

London - Surrey Research Ethics Committee

Annual Report

01 April 2016 - 31 March 2017



Part 1 – Committee Membership and Training

Name of REC:	London - Surrey Research Ethics Committee
Type of REC:	Authorised REC
Type of Flag:	None
Chair:	Dr Mark Atkins
Vice-Chair:	Mrs Chrissie Lawson
Alternate Vice-Chair:	Vacant (until 26/05/2016j) Mr Robin Walsh (26/05/2016 – present)
REC Manager:	Mr Rajat Khullar
REC Assistant:	Mr Wai Yeung
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Chair's overview of the past year:

The Committee has had another successful and productive year as confirmed by data within this form. There have been some departures of members, including our chair Dr Mark Atkins. To all of these, Mark and I would want to thank them for their hard work and support over the past year. The committee has continued to manage well with reduced numbers but we have now interviewed a number of candidates from a wide variety of backgrounds and expect these new members will enhance the functioning of the next committee year. The committee members work extremely well together and are respectful of other peoples' opinion, and produce high quality evaluations and some very lively debate.

We would like to thank the staff at the Bristol office for their invaluable support. We look forward to the coming year and the opportunity to make our contribution to facilitating high quality medical research.

Chrissie Lawson

London - Surrey Research Ethics Committee Membership

Name	Profession	Expert or Lay	Dates	
			Appointed	Left
Dr Mark Atkins	Consultant Virologist	Expert	03/06/2014	31/03/2017
Dr John Morton Broughall	Retired (Ex Medical Scientific Liaison)	Lay	01/08/2016	
Dr Cynthia Ruth Butlin	Medical advisor to 2 programmes (skilled volunteer)	Expert	19/09/2016	
Miss Elizabeth Cheshire	Consultant in Emergency Medicine	Expert	01/06/2010	31/12/2016
Dr Benedict Creagh-Brown	Consultant Physician	Expert	08/04/2014	
Miss Hayley-Jo Grafton	Psychology student	Lay Plus	22/08/2016	
Ms Wendy Joy	Retired Support Worker	Lay Plus	12/01/2011	03/02/2017
Mrs Chrissie Lawson	Nurse Specialist	Expert	01/05/2006	
Dr Charles Li	Consultant Physician	Expert	12/01/2011	18/05/2016
Miss Deborah Malins	Managing Director (retired)	Lay	19/01/2016	
Mr Michael Morris	Managing Partner of Law Firm	Lay Plus	04/10/2007	
Ms Rosemary Murphy	Vice President Business Intelligence	Lay	01/08/2016	
Ms Janet Oakeshott	Retired Specialist Nurse	Lay	01/04/2014	
Mr Michael Pettit	Senior Lecturer in Pharmacy Practice	Expert	10/12/2015	
Mr Richard Robinson	Retired volunteer in advice agency and town councillor	Lay Plus	01/08/2016	01/09/2016
Mr Robin Walsh	Retired Professor of Physical Chemistry	Lay Plus	29/05/2013	

London - Surrey Research Ethics Committee: Deputy Members

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

Name	Profession	Status	Meeting date attended
Dr. Mike Proven	Coordinator for QA in Research	Lay Plus	07/06/2016
Mr John Richardson	Retired Director of COREC: former Ecumenical Officer for Churches Together in South London	Lay Plus	07/06/2016
Dr Ayse Baxter	Pharmaceutical Physician	Expert	25/05/2016

