

**London - Stanmore Research Ethics Committee**

**Annual Report**

**01 April 2015 - 31 March 2016**



## 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 & Qualitative
<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>	Ms Julie Kidd
<b>REC Assistant:</b>	Miss Sivatharshini Sivakumaran - July 2015 until March 2016 Mr Suubi Kawooya - March 2016 – present
<b>Committee Address:</b>	HRA, Skipton House, 80 London Road London SE1 6LH
<b>Telephone:</b>	020707 22554
<b>Email:</b>	Nrescommittee.London-Stanmore@nhs.net

### 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 advise applicants from their own experience.

## 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 Mike Hetreed	Consultant Anaesthetist	Expert	17/06/2009	
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	
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 Marina Wells	Midwife/Matron	Expert	16/06/2009	03/11/2014
Mrs Shirley Williams	Retired Nurse	Lay	17/06/2009	

## London - Stanmore Research Ethics Committee : Deputy Members

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

Name	Profession	Status	Meeting date attended
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**London - Stanmore Research Ethics Committee : Members' Declarations of Interest:**

<b>Name</b>	<b>Declaration of Interest</b>	<b>Date</b>
Mrs Marion Cumbers	- Member RNOH Patient Group- Lay representative TARVA ample trial steering committee- Patient and public involvement	18/02/2016
Dr Geraldine Edge	I am the Designated Individual for the Human Tissue Authority at the Royal National Orthopaedic Hospital NHS Trust which occasionally submits applications to the HRA.	31/03/2016
Dr Anthony Gilbert	HVIVO shareholder	31/03/2016
Dr Mike Hetreed	Expert member (physician anaesthetist), no change in last 12 months.	18/02/2016
Mrs Rosemary Hill	Shares in Astra Zeneca	30/03/2016
Dr Anthony Kaiser	I have retired and returned to the NHS Part Time (8 sessions/per week) - Date of Occurrence: August 2015.	04/02/2016
Mrs Elayne Nasr	No interests declared	31/03/2016
Dr Carol Pellowe	- Member of infection prevention society (retired section)- Retired from paid employment and did not renew registration.	18/02/2016
Mrs Susan Ruben	No declared interests	18/02/2016
Mr George Verghese	No declared interests	18/02/2016
Mrs Shirley Williams	Volunteer on Patient group at RNOH	31/03/2016

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

Month	Date	Number of Members Present at Meeting
April	09/04/2015	7
May	07/05/2015	10
June	04/06/2015	9
July	02/07/2015	9
September	03/09/2015	12
October	01/10/2015	12
December	03/12/2015	8
January	07/01/2016	11
February	04/02/2016	8
March	03/03/2016	9

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
April	22/04/2015	3
June	15/06/2015	3
July	15/07/2015	3
August	17/08/2015	3
September	15/09/2015	4
October	15/10/2015	3
November	16/11/2015	4
December	10/12/2015	4
January	12/01/2016	3
February	11/02/2016	3
March	16/03/2016	3

11 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	03/04/2015	2
April	15/04/2015	2
May	14/05/2015	2
June	04/06/2015	2
June	18/06/2015	2
June	25/06/2015	2
July	06/07/2015	2
July	22/07/2015	2
August	21/08/2015	2

September	09/09/2015	2
September	20/09/2015	2
October	23/10/2015	2
November	16/11/2015	2
November	27/11/2015	2
November	30/11/2015	2
December	15/12/2015	2
December	21/12/2015	2
January	14/01/2016	2
January	20/01/2016	2
February	14/02/2016	2
March	01/03/2016	3
March	24/03/2016	2

22 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**

<b>Name</b>	<b>Number of Meetings Attended</b>
Mr Gordon Coleman	7
Mrs Marion Cumbers	5
Dr Geraldine Edge	8
Dr Anthony Gilbert	9
Dr Mike Hetreed	8
Mrs Rosemary Hill	10
Dr Anthony Kaiser	8
Mrs Elayne Nasr	7
Dr Carol Pellowe	9
Mrs Susan Ruben	9
Ms Gill Thurlow	5
Mr George Verghese	4
Mrs Shirley Williams	6

