

**London - Stanmore Research Ethics Committee**

**Annual Report**

**01 April 2016 - 31 March 2017**



## Part 1 – Committee Membership and Training

<b>Name of REC:</b>	London - Stanmore Research Ethics Committee
<b>Type of REC:</b>	Authorised
<b>Type of Flag:</b>	Medical Devices and Qualitative Research
<b>Chair:</b>	Mrs Rosemary Hill
<b>Vice-Chair:</b>	Dr Anthony Gilbert
<b>Alternate Vice-Chair:</b>	Dr Anthony Kaiser
<b>REC Manager:</b>	Mr Patrick Walsh (January 2017- March 2017) Mrs Julie Kidd (April 2016- January 2017)
<b>REC Assistant:</b>	Mrs Asha Jama (January 2017- March 2017) Mr Suubi Kawooya (April 2016- July 2016) Mrs Fola Ovie-Afabor (July 2016- November 2016)
<b>Committee Address:</b>	Ground Floor NRES/HRA 80 London Road London SE1 6LH
<b>Telephone:</b>	020 7972 2561
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## Chair's overview of the past year:

The Committee had an interesting and worthwhile year.

We are flagged for medical devices and for qualitative research. It seems that not all qualitative research has been recorded as such; much of the student applications were qualitative work.

The Committee are enthusiastic and very willing; we have specialists in a wide variety of fields, including medical device studies and qualitative research. We have quite a few members who have conducted research themselves and have been in a position to give advice to applicants from their own experience.

The Committee welcomed Patrick Walsh and Asha Jama to the REC administrative team.

## London - Stanmore Research Ethics Committee Membership

Name	Profession	Expert or Lay	Dates	
			Appointed	Left
Mr Gordon Coleman	Retired - Justice of Peace	Lay Plus	26/06/2009	
Mrs Marion Cumbers	Retired Librarian	Lay Plus	16/06/2009	
Dr Geraldine Edge	Consultant Anaesthetist	Expert	16/06/2009	
Dr Anthony Gilbert	Medical Doctor	Expert	21/06/2009	
Dr Lisa Griffiths	Neurophysiology Technician	Lay Plus	05/01/2017	
Dr Mike Hetreed	Consultant Anaesthetist	Expert	17/06/2009	06/10/2016
Mrs Rosemary Hill	Statistician	Lay	18/06/2009	
Dr Anthony Kaiser	Consultant Neonatologist	Expert	01/12/2013	
Mrs Elayne Nasr	Retired School Matron	Lay Plus	17/06/2009	
Dr Carol Pellowe	Senior Lecturer - Infection Control - retired	Expert	17/06/2009	
Mrs Susan Ruben	Pharmacist / Pharmacy Manager	Expert	09/12/2011	
Mrs Yasmin Shaik	Administrative	Lay	09/08/2016	
Ms Gill Thurlow	Consultant Nurse - Rehabilitation and Pain Management Programmes	Expert	17/06/2009	03/12/2015
Mr George Verghese	Orthopaedic Surgeon	Expert	01/07/2011	
Mrs Shirley Williams	Retired Nurse	Lay	17/06/2009	

**London - Stanmore Research Ethics Committee: Members' Declarations of Interest:**

<b>Name</b>	<b>Declaration of Interest</b>	<b>Date</b>
Mr Gordon Coleman	None	15/03/2017
Mrs Marion Cumbers	Lay Representative, TARVA ankle research project, RNOH Lay Representative, Statins and Pragmatic Trials research projects, Farr Institute, (Tjeerd van Staa) Lay representative, Neonatal Clinical Studies Group, Medicines for Children Research NetworkPublic representative, Member of RNOH Patient GroupJAG Lay Assessor, Royal College of Physicians, London (in training) Member, CLL Support Ambassador for Bloodwise	15/03/2017
Dr Geraldine Edge	Consultant Anaesthetist - RNOH - affiliated to UCL and UCLH for research programmes	15/03/2017
Dr Anthony Gilbert	HVIVO shareholder	15/03/2017
Dr Lisa Griffiths	None	03/01/2017
Mrs Rosemary Hill	Shares in Astra Zeneca	15/03/2017
Dr Anthony Kaiser	None	15/03/2017
Mrs Elayne Nasr	None	15/03/2017
Dr Carol Pellowe	Member of infection prevention society (retired section)Lay member of the Royal College of Anaesthetists' Lay Committee	15/03/2017
Mrs Susan Ruben	None	15/03/2017
Mrs Yasmin Shaik	None	15/03/2017
Mr George Verghese	None	15/03/2017
Mrs Shirley Williams	Volunteer on Patient group at RNOH	15/03/2017

