

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

Annual Report

01 April 2017 - 31 March 2018



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:	Mrs Jennifer Bostock
REC Manager:	Tina Cavaliere
REC Assistant:	Charlotte Ferris Rebecca Howling Mr Paolo Buscemi
Committee Address:	Level 3, Block B Whitefriars Lewins Mead Bristol BS1 2NT
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**Camberwell St Giles REC
Chair's report**

I have now completed seven years as Chair of the committee and once again I express gratitude 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. Given our history as a committee with links to the Institute of Psychiatry, Psychology and Neurosciences, most relate to mental health and we have a good number involving participants unable to consent for themselves. But ante-natal and end-of-life care have both featured on our agendas, plus many concerned with conditions between these two extremes. 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 are becoming accustomed to reviewing social care research and I think we are developing an expertise that helps these projects meet high ethical standards.

We said good-bye to four excellent members, Alison Higgs, Justine Antill, Hilary Lavender and Rob McDowall; two others, Naomi Hare and Debbie Horney, have been, respectively, on maternity and matrimony leave. For a time we were on the edge of being inquorate but co-optees rescued us and we never actually dipped below seven. We have now welcomed Tom Gale, Larissa Revill and Mike Millar, so, for the moment, are feeling good. We are however always on the lookout for new people and I must confess that this, as well as the wider benefit to the REC world, is in my mind when I volunteer to interview potential members!

As I said last year, it was a real joy to welcome back Tina Cavaliere as our REC Manager and I am even more delighted to say this year that she is still with us. Her experience is considerable, her knowledge is vast and her minutes are impeccable – what more could a Chair want! She has been well-supported by Charlotte Ferris, Rebecca Howling and now Paolo Buscemi, and it a real strength for me to know that our organisation is in competent 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 encourage significant research and to protect those who participate in it. I look forward to more of the same in the coming months.

John Richardson
22 May 2018

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	07/12/2017	
Dr Ana Bajo	Lecturer	Expert	07/03/2013		
Mrs Jennifer Bostock	Philosopher of Psychiatry	Lay Plus	01/12/2008		
Mr Thomas Gale	Freelance Translator	Lay Plus	14/12/2017		
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	22/05/2017	19/05/17	
Mrs Deborah Horney	Research Associate / Trial Manager	Expert	01/04/2016		
Dr Hilary Lavender	Retired General Practitioner (GP)	Expert	16/11/2015	11/01/2018	
Mr Robert McDowall	Research Coordinator	Lay	26/08/2016	01/02/2018	
Dr Michael Millar	Consultant in Infection (Barts Health)	Expert	01/03/2018		
Mrs Larissa Revill	Laboratory Manager/Researcher: Women's Health	Expert	09/03/2018		
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
None			

London - Camberwell St Giles Research Ethics Committee: Co-opted Members

Name	Profession	Status	Meeting date attended
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Dr Anna Barnes	Associate Director	Lay	20/10/2017
Dr Cynthia Ruth Butlin	Retired Medical Practitioner	Expert	19/01/2018
Mrs Stephanie Cooper	Solicitor	Lay	21/07/2017
Ms Stephanie Ellis BEM	Former Civil Servant (retired)	Lay Plus	16/06/2017
Ms Ann Quinn	Social Worker	Expert	19/01/2018
Mrs Carol Richardson	Senior Nurse (Retired)	Lay	16/06/2017
Mr Sean Bolton	Lay Public Involvement Advisor	Lay Plus	21/07/2017