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

<b>Name</b>	<b>Number of Meetings Attended</b>
Dr Geraldine Edge	1
Dr Anthony Gilbert	3
Dr Mike Hetreed	1
Mrs Rosemary Hill	9
Dr Anthony Kaiser	5
Mrs Elayne Nasr	4
Dr Carol Pellowe	4
Mrs Susan Ruben	3
Ms Gill Thurlow	1
Mr George Verghese	4
Mrs Shirley Williams	1

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

<b>Name</b>	<b>Number of Meetings Attended</b>
Mrs Marion Cumbers	2
Dr Anthony Gilbert	1
Dr Mike Hetreed	3

Mrs Rosemary Hill	22
Dr Anthony Kaiser	4
Dr Carol Pellowe	6
Mrs Susan Ruben	3
Ms Gill Thurlow	2
Mr George Verghese	2



**Training 01 April 2015 - 31 March 2016**

<b>Name of Member</b>	<b>Date</b>	<b>Event(s) attended</b>
Mr Gordon Coleman	07/01/2016	Ethical Considerations in Minors
Mrs Marion Cumbers	07/01/2016	Ethical Considerations in Minors
Dr Geraldine Edge	13/08/2015	Local Training Day
Dr Anthony Gilbert	13/08/2015	Local Training Day
Dr Anthony Gilbert	07/01/2016	Ethical Considerations for minors
Dr Mike Hetreed	07/01/2016	Ethical Considerations in Minors
Mrs Rosemary Hill	19/05/2015	Chair's NREAP Meeting
Mrs Rosemary Hill	19/05/2015	Chair's Meeting
Mrs Rosemary Hill	02/11/2015	Chair's NREAP Meeting
Mrs Rosemary Hill	07/01/2016	Ethical Consideration for Research on Minors
Dr Anthony Kaiser	12/06/2015	Equality & Diversity
Dr Anthony Kaiser	13/08/2015	Local Training Day
Dr Anthony Kaiser	07/01/2016	Ethical Considerations in Minors
Mrs Elayne Nasr	17/05/2015	E&D training
Dr Carol Pellowe	07/01/2016	Ethical Considerations in Minors
Mrs Susan Ruben	07/01/2016	Ethical Considerations in Minors
Mr George Verghese	30/04/2015	Equality & diversity
Mr George Verghese	07/01/2016	Ethical Considerations in Minors
Mr George Verghese	16/03/2016	Qualitative Training
Mrs Shirley Williams	13/08/2015	Local Training Day
Mrs Shirley Williams	07/01/2016	Ethical Considerations in Minors

## 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	40	100.00
<b>Total Applications Reviewed</b>	<b>40</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	2
Number of applications withdrawn prior to the meeting	0
Number of student applications reviewed	15
Number of paediatric applications reviewed	6
Number of device applications reviewed	16
Number of prisoner applications reviewed	0
Number of applications involving adults unable consent reviewed	1
Number of applications reviewed that are funded by the US DHHS	0
Number of qualitative applications reviewed	7

**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	0	0.00
Favourable Opinion with Additional Conditions	8	20.00
Unfavourable Opinion	5	12.50
Provisional Opinion	27	67.50
Provisional Opinion Pending Consultation with Referee	0	0.00
<b>Total</b>	<b>40</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	25	62.50
Further Information Favourable Opinion with Additional Conditions	1	2.50
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	0	0.00
Favourable Opinion with Additional Conditions	8	20.00
Unfavourable Opinion	5	12.50
Provisional Opinion	1	2.50
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>40</b>	<b>100</b>

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

<b>Total Applications Reviewed</b>	<b>21</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	2
Number of studies withdrawn prior to the meeting	0
Number of student applications reviewed	8
Number of paediatric applications reviewed	2
Number of device applications reviewed	16
Number of qualitative applications reviewed	5