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

Month	Date	Number of Members Present at Meeting
April	07/04/2016	10
May	05/05/2016	9
June	02/06/2016	8
July	07/07/2016	8
September	01/09/2016	8
October	06/10/2016	12
December	08/12/2016	10
February	02/02/2017	9
March	02/03/2017	10

9 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	13/04/2016	3
May	14/05/2016	3
June	15/06/2016	4
July	13/07/2016	4
August	17/08/2016	3
October	12/10/2016	3
November	16/11/2016	3
December	14/12/2016	3
February	24/02/2017	4
March	24/03/2017	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	2
April	18/04/2016	2
June	01/06/2016	2
July	18/07/2016	2
August	03/08/2016	2
August	12/08/2016	2
August	31/08/2016	2
September	16/09/2016	2
September	30/09/2016	2
October	17/10/2016	2
October	31/10/2016	2

November	10/11/2016	2
November	18/11/2016	2
December	12/12/2016	2
December	12/12/2016	2
January	10/01/2017	2
January	16/01/2017	2
January	27/01/2017	2
February	23/02/2017	3
March	13/03/2017	2
March	31/03/2017	4

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

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

NONE

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

Name	Number of Meetings Attended
Mr Gordon Coleman	6
Mrs Marion Cumbers	6
Dr Geraldine Edge	9
Dr Anthony Gilbert	3
Dr Lisa Griffiths	2
Dr Mike Hetreed	5
Mrs Rosemary Hill	9
Dr Anthony Kaiser	7
Mrs Elayne Nasr	7
Dr Carol Pellowe	7
Mrs Susan Ruben	8
Mrs Yasmin Shaik	5
Mr George Verghese	4
Mrs Shirley Williams	6

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

Name	Number of Meetings Attended
Mrs Marion Cumbers	2
Dr Geraldine Edge	2
Dr Anthony Gilbert	3
Mrs Rosemary Hill	10
Dr Anthony Kaiser	7
Mrs Elayne Nasr	3
Dr Carol Pellowe	2
Mrs Susan Ruben	3
Mrs Yasmin Shaik	1

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

Name	Number of Meetings Attended
Mrs Marion Cumbers	3
Dr Geraldine Edge	3
Dr Anthony Gilbert	1
Mrs Rosemary Hill	21
Dr Anthony Kaiser	2
Mrs Elayne Nasr	4
Dr Carol Pellowe	6
Mrs Susan Ruben	2
Mrs Yasmin Shaik	2
Mr George Verghese	1

## Training 01 April 2016 - 31 March 2017

Name of Member	Date	Event(s) attended
Mrs Marion Cumbers	16/11/2016	Members Training Day
Mrs Marion Cumbers	16/02/2017	National Members Training Day
Dr Geraldine Edge	05/01/2017	Members Local Training
Dr Anthony Gilbert	16/06/2016	Research Quality Association Seminar
Dr Lisa Griffiths	05/01/2017	Members Local Training
Dr Lisa Griffiths	14/03/2017	Induction for members
Mrs Rosemary Hill	04/05/2016	Regional Chairs' Meeting
Mrs Rosemary Hill	05/01/2017	Members Local Training
Mrs Elayne Nasr	01/12/2016	'Do No harm' by Henry Marsh
Mrs Elayne Nasr	01/02/2017	Conflicts of interest
Dr Carol Pellowe	16/09/2016	Review research applications for funding for Royal College of Anaesthetists
Mrs Susan Ruben	05/01/2017	Members Local Training
Mrs Yasmin Shaik	06/12/2016	Members Induction
Mrs Yasmin Shaik	05/01/2017	Members Local Training
Mr George Verghese	05/01/2017	Members Local Training
Mrs Shirley Williams	05/01/2017	Members Local Training day