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

Name	Declaration of Interest	Date
Dr Ana Bajo	None	31/01/2018
Mrs Jennifer Bostock	Marie Stopes International. Save the Children. I am a co-application/investigator on a number of studies all of which are publically funded and hosted by university institutions in the uk they include: Oxford, Cambridge, KCL, Leeds, Kent, LSE, LSTMH, UCL, QMUL, Cardiff, Sussex & Warwick. I am a Peer Reviewer for the following organisations: NIHR, journal 'health expectations. I sit on the following research related Boards: PPI Reference Group (NETSCC NIHR); Public Implementation Group Quality Outcomes Research Unit (kent uni); School of Public Health (Sheffield Uni); Policy Research Unit (DH/NIHR).I Chair the following research Panels: Research Design Service London – Public Advisory Group APPOLLO Expert Advisory Group – QMUL	31/01/2018
Mr Thomas Gale	Translate medical documents professionally, and work often involves translating documentation linked to clinical trials (protocols, information sheets and consent forms, correspondences with ethics committees and regulators).	10/01/2018
Ms Biddy Gillman	None	31/01/2018
Mrs Deborah Horney	None	19/05/2017
Dr Hilary Lavender	None	31/01/2018
Mr Robert McDowall	Member of the Neurology Research Advisory Group at King's College Hospital	21/04/2017
Dr Michael Millar	Ongoing research activity as an investigator.	16/03/2018
Mrs Larissa Revill	Part funded for a PhD project by the Tommy's charity that funds research into still birth, premature birth and miscarriage. Work for the Imperial College Health Research which is part supported by the NIHR North West London.	14/03/2018
Mr John Richardson	In 2017 I was a member of a panel reviewing decisions about capacity made by KCL by the PhD student	31/01/2018
Mr John Richardson	None	21/04/2017
Dr Caroline Shackleton	None	31/01/2018
Dr Mark Tanner	Consultant Psychiatrist employed by Hertsfordshire Partnership University NHS Foundation Trust. Member of research interest group of employing trust.	31/01/2018
Mr James Uwalaka	Owner and director of OPJU Ltd. Manager and Quality Assurance of compliance at Chiltern International. Shareholdings in OPJU Ltd. Member of Research Quality Association.	31/01/2018

Meetings for Full Ethical Review 01 April 2017 - 31 March 2018:

Month	Date	Number of Members Present at Meeting
April	21/04/2017	11
May	19/05/2017	10
June	16/06/2017	9
July	21/07/2017	10
August	18/08/2017	10
October	20/10/2017	10
November	17/11/2017	7
December	15/12/2017	8
January	19/01/2018	8
March	16/03/2018	9

10 full committee meetings were held during the reporting period.

Proportionate Review Sub-Committee Meetings held during 01 April 2017 - 31 March 2018:

Month	Date	Number of Members Present at Meeting
May	11/05/2017	3
June	12/06/2017	3
August	07/08/2017	3
September	12/09/2017	3
November	06/11/2017	3

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

Sub-Committee Meetings held during 01 April 2017 - 31 March 2018:

Month	Date	Number of Members Present at Meeting
April	07/04/2017	2
April	21/04/2017	3
May	05/05/2017	2
May	05/05/2017	2
May	19/05/2017	2
June	02/06/2017	2
June	09/06/2017	1
June	16/06/2017	3
June	30/06/2017	3

July	14/07/2017	3
July	28/07/2017	3
August	04/08/2017	2
August	25/08/2017	2
September	08/09/2017	2
September	22/09/2017	4
October	06/10/2017	3
October	20/10/2017	2
November	03/11/2017	2
November	17/11/2017	2
December	01/12/2017	3
December	15/12/2017	3
December	22/12/2017	2
December	29/12/2017	2
January	19/01/2018	2
January	26/01/2018	2
February	09/02/2018	3
February	16/02/2018	2
March	02/03/2018	2
March	09/03/2018	3
March	16/03/2018	2
March	30/03/2018	2

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

Details of inquorate meeting held: 01 April 2017 - 31 March 2018

Date	Reason	Action taken
None		

Attendance of Members at full committee meetings: 01 April 2017 - 31 March 2018

Name	Number of Meetings Attended
Ms Justine Antill	1
Dr Ana Bajo	6
Mrs Jennifer Bostock	5
Mr Thomas Gale	2
Ms Biddy Gillman	9
Mrs Naomi Hare	4
Ms Alison Higgs	2
Mrs Deborah Horney	3
Dr Hilary Lavender	8
Mr Robert McDowall	7
Dr Michael Millar	1
Mrs Larissa Revill	1
Mr John Richardson	10
Dr Caroline Shackleton	10
Dr Mark Tanner	8
Mr James Uwalaka	6

Attendance of Members at proportionate review sub-committee meetings: 01 April 2017 - 31 March 2018

Name	Number of Meetings Attended
Dr Ana Bajo	1
Mrs Jennifer Bostock	2
Ms Biddy Gillman	1
Mrs Naomi Hare	1
Mrs Deborah Horney	1
Dr Hilary Lavender	1
Mr John Richardson	3
Dr Caroline Shackleton	1
Dr Mark Tanner	3
Mr James Uwalaka	1