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

<b>Decisions taken at proportionate review sub-committee meetings</b>	<b>Number</b>	<b>%</b>
Favourable Opinion with Standard Conditions	4	19.05
Favourable Opinion with Additional Conditions	6	28.57
No Opinion transfer to full committee for review	3	14.29
Provisional Opinion	8	38.10
Unfavourable Opinion	0	0.00
<b>Total</b>	<b>21</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>	4.00
<b>Number of completed applications for full ethical review</b>	40
<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>	11
<b>Number of completed applications over 40 days as a % of total</b>	27.50%
<b>Number of days taken to final decision – average (mean)</b>	36
<b>Number of completed proportionate review applications for ethical review</b>	18
<b>Number of completed proportionate review applications for ethical review over 14 days</b>	4
<b>Number of completed proportionate review applications over 14 days as a % of total</b>	22.22%
<b>Number of SSAs (non-Phase 1) reviewed</b>	1
<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>	48
<b>Number of completed substantial amendments over 35 days</b>	4
<b>Number of completed substantial amendments over 35 days as a % of total substantial amendments</b>	8.33%
<b>Number of completed substantial amendments over 28 days</b>	11
<b>Number of completed substantial amendments over 28 days as a % of total substantial amendments</b>	22.92%
<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 minor amendments received</b>	28
<b>Number of substantial amendments received for</b>	0

<b>information</b>	
<b>Number of substantial amendments received for new sites/PIs</b>	0
<b>Number of annual progress reports received</b>	41
<b>Number of safety reports received</b>	0
<b>Number of Serious Adverse Events received</b>	5
<b>Number of final reports received</b>	7

**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>
15/LO/0563	A relaxation intervention for pregnant women with hypertension	50
15/LO/0588	ShoulderLink	55
15/LO/0620	DESiVI	34
15/LO/0630	Natural History in Subjects with Fibrodysplasia Ossificans Progressiva	55
15/LO/0759	Ecotherapy and Quality of Life in Dementia- A Pilot Study	43
15/LO/0766	A novel robotic system for trans-anal endoscopic microsurgery	35
15/LO/0991	Retention of people with psychosis in the EPOS trial V1	32
15/LO/1007	Neurofeedback with fMRI for auditory hallucinations in schizophrenia	38
15/LO/1008	Low Birth-Weight in Newham: Parents' and professionals' experiences	29
15/LO/1051	NEST: NMDA-receptors in Epilepsy, Stroke and TBI.	29
15/LO/1101	Comparison of Ostomy Products (COOP)	31
15/LO/1329	Experiences of decision making in pre-dialysis patients ver.1	34
15/LO/1348	MyLifeHub: Internet of Things in Ophthalmic Care	39
15/LO/1420	BOND - Post-marketing clinical surveillance	36
15/LO/1496	Gender identity - young people who identify as neither male nor female	26
15/LO/1538	Essential tremor and brain MR guided focused ultrasound treatment	33
15/LO/1597	RejuvenAir™ System Chronic Bronchitis Version 2	36
15/LO/1628	CPLATFRM2104	26
16/LO/0007	Clinical Assessment of a Novel Microprobe Continuous Glucose Monitor	29
16/LO/0118	Valiant Evo International Clinical Trial	44
16/LO/0182	Smartphones for Continuous, Mobile Patient Assessment of Arthritis	54
16/LO/0207	Qualitative analysis of how individuals cope with stigma V1	53
16/LO/0209	The acute effects of Food Structure on Appetite Regulation	48
16/LO/0327	Outcomes after surgery for congenital cataract	53
16/LO/0400	Dopamine Receptor Imaging in Bipolar Disorder	42

<b>Further Information Favourable Opinion with Additional Conditions</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
16/LO/0379	SocketMaster	30

<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>

<b>Favourable Opinion with Additional Conditions</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
15/LO/0631	Volume blood flow in pregnancy	22
15/LO/0900	630-0012 Pulmonx LIBERATE Study	22
15/LO/1058	Ealing geko vs IPC	25
15/LO/1435	Intelligent oxygen therapy during activities of daily living	29
15/LO/2044	Clinical performance of Compass in the diagnosis of glaucoma, V5	35
15/LO/2049	The role of attachment in adherence to rehab programmes in SCI	25
16/LO/0183	Biomarkers of Delirium after Neck of Femur Fracture (BDA-NOF)	28
16/LO/0380	Midds Ankle Fracture	35

<b>Unfavourable Opinion</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
15/LO/0931	BOND - post marketing clinical follow up, medical device	21
15/LO/0980	Acquired Von Willebrand Syndrome and angiodysplasia in LVAD patients	50
15/LO/1128	Gender identity - young people who identify as neither male nor female	25
15/LO/2033	Brain Structure and function of children at risk for eating disorders	25
15/LO/2037	Tai chi for stroke survivors	38

