial Amendment 4 - 22.05.15	22/05/2015	9
11/LO/0376/AM08	CanTalk V3	Substantial Amendment 5 - 11.08.15	11/08/2015	12
11/LO/0376/AM10	CanTalk V3	Substantial Amendment 6 - 28.08.15	28/08/2015	7
11/LO/0927/AM20	World Hip Trauma Evaluation (WHiTE study)	Substantial Amendment 10	27/10/2015	3
11/LO/1274/AM02	Immunology of the intestine; features associated with	Substantial	01/12/2015	17

	autoimmunity	Amendment dated 01		
12/LO/0695/AM07	HLA Epitope-Matched Platelet Transfusion Study	Substantial Amendment 5	07/10/2015	12
12/LO/1023/AM13	The PREVENT Research Programme - Pilot and Feasibility Stage	Substantial Amendment 6 - 31.07.15	31/07/2015	6
12/LO/1023/AM14	The PREVENT Research Programme - Pilot and Feasibility Stage	Substantial Amendment 7	22/12/2015	21
12/LO/1117/AM01	Mood and brain serotonin function	Substantial Amendment 1 - 31.07.15	07/07/2015	13
12/LO/1117/AM02	Mood and brain serotonin function	Substantial Amendment 2 dated 14 January 2016	14/01/2016	12
12/LO/1770/AM03	Autism outcomes in young adults (Version 1)	Substantial Amendment - Protocol (Version 4) 19.2.15	20/02/2015	11
12/LO/2016/AM03	Mechanisms underlying treatment resistance in psychosis	Substantial Amendment 2	15/01/2016	13
13/LO/0466/AM07	Designing a mobile phone intervention to improve adherence - V1	Substantial Amendment 6 - 10.06.15	10/06/2015	12
13/LO/0690/AM05	Computerised Interventions for Thinking and Anxiety in Delusions	Substantial Amendment 5	17/12/2015	21
13/LO/1051/AM03	Improving cognitive functioning in borderline personality disorder	Substantial Amendment 3	10/12/2015	19
13/LO/1094/AM08	ADDRESS-PMR: The Diagnostic Accuracy of Ultrasound in Suspected PMR	Substantial Amendment 7 15.06.2015	15/06/2015	10
13/LO/1481/AM02	MARS 2	Substantial Amendment 2	02/10/2015	8
13/LO/1492/AM02	Cognitive Bias Modification Training in Eating Disorders.	Substantial Amendment 2 - 17.06.15	17/06/2015	9

13/LO/1595/AM08	CBT vs Standardised Medical Care to treat Dissociative Seizures	Substantial Amendment 5 - 10/3/15	10/03/2015	20
13/LO/1631/AM05	Group Schema Therapy for Borderline Personality Disorder	Substantial Amendment 6	09/03/2016	18
13/LO/1855/AM01	Stakeholders' views and experiences of perinatal mental health care	Substantial Amendment 1 - 06.08.15	30/07/2015	8
13/LO/1855/AM02	Stakeholders' views and experiences of perinatal mental health care	Substantial Amendment 2	22/12/2015	14
14/LO/0075/AM02	Well-being in pregnancy	30/03/2015	30/03/2015	10
14/LO/0075/AM04	Well-being in pregnancy	Substantial Amendment v3 27/05/2015	27/05/2015	13
14/LO/0075/AM06	Well-being in pregnancy	Substantial Amendment 4	17/07/2015	5
14/LO/0112/AM01	Living Together with Dementia: a Psychosocial Intervention for Couples	Substantial Amendment 1 20/5/15	20/05/2015	7
14/LO/0238/AM03	Characterisation & Clinical Outcome of Mentally-Disordered Offenders	Substantial amendment 3	01/11/2015	17
14/LO/0246/AM07	ROLCOL 1.0	Substantial Amendment 5	24/09/2015	13
14/LO/0501/AM05	SHARED study v1	Substantial Amendment 1 - 24.06.15	24/06/2015	12
14/LO/0556/AM03	Frame Fit - falls prevention for frame users.	Substantial Amendment 1 - 20.04.15	20/04/2015	10
14/LO/0597/AM02	Depression: a trial of antenatal guided self help for women (DAWN)	Substantial Amendment v3 28 05 15	28/05/2015	9
14/LO/0597/AM03	Depression: a trial of antenatal guided self help for women (DAWN)	Substantial Amendment 3 - 22.07.15	22/07/2015	14
14/LO/0736/AM06	VALID WPs 3/4: Pilot trial and RCT of COTiD-UK	Substantial Amendment 7	24/11/2015	13