Attendance of Members at sub-committee meetings: 01 April 2017 - 31 March 2018

Name	Number of Meetings Attended
Dr Ana Bajo	5
Mrs Jennifer Bostock	3
Ms Stephanie Ellis	1
Miss Stephanie Ellis, BEM	1
Ms Biddy Gillman	1

Mrs Deborah Horney	2
Dr Hilary Lavender	4
Mr Robert McDowall	8
Mr John Richardson	31
Dr Caroline Shackleton	7
Dr Mark Tanner	7
Mr James Uwalaka	3

Training 01 April 2017 - 31 March 2018

Name of Member	Date	Event(s) attended
Dr Ana Bajo	09/06/2017	Completed training reading as directed by REC manager
Dr Ana Bajo	19/02/2018	Evaluated 12 undergraduate projects in terms of ethics
Dr Ana Bajo	16/03/2018	Local In House Training - How to review REC applications
Mrs Jennifer Bostock	13/05/2017	E-ROC: Ethical Research Oversight Course
Mrs Jennifer Bostock	16/03/2018	Local In House Training - How to review REC applications
Mr Thomas Gale	26/02/2018	Induction for RES Members
Mr Thomas Gale	26/02/2018	Equality Diversity and Human Rights
Mr Thomas Gale	16/03/2018	Local In House Training - How to review REC applications
Ms Biddy Gillman	28/02/2018	Research on adults lacking capacity
Ms Biddy Gillman	16/03/2018	Local In House Training Day - How to review REC applications
Mrs Naomi Hare	26/04/2017	Read BMJ article on 'Should Research Ethics Committees report bias'
Mrs Naomi Hare	01/05/2017	Read NRES Guidance on Medical Devices
Mrs Naomi Hare	06/06/2017	Read Governance arrangements for RECs (DoH 2012)
Ms Alison Higgs	14/11/2017	Increased understanding of complex cases
Ms Alison Higgs	04/02/2018	Developed understanding of key ethical issues
Dr Hilary Lavender	28/04/2017	BMJ Article on should RECs report bias
Dr Michael Millar	16/03/2018	Local In House Training - How to review a full REC application
Dr Michael Millar	26/03/2018	Equality Diversity and Human Rights
Mrs Larissa Revill	16/03/2018	Local In House Training Day - How to review a full REC application
Mr John Richardson	14/11/2017	Health Related Findings in Research
Mr John Richardson	24/11/2017	HRA National Chairs' Day and Policy Event
Mr John Richardson	16/03/2018	Local In House Training - How to review REC applications
Mr John Richardson	24/03/2018	Equality Diversity and Human Rights
Dr Caroline Shackleton	12/12/2017	National Members Training Day
Dr Caroline Shackleton	12/03/2018	Equality Diversity and Human Rights

Dr Caroline Shackleton	16/03/2018	Local In House Training - How to review REC applications
Dr Mark Tanner	12/12/2017	National Members Training Day
Dr Mark Tanner	16/03/2018	Local In House Training - How to review REC applications
Mr James Uwalaka	26/05/2017	Data Storage, Retention, Destruction and Archival - Version 1
Mr James Uwalaka	10/11/2017	Escalation, Assessment, Management and Reporting of Serious Breaches of GCP or the Trial Protocol / Clinical Investigation Plan - Version 2
Mr James Uwalaka	17/12/2017	Management of Blinded Materials - Version 4
Mr James Uwalaka	21/12/2017	Randomisation Codes and Treatment Assignments for Clinical Trials - Version 9
Mr James Uwalaka	04/01/2018	Unblinding of Clinical Trials - Version 6
Mr James Uwalaka	16/03/2018	Local In House Training - How to review REC applications

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	41	100.00
Total Applications Reviewed	41	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	17
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	6
Number of applications reviewed that are funded by the US DHHS	0
Number of qualitative applications reviewed	11

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	2.44
Favourable Opinion with Additional Conditions	4	9.76
Unfavourable Opinion	3	7.32
Provisional Opinion	32	78.05
Provisional Opinion Pending Consultation with Referee	1	2.44
Total	41	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	33	80.49
Further Information Favourable Opinion with Additional Conditions	0	0.00
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	1	2.44
Favourable Opinion with Additional Conditions	4	9.76
Unfavourable Opinion	3	7.32
Provisional Opinion	0	0.00
Provisional Opinion Pending Consultation with Referee	0	0.00
Further Information response not complete	0	0.00
No decision entered on system	0	0.00
Number of studies withdrawn after the meeting	0	0.00
Total	41	100