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

Name	Declaration of Interest	Date
Dr Mark Atkins	Consultant Pathologist for the Doctors Laboratory (TDL) London	14/04/2016
Dr John Morton Broughall	MD and owner of JB Technology Ltd. Contract consultancy in area of in vitro diagnostics. No current contracts, company will probably close by end of 2016. Volunteer for Antibiotic Research UK (ANTRUK). Charity raises money to fund research into methods of overcoming antibiotic resistance. All in vitro studies, no clinical work.	16/08/2016
Dr Cynthia Ruth Butlin	Working as associate hospital manager for Sussex Partnership Foundation Trust which conducts research on mental health issues.	04/10/2016
Dr Benedict Creagh-Brown	Clinical Lead for Critical Care research in NIHR CRN KSS. Member RSCH RD&I committee Chair, ICU/Anaesthesia research group at RSCH (SPACeR)	09/02/2017
Miss Hayley-Jo Grafton	None	21/10/2016
Mrs Chrissie Lawson	None	09/02/2017
Miss Deborah Malins	Small holding of shares in Novartis and GlaxoSmithKline	31/03/2017
Mr Michael Morris	Small shareholder (direct) at Glaxo Smith Kline	31/03/2017
Ms Rosemary Murphy	CMED Group holdings and CRO and Technology Company.	05/09/2016
Ms Janet Oakeshott	None	31/03/2017
Mr Michael Pettit	None	31/03/2017
Mr Richard Robinson	Share holdings in GSK and AstraZenica	09/09/2016
Mr Robin Walsh	None	31/03/2017

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

Month	Date	Number of Members Present at Meeting
April	05/04/2016	8
May	03/05/2016	6
May	25/05/2016	7
June	07/06/2016	8
September	06/09/2016	12
October	04/10/2016	11
November	01/11/2016	12
December	06/12/2016	9

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	05/04/2016	3
May	03/05/2016	3
June	07/06/2016	3
July	05/07/2016	3
September	06/09/2016	3
October	04/10/2016	3
November	01/11/2016	3
December	06/12/2016	3
January	10/01/2017	3
February	14/02/2017	3
March	14/03/2017	3

11 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	04/04/2016	2
April	18/04/2016	2
May	06/05/2016	2
May	27/05/2016	2
June	10/06/2016	2
June	27/06/2016	2
July	11/07/2016	2
August	03/08/2016	2
August	22/08/2016	2
September	02/09/2016	2
September	21/09/2016	2
October	17/10/2016	2

November	01/11/2016	2
November	23/11/2016	2
December	06/12/2016	2
December	23/12/2016	2
January	12/01/2017	2
February	09/02/2017	2
March	08/03/2017	3
March	16/03/2017	3

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

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

Date	Reason	Action taken
03/05/2016	There were less than 7 members present.	The applications were discussed but no decision made and they were further reviewed and an opinion given by a quorate teleconference on 25/05/2016

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

Name	Number of Meetings Attended
Dr Mark Atkins	7
Dr John Morton Broughall	3
Dr Cynthia Ruth Butlin	3
Dr Benedict Creagh-Brown	2
Miss Hayley-Jo Grafton	3
Ms Wendy Joy	7
Mrs Chrissie Lawson	7
Miss Deborah Malins	7
Mr Michael Morris	6
Ms Rosemary Murphy	4
Ms Janet Oakeshott	5
Mr Michael Pettit	6
Mr Richard Robinson	3
Mr Robin Walsh	6

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

Name	Number of Meetings Attended
Dr Mark Atkins	11
Ms Wendy Joy	1
Mrs Chrissie Lawson	11
Miss Deborah Malins	2
Mr Robin Walsh	8

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

Name	Number of Meetings Attended
Dr Mark Atkins	20
Mrs Chrissie Lawson	20
Mr Robin Walsh	2

Training 01 April 2016 - 31 March 2017

Name of Member	Date	Event(s) attended
Dr Mark Atkins	02/06/2016	NREAP / REC Chairs' Network Meeting: South Central
Dr Ayse Baxter	04/09/2016	Equality & Diversity
Dr John Morton Broughall	12/10/2016	Equality Diversity & Human Rights
Dr John Morton Broughall	12/10/2016	Members Induction training
Dr John Morton Broughall	06/12/2016	REC Members' Induction
Dr Cynthia Ruth Butlin	11/10/2016	New REC members induction course
Dr Cynthia Ruth Butlin	22/10/2016	Equality Diversity and Human Rights
Dr Cynthia Ruth Butlin	25/10/2016	Qualitative Research and Ethical Review
Miss Hayley-Jo Grafton	05/10/2016	Induction for new REC members
Miss Hayley-Jo Grafton	17/10/2016	Equality Diversity & Human Rights
Miss Hayley-Jo Grafton	06/12/2016	REC Members' Induction
Mrs Chrissie Lawson	01/12/2016	Training - Nat Train Day for Chairs
Miss Deborah Malins	14/07/2016	Training- Personal Data in Research - A Workshop
Mr Michael Morris	16/11/2016	Local training for RECs
Ms Rosemary Murphy	05/09/2016	Local training day for REC Members
Ms Rosemary Murphy	04/10/2016	Members' Induction Training
Ms Rosemary Murphy	13/10/2016	Equality Diversity & Human Rights
Mr Michael Pettit	25/05/2016	Equality Diversity and Human Rights
Mr Michael Pettit	26/10/2016	Qualitative Research and Ethical Review
Mr John Richardson	22/03/2017	National Members Training Day
Mr John Richardson	27/03/2017	Chairs Review Programme
Mr Richard Robinson	24/10/2016	Equality Diversity and Human Rights