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

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



<b>Applications for full ethical review – Study Type</b>	<b>Number</b>	<b>%</b>
Clinical Trial of Investigational Medicinal Product	0	0.00
Phase 1	0	0.00
Gene Therapy	0	0.00
Research Tissue Bank (including renewals)	0	0.00
Research Database (including renewals)	0	0.00
Others	34	100.00
<b>Total Applications Reviewed</b>	<b>34</b>	<b>100</b>

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

Number of applications made invalid by the REC Manager	5
Number of applications withdrawn prior to the meeting	0
Number of student applications reviewed	9
Number of paediatric applications reviewed	7
Number of device applications reviewed	10
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	6

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

<b>Decisions taken at meetings following review of applications</b>	<b>Number</b>	<b>%</b>
Favourable Opinion with Standard Conditions	1	2.94
Favourable Opinion with Additional Conditions	7	20.59
Unfavourable Opinion	1	2.94
Provisional Opinion	25	73.53
Provisional Opinion Pending Consultation with Referee	0	0.00
<b>Total</b>	<b>34</b>	<b>100</b>
Number of studies sent back to full committee meeting for final opinion	0	

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

Status of applications at date of generation of report	Number	%
Further Information Favourable Opinion with Standard Conditions	24	70.59
Further Information Favourable Opinion with Additional Conditions	1	2.94
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	1	2.94
Favourable Opinion with Additional Conditions	7	20.59
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
<b>Total</b>	<b>34</b>	<b>100</b>

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

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

Number of applications made invalid by the REC Manager	4
Number of studies withdrawn prior to the meeting	1
Number of student applications reviewed	11
Number of paediatric applications reviewed	5
Number of device applications reviewed	0
Number of qualitative applications reviewed	6

**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	3	11.11
Favourable Opinion with Additional Conditions	1	3.70
No Opinion transfer to full committee for review	4	14.81
Provisional Opinion	19	70.37
Unfavourable Opinion	0	0.00
<b>Total</b>	<b>27</b>	<b>100</b>

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

<b>Average number of applications reviewed per full meeting</b>	3.78
<b>Number of completed applications for full ethical review</b>	34
<b>Number of completed applications for full ethical review over 60 days</b>	0
<b>Number of completed applications over 60 days as a % of total</b>	0.00%
<b>Number of completed applications for full ethical review over 40 days</b>	12
<b>Number of completed applications over 40 days as a % of total</b>	35.29%
<b>Number of days taken to final decision – average (mean)</b>	37
<b>Number of completed proportionate review applications for ethical review</b>	22
<b>Number of completed proportionate review applications for ethical review over 14 days (Please note, the timeline for the review of PR applications was extended from 14 to 21 calendar days in December 2016)</b>	6
<b>Number of completed proportionate review applications for ethical review over 21 days</b>	2
<b>Number of completed proportionate review applications over 14 days as a % of total</b>	27.27%
<b>Number of SSAs (non-Phase 1) reviewed</b>	6
<b>Number of completed applications for SSA review over 25 days</b>	0
<b>Number of completed applications for SSA review over 25 days as % of all non- Phase 1 SSAs</b>	0.00%
<b>Number of SSAs (Phase 1) reviewed</b>	0
<b>Number of completed applications for SSA review over 14 days</b>	0
<b>Number of completed applications for SSA review over 14 days as % of all Phase 1 SSAs</b>	0.00%
<b>Number of substantial amendments reviewed</b>	56
<b>Number of completed substantial amendments over 35 days</b>	2
<b>Number of completed substantial amendments over 35 days as a % of total substantial amendments</b>	3.57%
<b>Number of completed substantial amendments over 28 days</b>	6
<b>Number of completed substantial amendments over 28 days as a % of total substantial amendments</b>	10.71%
<b>Number of modified amendments reviewed</b>	1
<b>Number of completed modified amendments over 14 days</b>	0
<b>Number of completed modified amendments over 14 days as a % of total modified amendments</b>	0.00%