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

Total Applications Reviewed	11
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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	4
Number of studies withdrawn prior to the meeting	0
Number of student applications reviewed	4
Number of paediatric applications reviewed	2
Number of device applications reviewed	0
Number of qualitative applications reviewed	1

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	36.36
Favourable Opinion with Additional Conditions	0	0.00
No Opinion transfer to full committee for review	4	36.36
Provisional Opinion	3	27.27
Unfavourable Opinion	0	0.00
Total	11	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	4.10
Number of completed applications for full ethical review	41
Number of completed applications for full ethical review over 60 days	2
Number of completed applications over 60 days as a % of total	4.88%
Number of completed applications for full ethical review over 40 days	8
Number of completed applications over 40 days as a % of total	19.51%
Number of days taken to final decision – average (mean)	36
Number of completed proportionate review applications for ethical review	7
Number of completed proportionate review applications for ethical review over 21 days	1
Number of completed proportionate review applications over 21 days as a % of total	14.29%
Number of SSAs (non-Phase 1) reviewed	12
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	55
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	6
Number of completed substantial amendments over 28 days as a % of total substantial amendments	10.91%
Number of modified amendments reviewed	0
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	70
Number of substantial amendments received for information	0
Number of substantial amendments received for new sites/PIs	0
Number of annual progress reports received	25
Number of safety reports received	0
Number of Serious Adverse Events received	9
Number of final reports received	5

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
17/LO/0621	STARRT-AKI	38
17/LO/0641	PROMESA	84
17/LO/0704	Acceptance and Commitment Therapy for older people with GAD v1	30
17/LO/0705	TRUST	34
17/LO/0818	Human rights in care homes	43
17/LO/0861	Cognitive Emotional Dysregulation of FMR1 Premutation Carrier Mothers	49
17/LO/0876	Evaluation of CRT in an inpatient ED service for young people (V1)	34
17/LO/0958	Comorbid Conditions in ADHD	32
17/LO/0963	Personalised movement for people with memory problems in care homes	43
17/LO/0983	Brain stimulation and cognitive training in ADHD	32
17/LO/1119	CPPOpt Guided Therapy; Assessment of Target Effectiveness and Safety	38
17/LO/1144	BAC study	28
17/LO/1154	RADAR-MDD v0.1	41
17/LO/1308	Who wants to be an Approved Mental Health Professional?	54
17/LO/1342	Rumination Study	37
17/LO/1349	The TRESORA study version 1	37
17/LO/1352	Feasibility of antenatal group to improve reflective functioning	32
17/LO/1577	An ethnographic analysis of bulimia nervosa	37
17/LO/1578	Middle finger length to determine paediatric endotracheal tube size	28
17/LO/1681	Enhancing service user involvement in care planning	37
17/LO/1692	Long-term outcomes in Hirschprung's disease	39
17/LO/1712	A model of patients' perspectives of recovery in secure services	35
17/LO/1828	End of Life Care in Care Homes	34
17/LO/1950	The PAIR Study	31
17/LO/1960	Socio-emotional function and comorbidities in anorexia nervosa V1.2.	37
17/LO/2066	Clinical outcomes after Traumatic Brain Injury	26
17/LO/2074	The Antidepressant Advisor - version 1	27
17/LO/2080	INSIGHT project: Isolation and Loneliness in care homes	29
18/LO/0011	The Second Conversation Model	32
18/LO/0015	Pilot of the Preparation Star, an new version of the Outcomes Star	62
18/LO/0056	Qualitative study of health inequalities in SMI	38
18/LO/0077	APTT version 1	29

18/LO/0432	DRAGON	42
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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
17/LO/0785	EXPLORING GAY MEN'S EXPERIENCES OF SHAME V1	28

Favourable Opinion with Additional Conditions		
REC Reference	Title	Number of Days on Clock
17/LO/0830	Developing tools to study the safety of ICU patient mobilisation v1	28
17/LO/1314	Acceptance and Commitment Therapy for older people with GAD v1	25
17/LO/1729	Shifting Shapes: Supporting quality and choice in local care markets	32
17/LO/2077	Life Skills Training for Adults with Learning Disabilities/Autism	23

Unfavourable Opinion		
REC Reference	Title	Number of Days on Clock
17/LO/0639	Mindfulness in Patients With Mild Cognitive Impairment	25
17/LO/1128	Involving people with dementia in research v1	27
17/LO/1292	A grounded theory study of PTSD following ICU	25