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)	1	2.94
Others	33	97.06
Total Applications Reviewed	34	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	14
Number of paediatric applications reviewed	3
Number of device applications reviewed	0
Number of prisoner applications reviewed	0
Number of applications involving adults unable consent reviewed	0
Number of applications reviewed that are funded by the US DHHS	0
Number of qualitative applications reviewed	5

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	2.94
Favourable Opinion with Additional Conditions	9	26.47
Unfavourable Opinion	1	2.94
Provisional Opinion	23	67.65
Provisional Opinion Pending Consultation with Referee	0	0.00
Total	34	100
Number of studies sent back to full committee meeting for final opinion	3	

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	67.65
Further Information Favourable Opinion with Additional Conditions	0	0.00
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	1	2.94
Favourable Opinion with Additional Conditions	9	26.47
Unfavourable Opinion	1	2.94
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	34	100

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

Total Applications Reviewed	34
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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	3
Number of studies withdrawn prior to the meeting	1
Number of student applications reviewed	12
Number of paediatric applications reviewed	4
Number of device applications reviewed	2
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	13	38.24
Favourable Opinion with Additional Conditions	5	14.71
No Opinion transfer to full committee for review	1	2.94
Provisional Opinion	15	44.12
Unfavourable Opinion	0	0.00
Total	34	100

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

Average number of applications reviewed per full meeting	4.25
Number of completed applications for full ethical review	34
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	5.88%
Number of days taken to final decision – average (mean)	32
Number of completed proportionate review applications for ethical review	33
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)	7
Number of completed proportionate review applications for ethical review over 21 days	2
Number of completed proportionate review applications over 14 days as a % of total	21.21%
Number of SSAs (non-Phase 1) reviewed	1
Number of completed applications for SSA review over 25 days	0
Number of completed applications for SSA review over 25 days as % of all non- Phase 1 SSAs	0.00%
Number of SSAs (Phase 1) reviewed	0
Number of completed applications for SSA review over 14 days	0
Number of completed applications for SSA review over 14 days as % of all Phase 1 SSAs	0.00%
Number of substantial amendments reviewed	51
Number of completed substantial amendments over 35 days	3
Number of completed substantial amendments over 35 days as a % of total substantial amendments	5.88%
Number of completed substantial amendments over 28 days	4
Number of completed substantial amendments over 28 days as a % of total substantial amendments	7.84%
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	87

Number of substantial amendments received for information	0
Number of substantial amendments received for new sites/PIs	0
Number of annual progress reports received	0
Number of safety reports received	0
Number of Serious Adverse Events received	0
Number of final reports received	0