<b>Number of non-substantial amendments received</b>	82
<b>Number of substantial amendments received for information</b>	0
<b>Number of substantial amendments received for new sites/PIs</b>	0
<b>Number of annual progress reports received</b>	48
<b>Number of safety reports received</b>	0
<b>Number of Serious Adverse Events received</b>	5
<b>Number of final reports received</b>	10

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

<b>Further Information Favourable Opinion with Standard Conditions</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
16/LO/0613	Comparison of Laser Doppler and SIAscope for the assessment of burns	59
16/LO/0634	X-LAB	56
16/LO/0635	X-MINS	57
16/LO/0671	CAPTOE	35
16/LO/0828	Insights into user experiences of weight management services	26
16/LO/0830	Effects of comp base training with/out TMS on motor and cognition	27
16/LO/0854	Fluids in Shock (FiSh) External Pilot Study Version 1.0	35
16/LO/0878	everlinQ endoAVF EU Study v1.0	31
16/LO/1044	DETECT II	42
16/LO/1153	(duplicate) A Model of Sibling Relationships in PHIV+	48
16/LO/1185	UK - EHL Outcome Registry	59
16/LO/1223	Randomized cross-over comparison of double mini PET test	44
16/LO/1533	Journey II CR total Knee System	59
16/LO/1571	Difficult Conversations	31
16/LO/1795	Geko versus Intermittent Pneumatic Compression in Venous Leg Ulcer	27
16/LO/1796	CONTOUR (A4062)	26
16/LO/1805	Vitamin D to resolve inflammation after tuberculosis (ResolveD-TB)V5.1	42
16/LO/2022	The effect of 670nm Light on Visual Function in Aging and AMD	41
16/LO/2081	Identification of novel MRI features in brain tumours - a pilot study	31
16/LO/2152	Developing the content of the S-PROM	37
17/LO/0037	A novel robotic system for trans-anal surgery	55
17/LO/0366	ROBIN, V2	36
17/LO/0403	Pancreatic Surgery- pre-operative exercise programme	38

<b>Further Information Favourable Opinion with Additional Conditions</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
17/LO/0166	The Effects of Whole Body Unloading on Physiological Function	41

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

<b>Favourable Opinion with Standard Conditions</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
16/LO/0645	Equality for CYP with learning disabilities (LD) - Phases 2-4	34

<b>Favourable Opinion with Additional Conditions</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
16/LO/1079	Identifying an environmental factor for Crohn's disease	16
16/LO/1091	Ealing geko VLU study	16
16/LO/1208	Premature Ovarian Insufficiency Study (Version1)	31
16/LO/1245	The HeartSpare Plus 1B Trial	28
16/LO/1541	Measures of lower limb venous blood flow with Sequential Compression	22
16/LO/1590	QLQ-MEL38 Validation Study	22
17/LO/0395	Qualitative interviews with perpetrator/ survivor dyads	22

<b>Unfavourable Opinion</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
17/LO/0063	Critical moments in physician-patient conversations on endometriosis	39

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

<b>Provisional Opinion Pending Consultation with Referee</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>

Further information response not complete		
REC Reference	Title	Number of Days on Clock
17/LO/0410	TONICS feasibility RCT	n/a

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/0918	Evaluating the ten year impact of the Productive Ward	15
16/LO/1148	Measurement of wire deflection on loading may indicate bone union	16
16/LO/1336	Tocilizumab mono therapy versus other biologic mono therapy in RA	13
16/LO/1551	Abnormal Patient Test Results Study	14
16/LO/1563	EVALUATION OF PILOT PROJECT OF BRIEF PARENT-YOUNG CHILD PSYCHOTHERAPY	23
16/LO/1896	Perceptions of adults with lower limb external fixation devices	12
16/LO/2062	Evaluation of proprioceptive disturbances in adolescent scoliosis	7
16/LO/2070	Disease progression and wait times in dermatological patients v1	12
16/LO/2218	Exercise Beliefs and Barriers in Pregnancy (EBBP)	8
16/LO/2223	Website evaluation	15
17/LO/0379	Impact of androgen deprivation therapy on microenvironment of PCa	14
17/LO/0382	Barriers and Facilitators to exercise for LLAs. Version 1	22
17/LO/0549	Re-framing stop smoking services in response to e-cigarette use	13
17/LO/0555	sensor-based gait analysis in patients with HSP	21