Provisional Opinion		
REC Reference	Title	Number of Days on Clock

Provisional Opinion Pending Consultation with Referee		
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REC Reference	Title	Number of Days on Clock
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Further information response not complete

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

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

Further Information Favourable Opinion with Standard Conditions

REC Reference	Title	Number of Days on Clock
17/LO/1371	Troponin T Haemolysis Study	17
17/LO/1931	Detection of Pseudomonas aeruginosa in Cystic Fibrosis	15
17/LO/1933	Evaluating patient access to CF patients and healthcare professionals	16

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
17/LO/0816	Study of tissue resident T cells and their regulation	22
17/LO/1369	Analytical validation - performance characteristics - Almac TST-170	7
17/LO/1512	e-Bug PE GP Record Study	8
17/LO/1587	Profiling T Cell Responses During Dengue Infection	8

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

Unfavourable Opinion		
REC Reference	Title	Number of Days on Clock

Provisional Opinion		
REC Reference	Title	Number of Days on Clock

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

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
06/Q0706/50/AM15	AddNeuroMed	Amendment 14 27/07/17	05/12/2017	21
08/H0807/95/AM07	Dopaminergic function and treatment response	7	12/07/2017	10
09/H0807/12/AM10	Nutrition, Eating and Stress in Pregnancy: a study of risk mechanisms	8	22/05/2017	20
10/H0807/23/AM10	Injured Spinal Cord Pressure Evaluation (ISCoPE) [v.1]	8	12/05/2017	11
10/H0807/23/AM11	Injured Spinal Cord Pressure Evaluation (ISCoPE) [v.1]	Amendment 9 03/11/2017	03/11/2017	34
10/H0807/23/AM12	Injured Spinal Cord Pressure Evaluation (ISCoPE) [v.1]	Amendment 10 04/01/2018	04/01/2018	10
10/H0807/93/AM07	Brain Function in Rolandic Epilepsy	4 14/12/2017	14/12/2017	9
11/LO/0927/AM30	World Hip Trauma Evaluation (WHiTE study)	AM14 12 January 2018	12/01/2018	3
12/LO/1023/AM17	The PREVENT Research Programme - Pilot and Feasibility Stage	9 - 4th October 2017	04/10/2017	11
12/LO/1117/AM04	Mood and brain serotonin function	3	19/10/2017	15
12/LO/1117/AM05	Mood and brain serotonin function	4 Date: 11/01/2018	11/01/2018	11
12/LO/2016/AM05	Mechanisms underlying treatment resistance in psychosis	5 22/02/2017	07/03/2017	21
13/LO/1481/AM10	MARS 2	9	04/10/2017	24
13/LO/1631/AM06	Group Schema Therapy for Borderline Personality Disorder	Amendment 7: 10/10/2017	10/10/2017	20
13/LO/1876/AM01	Response assessment in head & neck cancer using multi-parametric MRI	1.0	20/08/2015	9
14/LO/0241/AM02	Immunity after Yellow Fever vaccination - YETI research	2	13/06/2017	13
14/LO/0477/AM05	Long term neurobiological impact of early deprivation	Amendment 4, 07/09/2017	07/09/2017	20
14/LO/0578/AM03	Social anxiety in autism-spectrum disorder: a mixed-methods study	3	05/05/2017	17
14/LO/0578/AM06	Social anxiety in autism-spectrum disorder: a mixed-methods study	6	13/10/2017	17
14/LO/0736/AM15	VALID WPs 3/4: Pilot trial and RCT of COTiD-UK	18	24/10/2017	17
15/LO/0057/AM11	Persistent Physical Symptoms - waiting list cluster RCT	Substantial	12/12/2017	21