<b>Provisional Opinion</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
16/LO/0191	Reducing social isolation and loneliness in Salford - Pilot Study	n/a

<b>Provisional Opinion Pending Consultation with Referee</b>		
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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
15/LO/1274	An Analysis of Long-Term Health Outcomes in Ex-Cricketers	11
15/LO/1638	Weight regain in patients post bariatric surgery.	8
15/LO/1639	Preclinical Development of Immunotherapy in Pancreatic cancer	12
15/LO/2043	A phenomenological study:"lived-experience after ectopic pregnancy	14
15/LO/2166	Multimodal imaging of ocular surface vasculature	20
16/LO/0321	Self-Management after Therapy for depression (SMarT)	13
16/LO/0324	REDUCER-I	16

#### Further Information Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
15/LO/1137	Effective Home Support Dementia Care: Costs Informal & Formal Care v.1	15

#### Further Information Unfavourable Opinion

REC Reference	Title	Number of Days on Clock
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<b>Favourable Opinion with Standard Conditions</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
15/LO/1455	The Relationship Between Obesity and Venous Disease (version 1)	10
15/LO/1643	BRAVO-EPIC and VESPER studies	13
15/LO/1865	Plasma sodium concentration and the risk of cardiovascular disease	10
15/LO/2168	3-Dimensional Cardiovascular Anatomy System (3D-CAS)	19

<b>Favourable Opinion with Additional Conditions</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
15/LO/1127	The role of collaborative team sport in mental health recovery	14
15/LO/1872	Changes in chronic pain experience V 1.0	6
16/LO/0097	TYA Cancer Patient Experiences	12
16/LO/0102	Using the iPad to detect visual field defects in stroke patients	3
16/LO/0104	International validation of the EORTC QLQ-CAX24	6
16/LO/0488	Patient's Views on Surgeon Specific Mortality Data	14

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

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

<b>Further information response not complete</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>

<b>Withdrawn after the meeting</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>

**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>
09/H0724/25/AM02	Phenotype/genotype correlation of Fuchs corneal dystrophy	V2	23/11/2015	18
10/H0724/38/AM03	SCD	Substantial Amendment 03 - 21s	17/09/2015	8
12/LO/1724/AM09	FiGaRO	v14.2, 21.1.16	21/01/2016	7
12/LO/1751/AM10	Development, Feasibility Testing and Refinement of HELP	4	26/03/2015	15
13/LO/0584/AM09	The POPPY St. Mary's MRI Sub-study	4	02/09/2015	19
13/LO/1254/AM04	EVERREST: Developing a therapy for Fetal Growth Restriction	AM 4; Date: 23 September	24/09/2015	18
13/LO/1254/AM05	EVERREST: Developing a therapy for Fetal Growth Restriction	5	07/12/2015	29
13/LO/1274/AM02	FOrMAT	2	07/08/2015	5
13/LO/1639/AM02	Correction of Angular Deformities in Knee Arthrosis	2	28/02/2015	8
13/LO/1643/AM03	Transgenerational aspects of PCOS	3	20/04/2015	24
13/LO/1741/AM05	Micra Transcatheter Pacing Study. Version 1. 19th June 2013.	4	12/06/2015	30
13/LO/1832/AM02	SAFETY AND EFFICACY EVALUATION OF HAIRSTETICS' HAIR IMPLANT	Amendment 6; Date: 30th July 2	21/10/2015	8
13/LO/1837/AM01	Radiocyst 01	001	22/06/2015	7
14/LO/0328/AM02	VMET 2	1	10/03/2015	34
14/LO/0328/AM03	VMET 2	AM03	14/11/2015	23
14/LO/0376/AM01	CLN0016	CLN0016 Version B,	09/10/2013	14
14/LO/0376/AM02	CLN0016	CLN0016 Rev D, Date: 24th Aug	16/10/2015	5
14/LO/0557/AM03	SCOPE-ME PREM development	Amendment 2; Date: 16.10.2015	19/10/2015	5
14/LO/0663/AM03	Brain connectivity in ASD: a biomarker to predict treatment response	3.0	17/03/2015	26
14/LO/0677/AM03	Preterm birth and executive attention	Amendment 3.0	14/07/2015	29