14/LO/0736/AM07	VALID WPs 3/4: Pilot trial and RCT of COTiD-UK	Substantial Amendment 9	02/12/2015	27
14/LO/0736/AM08	VALID WPs 3/4: Pilot trial and RCT of COTiD-UK	Substantial Amendment 10	04/02/2016	17
14/LO/0749/AM01	Functional imaging in ALK neuroblastoma v2.0 4th November 2013	Substantial Amendment 1 - 07.07.15	07/07/2015	8
14/LO/0765/AM02	The effectiveness of perinatal mental health services	Substantial Amendment - 15.05.15	15/05/2015	13
14/LO/0765/AM03	The effectiveness of perinatal mental health services	3	15/02/2016	10
14/LO/1049/AM01	MILESTONE version 1.0	1.0	20/03/2015	22
14/LO/1049/AM02	MILESTONE version 1.0	1.0	20/04/2015	14
14/LO/1097/AM01	Transoesophageal echocardiography in cardiac surgery Version 1	Substantial Amendment - 15/4/15	15/04/2015	8
14/LO/1148/AM01	ACCESSCare Project	Substantial Amendment 1	12/03/2015	27
14/LO/1289/AM01	The endocannabinoid system and brain function	Substantial Amendment 1	27/08/2015	26
14/LO/1384/AM01	IMPACT OF DIETARY SUPPLEMENTATION ON FUNCTIONAL OUTCOME FOLLOWING DRF	Substantial Amendment 1 - 09.09.15	09/09/2015	10
14/LO/1413/AM01	Imaging of Compulsive Syndromes	Substantial amendment 1	03/02/2016	10
14/LO/1436/AM02	Impact of Pain and Somatosensory Phenotype on Carpal Tunnel Surgery	Substantial Amendment 2	08/11/2015	13
14/LO/1477/AM07	Evaluation of internet-based STI testing in Lambeth and Southwark	Substantial Amendment 5 - 02.06.15	02/06/2015	7
14/LO/1477/AM08	Evaluation of internet-based STI testing in Lambeth and Southwark	Substantial Amendment 6 - 17.08.15	17/08/2015	14
14/LO/1477/AM09	Evaluation of internet-based STI testing in Lambeth and Southwark	Substantial Amendment 7	05/10/2015	6
14/LO/2115/AM01	The influence of oxytocin on eating behaviours and stress	Amendment 1 -	17/06/2015	20

		17/06/15. Protocol V2 09/6/15		
14/LO/2193/AM01	GRO-HD	Substantial Amendment 1.0 - 12/3/15	12/03/2015	16
14/LO/2193/AM02	GRO-HD	Substantial Amendment 2	08/12/2015	17
15/LO/0057/AM05	Persistent Physical Symptoms - waiting list cluster RCT	Substantial Amendment 2 - 13.07.15	13/07/2015	35
15/LO/0057/AM07	Persistent Physical Symptoms - waiting list cluster RCT	Substantial Amendment 3 - 26.08.15	26/08/2015	13
15/LO/0057/AM08	Persistent Physical Symptoms - waiting list cluster RCT	Substantial Amendment 4	18/12/2015	15
15/LO/0058/AM01	PRINCE Secondary (version 1)	Substantial Amendment 1	04/03/2015	28
15/LO/0058/AM03	PRINCE Secondary (version 1)	Substantial Amendment 2 - 13/05/2015	13/05/2015	11
15/LO/0058/AM05	PRINCE Secondary (version 1)	Substantial Amendment 3 - 02.07.15	02/07/2015	12
15/LO/0058/AM06	PRINCE Secondary (version 1)	Substantial Amendment 4	28/09/2015	16
15/LO/0058/AM08	PRINCE Secondary (version 1)	Substantial Amendment 5	13/01/2016	16
15/LO/0081/AM01	Feasibility RCT of CBT for Depersonalisation in psychosis	Substantial Amendment 1 - 22.05.15	22/05/2015	6
15/LO/0100/AM01	Brain network structures in Idiopathic Generalised Epilepsy (IGE)	Substantial Amendment 1	22/02/2016	10
15/LO/0279/AM03	The role of phosphodiesterase 10A in early de novo sporadic PD	Substantial Amendment 1 - 02.07.15	02/07/2015	6
15/LO/0577/AM01	Neuromodulation in Depression (NeuroMooD)	Substantial Amendment 1	20/12/2015	23

15/LO/0592/AM01	Spasticity and Contractures at the ankle after head injury	Substantial Amendment 1	05/12/2015	8
15/LO/0939/AM01	Thinking and Social Skills in Functional Neurological Symptoms	Substantial Amendment 1	24/02/2016	7
15/LO/1183/AM01	Information following surgery for lung cancer	Substantial Amendment 1 - 13.08.15	13/08/2015	20

Unfavourable opinion

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
14/LO/0477/AM02	Long term neurobiological impact of early deprivation	Amendment 2: 17/04/2015	24/04/2015	11

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
14/LO/0477/AM02/1	Long term neurobiological impact of early deprivation	Modified Amendment to Sub-Amend 2 - 04.06.15	10/06/2015	2
15/LO/0057/AM01/1	Persistent Physical Symptoms - waiting list cluster RCT	Modified Amendment to Amendment 1 (10.03.2015) Response to REC - 9.4.15	08/04/2015	1

Unfavourable opinion timeline

Amendment REC	Title	Version	Date	Number of Days on
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Reference				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 14 day timeline

REC Reference	Title	Number of Days on Clock
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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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