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/0561	Compassion and acceptance following stroke	32
16/LO/0565	IMProVe version 1.0	29
16/LO/0583	Parental Involvement and Adolescent Help Seeking	37
16/LO/0591	Establishment of MRI library to optimise treatment workflows for MRL	34
16/LO/0826	Scaphoid MRI	36
16/LO/0832	People with ID/ASC detained under Section 37/41: service user views	36
16/LO/1075	Women's Experience of Sexuality After Spinal Cord Injury	28
16/LO/1076	Kent Medicine Support in Stroke and TIA (KeMiST)	30
16/LO/1574	Medicines management in people with Alzheimer's Disease v1.0	27
16/LO/1598	Development of an online treatment programme for child anxiety	23
16/LO/1643	TOLERANCE AND ACCEPTABILITY EVALUATION OF AYMES 'OSLO'	23
16/LO/1644	TOLERANCE AND ACCEPTABILITY EVALUATION OF AYMES 'PRAGUE'	23
16/LO/1645	TOLERANCE AND ACCEPTABILITY EVALUATION OF AYMES 'BERLIN'	26
16/LO/1771	Relapse Prevention (RP) Trial	32
16/LO/1802	Technology Integrated Health Management (TIHM)	32
16/LO/1804	The Lived Experience of Delirium	30
16/LO/1973	CEB-VECTRA ECG	34
16/LO/1985	Clients with BPD experience of Cognitive Analytic therapy	31
16/LO/2069	Frequent Detainees under Section 136	35
16/LO/2140	Diagnosis of OASIs using Transperineal Ultrasound- Version 1	33
16/LO/2145	Real-World PBC patient pathways in South East England	42
16/LO/2146	Building a loco-regional hepatology database for South East England	42
16/LO/2151	An evaluation of MRI TIA patients with Obstructive Sleep Apnoea	35

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
16/LO/1065	Assessment of Amyloidosis Patient Pathways	27

Favourable Opinion with Additional Conditions		
REC Reference	Title	Number of Days on Clock
16/LO/0474	Decision making during episodes of acute illness	27
16/LO/0556	Social Factors, Care & CTOs. Service User & Practitioner Perspectives	27
16/LO/0771	Cortical control of shoulder muscles	35
16/LO/0850	Factors influencing women's preferences for treatment of their fibroid	36
16/LO/1685	Mindfulness for Paranoia	28
16/LO/1787	Pilot using abnormal loudness growth contours to fit hearing aids	28
16/LO/1921	Implementation of Anticipatory Care Planning Processes in D&G	29
16/LO/1949	AFAE	32
16/LO/2079	EDMONd-Elemental Diet in bowel obstruction	28

Unfavourable Opinion		
REC Reference	Title	Number of Days on Clock
16/LO/1087	Understanding the experience of anxiety in young people with ASD	31

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

Withdrawn after the meeting		
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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
16/LO/0631	Alcohol-related problems in people with cancer and their caregivers	14
16/LO/1104	Self-care and quality of life in Heart Failure (HF)	10
16/LO/1105	SAizenÂ® Long Term Observational study (SALTO)	10
16/LO/1666	What determines outcome in a subsequent pregnancy after stillbirth?	5
16/LO/1669	Optimising Hearing Aid Provision With Respect To Voice Perception	8
16/LO/1828	Investigating Corticosteroid Responsiveness	8
16/LO/2012	Feasibility of a RCT of the ACE programme	12
16/LO/2176	ImmunoSense Study	9
17/LO/0074	Foot ulcer treatment with the PulseFlowDF	20
17/LO/0283	EurValve Prospective	15
17/LO/0293	COQOL electronic data collection feasibility study	15
17/LO/0298	The role of the community pharmacist in breast cancer services v1.0	18
17/LO/0456	DuraGraft Registry 005-01	39
17/LO/0469	Burden of PAH-deficiency in adults	43

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
16/LO/0626	Health Economics and Patient Satisfaction of One-stop Fertility Clinic	7

16/LO/0628	Second primary cancers: retrospective survival study	13
16/LO/0867	Waiting Times and Treatment Outcomes for Cancer Patients	14
16/LO/1100	How much does the Home Talk service help children's talking skills?	12
16/LO/1292	VISTAS-Qual	10
16/LO/1295	Usability study of a post TKA prototype Tele-Rehabilitation platform	5
16/LO/1827	Perioperative Quality Improvement Programme: Patient Study	4
16/LO/1830	Cognitive Model of Cannabis Related Paranoia	6
16/LO/1831	Vitamin D and shoulder arthroscopy	7
16/LO/2013	The investigation of primary central nervous system lymphoma	10
16/LO/2177	Plantar pressure as a risk factor for foot ulceration in diabetes - V1	7
17/LO/0069	Observational Study in patients with ExPEC disease following TRUS-PNB	21
17/LO/0453	Memory and learning after brain injury (Version 1.0).	11

Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
16/LO/0623	Nerve Injury Patient Related Outcomes	13
16/LO/0864	Angiography in Perimesencephalic SAH	14
16/LO/1309	Phosphatidylserine and red cell membrane transport in SCD	7
16/LO/1664	Personally Important Moments post Acquired Brain Injury (ABI)	3
17/LO/0464	Core Outcome Set for Prevention of Oral Mucositis in Cancer Patients	10

Unfavourable Opinion

REC Reference	Title	Number of Days on Clock
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Provisional Opinion

REC Reference	Title	Number of Days on Clock
17/LO/0067	HIIT+PRT in BCS with MetS	n/a

Further information response not complete

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

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

Favourable opinion				
Amendment REC Reference	Title	Version	Date	Number of Days on Clock
07/H1109/181/AM02	Bacterial biosensors in chemotherapy pre-screening	1	10/06/2016	11
09/H0701/49/AM14	Post-marketing, Observational Registry of Humira in Psoriasis Patients	Administrative Change 4	05/08/2016	4
09/H0701/49/AM16	Post-marketing, Observational Registry of Humira in Psoriasis Patients	Substantial amendment 12 Chief	09/02/2017	11
11/LO/0476/AM03	Minitub:Prospective Registration Study on Sentinel Node (SN) Positive	UK03, 06/07/2016	06/07/2016	13
11/LO/1229/AM06	Phenotyping Achromatopsia patients in Preparation for Gene Therapy	Substantial Amendment 6 - 30 A	01/09/2016	8
11/LO/1672/AM07	Functional Assessment in early Breast cancer in Older patients	8 dated 28.09.16	30/09/2016	4
11/LO/1997/AM15	Development of a simple tool for diagnosis of water-loss dehydration.	Substantial amendment dated 07	07/06/2016	27
12/LO/0130/AM03	Surplus tissue from patients undergoing eye surgery	Substantial amendment 3 dated	14/04/2016	13
12/LO/0515/AM06	OPTIMA Version 1.0, 08 March 2012	Substantial Amendment 6, 27/09	30/09/2016	4
13/LO/0621/AM05	(May) Specificity of "4 Mountains" spatial memory test for Alzheimer's	2, 22 September 2016	22/09/2016	73
13/LO/1349/AM10	eGFR-C	Substantial amendment 5	18/04/2016	2
13/LO/1349/AM12	eGFR-C	6 dated 05.10.16	13/10/2016	5
13/LO/1398/AM03	Exercise CMR in Pulmonary Arterial Hypertension	Amendment 3, 23/2/2016	09/08/2016	2
14/LO/0525/AM03	Assessing alcohol misuse in cognitive impairment in the elderly.	Substantial amendment 4 dated	01/06/2016	7

14/LO/1842/AM02	ENDCaP-C Test Accuracy Study	Substantial amendment No 2	11/02/2016	23
14/LO/1842/AM06	ENDCaP-C Test Accuracy Study	Substantial amendment 3.0, 21s	21/02/2017	42
14/LO/1964/AM01	A pilot RCT of a brief mindfulness therapy in secondary care	Substantial amendment dated	05/04/2016	7
15/LO/0038/AM07	STRATA Version 1.0	4.0, 17/08/2016	07/09/2016	1
15/LO/0184/AM02	Dietary resistant starch from peas for healthy glucose homeostasis	SA2	07/02/2017	7
15/LO/0185/AM03	EORTC H&N Phase IV	2 13/04/2016	30/06/2016	19
15/LO/0596/AM04	Study of the effects of Vitamin D on immune responses to Tuberculosis	Amendment number 2 1st Feb 201	22/02/2017	29
15/LO/0624/AM03	In vivo Tau pathology in PSP and CBD	2.0, 25/08/2016	26/08/2016	6
15/LO/0793/AM01	Training healthcare assistants (HCAs) in Psychological First Aid (PFA)	1	22/11/2016	6
15/LO/0858/AM02	Quality of life&depression in Chronic kidney disease	Substantial amendment 1	09/02/2017	13
15/LO/0891/AM01	Effect of high- and low-fructose diets on intestinal fat production.	Substantial amendment 1	24/05/2016	11
15/LO/0891/AM02	Effect of high- and low-fructose diets on intestinal fat production.	Substantial amendment 2	03/11/2016	8
15/LO/0977/AM03	mHealth for antenatal mental health	1.3, Date 16 March 2016	07/04/2016	8
15/LO/1201/AM02	Enhanced management of patients and contact tracing for hepatitis B	Amendment number 2 27/10/2016	04/11/2016	7
15/LO/1414/AM02	Optimisation of neonatal ventilation	Substantial amendment 1	31/08/2016	6
15/LO/1968/AM01	Cardiac Troponin I monitoring pilot study	AM02	29/03/2016	10
15/LO/2051/AM04	The PRIME Study: Positive tRansltions through the MEnopause	PRIME Study, Sponsor Ref 15/07	07/11/2016	4
15/LO/2063/AM02	Vitamin D in CKD - Vascular Function, Structure and Immune Regulation	AM02	20/06/2016	7
15/LO/2082/AM02	The REACT (REtirement in ACTion) study - V1	1.3	12/05/2016	4