		Amendment 6 12/12/		
15/LO/0058/AM12	PRINCE Secondary (version 1)	7	21/07/2017	8
15/LO/0577/AM04	Neuromodulation in Depression (NeuroMooD)	Number 3, 17 Nov 2017	17/11/2017	12
15/LO/1197/AM01	Using Virtual Reality to Investigate Psychological Factors in Paranoia		26/04/2017	11
16/LO/0106/AM07	Visual Field Algorithm Study (vFAST)	4	02/08/2017	8
16/LO/0375/AM08	ENABLE - NGS	Amendment 6 13/10/2017	13/10/2017	29
16/LO/0466/AM03	Vitamin D in AKI Version 1	Amendment 2	09/08/2017	9
16/LO/0492/AM02	My Story, Our Future: Early Intervention in Psychosis – Life Stories	1	03/08/2017	7
16/LO/0609/AM06	Acceptance and Commitment Therapy for Muscle Disease (ACTMUS)	4	02/05/2017	14
16/LO/0609/AM09	Acceptance and Commitment Therapy for Muscle Disease (ACTMUS)	5	09/10/2017	6
16/LO/0893/AM03	INcOSA (Version 1)	1	24/02/2017	8
16/LO/1116/AM01	Multicenter Aggression subTyping Research in Conduct Syndromes	1	22/05/2017	20
16/LO/1137/AM02	Carer Skills training for inpatients with anorexia nervosa	2	13/10/2017	14
16/LO/1377/AM04	TRIANGLE: A novel patient and carer intervention for Anorexia Nervosa	2	18/07/2017	12
16/LO/1377/AM07	TRIANGLE: A novel patient and carer intervention for Anorexia Nervosa	3	13/10/2017	20
16/LO/1377/AM08	TRIANGLE: A novel patient and carer intervention for Anorexia Nervosa	Amendment 4, 08/11/2017	14/12/2017	19
16/LO/1422/AM01	A 2 arm feasibility trial to support postnatal weight management	5	29/01/2017	17
16/LO/1422/AM03	A 2 arm feasibility trial to support postnatal weight management	2, October 4th 2017	04/10/2017	30
16/LO/1503/AM02	Factors affecting uptake of orthodontic treatment among adults.	Amendment number 1. 10.09.17	10/09/2017	13
16/LO/1862/AM01	SlowMo trial: a digital therapy for people who fear harm from others.	1	22/05/2017	14
16/LO/1862/AM02	SlowMo trial: a digital therapy for people who fear harm from	2- 02/11/2017	07/12/2017	19

	others.			
16/LO/1882/AM03	First Episode & Rapid Early Intervention for Eating Disorders Upscaled	2	30/10/2017	13
16/LO/1882/AM04	First Episode & Rapid Early Intervention for Eating Disorders Upscaled	Number 3 Jan 2018	12/03/2018	29
16/LO/1910/AM02	Impact of almond nut consumption on markers of CVD & metabolic disease	2	11/05/2017	28
16/LO/1910/AM03	Impact of almond nut consumption on markers of CVD & metabolic disease	Amendment 3. 6th Oct 2017	06/10/2017	21
16/LO/2048/AM04	IARE II: needs & preferences of recently hospitalised older people	Substantial amendment 1 09/03/	14/03/2018	12
16/LO/2144/AM02	Exploring Anxiety in Parkinson's v1.0	1	21/08/2017	7
16/LO/2198/AM01	Exploring Lived Experiences of Females Receiving Autism Diagnosis	1	22/09/2017	6
17/LO/0370/AM01	Magnetic resonance imaging of Abdominal Lymph nodes (MAL) Version 1.0	1.0	18/05/2017	26
17/LO/0641/AM01	PROMESA	Amendment 1.0: 12DEC2017	12/12/2017	28
17/LO/0830/AM01	Developing tools to study the safety of ICU patient mobilisation v1	1	07/08/2017	7
17/LO/0958/AM01	Comorbid Conditions in ADHD	1	04/09/2017	9
17/LO/0983/AM01	Brain stimulation and cognitive training in ADHD	v2 21/11/2017	21/11/2017	29
17/LO/1308/AM01	Who wants to be an Approved Mental Health Professional?	1 01/11/2017	01/11/2017	24
17/LO/1314/AM01	Acceptance and Commitment Therapy for older people with GAD v1	Sub Amendment 1 - Changes to P	13/11/2017	31

Unfavourable opinion

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

Favourable opinion timeline

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
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Unfavourable opinion timeline				
Amendment REC Reference	Title	Version	Date	Number of Days on Clock

Table 11: Items exceeding timelines**Full applications for ethical review over 60 day timeline**

REC Reference	Title	Number of Days on Clock
17/LO/0641	PROMESA	84
18/LO/0015	Pilot of the Preparation Star, an new version of the Outcomes Star	62

Proportionate review applications for ethical review over 21 day timeline

REC Reference	Title	Number of Days on Clock
17/LO/0816	Study of tissue resident T cells and their regulation	22

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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