Further Information Favourable Opinion with Additional Conditions		
REC Reference	Title	Number of Days on Clock
16/LO/0661	Elastase in diabetes study v1.0	13
16/LO/1156	Trigeminal Neuralgia Patient Advisory Board Meeting	13

16/LO/1554	Self-Compassion, Depression, Anxiety, and Resilience in Epilepsy	11
16/LO/1889	Implementation of recovery-oriented practice in mental health services	14

#### 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/0672	Antiplatelet monitoring in children on VAD support	9
16/LO/2086	What Explains Cancer Costs in England?	6
17/LO/0551	Novel viral markers for the management of patients with chronic HBV	12

#### Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
16/LO/1325	faecal bile acid study	14

#### Unfavourable Opinion

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

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

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

REC Reference	Title	Number of Days on Clock
16/LO/1145	Appointment Allocation Systems of GP Practices in Tayside	6



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

<b>Favourable opinion</b>				
<b>Amendment REC Reference</b>	<b>Title</b>	<b>Version</b>	<b>Date</b>	<b>Number of Days on Clock</b>
08/H0724/35/AM07	MRI assessment of liver haemodynamics - Version 1	5 (dated October 2016)	01/10/2016	22
11/LO/0922/AM03	OVATION Post Market Study	Amendment II (Our AM03)	24/08/2016	13
12/LO/0491/AM08	Surgical Replacement & Transcatheter Aortic Valve Implantation SURTAVI	Amendment 6 (Our AM08)	14/09/2016	8
12/LO/0810/AM03	Cardiovascular Changes in Pregnancy (CVP)	2	27/10/2016	36
12/LO/0837/AM03	Association of human papillomavirus (HPV) and breast tumours	2	10/03/2016	11
12/LO/1320/AM01	ANCHOR REGISTRY - Protocol CD03469-01	Amendment 1 (Our AM01)	30/09/2016	5
13/LO/0793/AM03	Investigation of balance strategies following postural perturbation	2	01/08/2016	29
13/LO/0969/AM04	Visual processing and working memory deficits in schizophrenia	2	14/10/2016	23
13/LO/1254/AM06	EVERREST: Developing a therapy for Fetal Growth Restriction	6	16/06/2016	17
13/LO/1254/AM07	EVERREST: Developing a therapy for Fetal Growth Restriction	7	09/03/2017	18
13/LO/1274/AM03	FOrMAT	Amendment 3 (Our AM03)	01/07/2016	22
13/LO/1639/AM03	Correction of Angular Deformities in Knee Arthrosis	3	06/03/2017	27
13/LO/1837/AM03	Radiocyst 01	3	10/10/2016	32
13/LO/1837/AM05	Radiocyst 01	2	08/11/2016	7
14/LO/0328/AM04	VMET 2	4	15/06/2016	13
14/LO/0361/AM01	3D Transoesophageal Echocardiographic Assessment of the Mitral Valve	v 1.3 29 Feb 2016	01/03/2016	11
14/LO/0376/AM04	CLN0016	3	19/01/2017	19
14/LO/0663/AM04	Brain connectivity in ASD: a biomarker to predict treatment response	4	11/01/2017	8
14/LO/0843/AM02	Beyond TME version 1.2	3	17/11/2016	24
14/LO/1611/AM06	Cook IVC filter Study (12-018)	5	04/07/2016	7
14/LO/1611/AM09	Cook IVC filter Study (12-018)	6	31/10/2016	6