15/LO/2082/AM03	The REACT (REirement in ACTION) study - V1	3 - V1.4 dated 13.09.16	28/10/2016	4
15/LO/2091/AM01	SoMoVe v1	1, 23rd August 2016	01/09/2016	4
15/LO/2101/AM01	SPRINTT Project	Substantial amendment 1	15/06/2016	12
15/LO/2101/AM03	SPRINTT Project	Substantial amendment 2	03/08/2016	2
15/LO/2101/AM06	SPRINTT Project	Substantial amendment 3	14/02/2017	44
16/LO/0041/AM01	Trace Element Malnutrition in Paediatric Renal Disease	Substantial amendment 1 dated	12/05/2016	5
16/LO/0064/AM01	The Role of Error Signals for Awareness of Cognitive Deficits	Study Protocol v3 (25th April	22/06/2016	12
16/LO/0072/AM01	Remediation of Social Cognition in Schizophrenia	1	29/02/2016	14
16/LO/0556/AM03	Social Factors, Care & CTOs. Service User & Practitioner Perspectives	1	22/11/2016	8
16/LO/1065/AM01	Assessment of Amyloidosis Patient Pathways	1 dated 16.11.16	18/11/2016	4
16/LO/1076/AM02	Kent Medicine Support in Stroke and TIA (KeMiST)	Amendment 1, 15th August 2016	17/08/2016	12
16/LO/1076/AM03	Kent Medicine Support in Stroke and TIA (KeMiST)	2	19/11/2016	4
16/LO/1105/AM01	SAizenÂ® Long Term Observational study (SALTO)	Amendment 1, 09 September 2016	09/09/2016	9
16/LO/1827/AM01	Perioperative Quality Improvement Programme: Patient Study	1.0 12/10/16	21/10/2016	5
16/LO/1827/AM03	Perioperative Quality Improvement Programme: Patient Study	2.0 01/12/16	19/12/2016	16
16/LO/1985/AM01	Clients with BPD experience of Cognitive Analytic therapy	1 dated 31.01.17	31/01/2017	9

Unfavourable opinion

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
11/LO/1404/AM03	Upper Airway Function during Exercise in Patients with Asthma	#2, 10/10/2016 Version 4	24/11/2016	14
15/LO/0253/AM01	MAGnetic Resonance imaging in COeliac disease (MARCO) Version 1.0	MARCO V1.1 10 June 2016	11/08/2016	4

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
15/LO/0253/AM01/1	MAGnetic Resonance imaging in COeliac disease (MARCO) Version 1.0	SA01/16	07/09/2016	1

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

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

REC Reference	Title	Number of Days on Clock
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Proportionate review applications for ethical review over 14 day timeline

REC Reference	Title	Number of Days on Clock
17/LO/0456	DuraGraft Registry 005-01	39
17/LO/0469	Burden of PAH-deficiency in adults	43

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
13/LO/0621/AM05	(May) Specificity of "4 Mountains" spatial memory test for Alzheimer's	2, 22 September 2016	22/09/2016	73
14/LO/1842/AM06	ENDCaP-C Test Accuracy Study	Substantial amendment 3.0,	21/02/2017	42
15/LO/2101/AM06	SPRINTT Project	Substantial amendment 3	14/02/2017	44

Modified Amendments over 14 day timeline

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
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