14/LO/1611/AM10	Cook IVC filter Study (12-018)	7 dated 3rd January 2017	04/01/2017	13
14/LO/2099/AM02	Effect of 670 nm Light on Retinal Function in Birdshot V1	2	16/03/2016	35
14/LO/2160/AM02	Improving the detection of active TB in A&E departments (ACE Study)	3	26/02/2016	11
14/LO/2160/AM03	Improving the detection of active TB in A&E departments (ACE Study)	V3	13/04/2015	1
14/LO/2160/AM04	Improving the detection of active TB in A&E departments (ACE Study)	1.1	12/07/2016	41
15/LO/0164/AM02	Knee functions and rehabilitation 12 months after knee replacement	AM02 (Our AM02)	05/07/2016	14
15/LO/0630/AM06	Natural History in Subjects with Fibrodysplasia Ossificans Progressiva	4	24/03/2016	8
15/LO/0766/AM01	A novel robotic system for trans-anal endoscopic microsurgery	First Amendment, Protocol 1.4	01/03/2016	19
15/LO/0900/AM04	630-0012 Pulmonx LIBERATE Study	3	09/02/2016	31
15/LO/0900/AM06	630-0012 Pulmonx LIBERATE Study	4	16/11/2016	14
15/LO/1051/AM02	NEST: NMDA-receptors in Epilepsy, Stroke and TBI.	Amendment 1 (Our AM02)	06/09/2016	9
15/LO/1101/AM01	Comparison of Ostomy Products (COOP)	Substantial Amendment #1 (Our	15/08/2016	18
15/LO/1274/AM06	An Analysis of Long-Term Health Outcomes in Ex-Cricketers	3	17/10/2016	25
15/LO/1597/AM02	RejuvenAir <sup>®</sup> System Chronic Bronchitis Version 2	Amendment 2 (Our AM02)	17/10/2016	12
15/LO/2044/AM01	Clinical performance of Compass in the diagnosis of glaucoma, V5	1	19/01/2017	22
16/LO/0118/AM01	Valiant Evo International Clinical Trial	1	12/04/2016	6
16/LO/0118/AM04	Valiant Evo International Clinical Trial	3	22/03/2017	15
16/LO/0207/AM01	Qualitative analysis of how individuals cope with stigma V1	1	13/04/2016	25
16/LO/0321/AM01	Self-Management after Therapy for depression (SMarT)	Amendment 1 (Our AM01)	14/09/2016	6
16/LO/0379/AM01	SocketMaster	1.0 (Our AM01)	28/07/2016	18
16/LO/0380/AM01	Mids Ankle Fracture	v1.1	27/09/2016	14
16/LO/0488/AM01	Patient's Views on Surgeon Specific Mortality Data	Amendment 1 (Our AM01)	01/08/2016	27

16/LO/0645/AM01	Equality for CYP with learning disabilities (LD) - Phases 2-4	1	19/07/2016	18
16/LO/0645/AM02	Equality for CYP with learning disabilities (LD) - Phases 2-4	2 (Our AM02)	09/09/2016	10
16/LO/0645/AM03	Equality for CYP with learning disabilities (LD) - Phases 2-4	3	02/11/2016	21
16/LO/0671/AM01	CAPTOE	1	24/06/2016	8
16/LO/0671/AM03	CAPTOE	2 (Our AM03)	14/10/2016	16
16/LO/0878/AM03	everlinQ endoAVF EU Study v1.0	2	21/02/2017	25
16/LO/0918/AM06	Evaluating the ten year impact of the Productive Ward	Amendment 01 (Our AM06)	01/08/2016	26
16/LO/0918/AM08	Evaluating the ten year impact of the Productive Ward	3	17/01/2017	19
16/LO/1044/AM04	DETECT II	2	18/10/2016	28
16/LO/1185/AM03	UK - EHL Outcome Registry	1	05/12/2016	11
16/LO/1325/AM01	faecal bile acid study	1	09/11/2016	28
16/LO/1571/AM03	Difficult Conversations	1	02/02/2017	26
16/LO/1796/AM01	CONTOUR (A4062)	1	25/11/2016	7

#### 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
14/LO/0677/AM04/1	Preterm birth and executive attention	4.1	22/06/2016	6

#### 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
16/LO/1563	EVALUATION OF PILOT PROJECT OF BRIEF PARENT-YOUNG CHILD PSYCHOTHERAPY	23
17/LO/0382	Barriers and Facilitators to exercise for LLAs. Version 1	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
12/LO/0810/AM03	Cardiovascular Changes in Pregnancy (CVP)	2	27/10/2016	36
14/LO/2160/AM04	Improving the detection of active TB in A&E departments (ACE Study)	1.1	12/07/2016	41

**Modified Amendments over 14 day timeline**

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
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