		16 June 2015		
14/LO/1090/AM04	Endobronchial valve vs. Standard of care in heterogeneous emphysema	Am04	21/04/2015	15
14/LO/1090/AM05	Endobronchial valve vs. Standard of care in heterogeneous emphysema	5; Dated: 25 September 2015	25/09/2015	13
14/LO/1157/AM01	PRIME: PRostate Imaging for Margin Evaluation	1	09/11/2015	42
14/LO/1209/AM01	Daisy Project: dysphagia following acute cervical spinal cord injury	SA1	19/11/2015	5
14/LO/1264/AM01	Image guidance with image overlay for laparoscopic surgery	Amendment No. 1. 13/08/2015	09/09/2015	13
14/LO/1488/AM03	QoL and Resilience following Orthognathic surgery- version 1	Amendment number: 2 10/08/2015	19/08/2015	34
14/LO/1611/AM02	Cook IVC filter Study (12-018)	1	06/05/2015	44
14/LO/1611/AM03	Cook IVC filter Study (12-018)	Amendment number 2, dated July	08/09/2015	13
14/LO/1611/AM04	Cook IVC filter Study (12-018)	AM03	01/01/2016	11
14/LO/1659/AM01	The Scenario Test Research Project version 1	1	08/01/2016	10
14/LO/1662/AM02	THEPCA (V1)	2	06/11/2015	42
14/LO/2099/AM01	Effect of 670 nm Light on Retinal Function in Birdshot V1	1	04/11/2015	27
14/LO/2160/AM01	Improving the detection of active TB in A&E departments (ACE Study)	2	02/07/2015	7
15/LO/0164/AM01	Knee functions and rehabilitation 12 months after knee replacement	01	19/06/2015	15
15/LO/0206/AM01	Shared Reading and Physical Health, Jan 2015	AM 01	12/06/2015	12
15/LO/0216/AM01	Women's experiences of second degree perineal tears: Version 2.1	1	19/03/2015	6
15/LO/0216/AM03	Women's experiences of second degree perineal tears: Version 2.1	3.1	09/04/2015	10
15/LO/0630/AM02	Natural History in Subjects with Fibrodysplasia Ossificans Progressiva	Amendment nÅ°2 (15 June 15) and	04/09/2015	14
15/LO/0630/AM03	Natural History in Subjects with Fibrodysplasia Ossificans Progressiva	2	10/11/2015	15
15/LO/0708/AM04	Understanding friendships in BAH youth	1, Date:	16/09/2015	11

		16/09/2015		
15/LO/0759/AM01	Ecotherapy and Quality of Life in Dementia- A Pilot Study	1	04/06/2015	2
15/LO/0900/AM02	630-0012 Pulmonx LIBERATE Study	2 UK; Date: 15 September 2015	25/09/2015	14
15/LO/1058/AM01	Ealing geko vs IPC	1.0; Date: 18 Sept 2015	30/09/2015	9
15/LO/1274/AM01	An Analysis of Long-Term Health Outcomes in Ex-Cricketers	Amendment 1, 02/09/2015	02/09/2015	18
15/LO/1274/AM02	An Analysis of Long-Term Health Outcomes in Ex-Cricketers	2; Date: 28/09/2015	28/09/2015	18
15/LO/1597/AM01	RejuvenAir <sup>®</sup> System Chronic Bronchitis Version 2	1	11/11/2015	29

### Unfavourable opinion

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
14/LO/0677/AM04	Preterm birth and executive attention	4.0	04/12/2015	41
14/LO/0843/AM01	Beyond TME version 1.2	AM01	15/06/2015	35

**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/0843/AM01/1	Beyond TME version 1.2	Version 1.4	08/03/2016	14

### Unfavourable opinion timeline - NONE

**Table 11: Items exceeding timelines****Full applications for ethical review over 60 day timeline - NONE****Proportionate review applications for ethical review over 14 day timeline**

REC Reference	Title	Number of Days on Clock
15/LO/1137	Effective Home Support Dementia Care: Costs Informal & Formal Care v.1	15
15/LO/2166	Multimodal imaging of ocular surface vasculature	20
15/LO/2168	3-Dimensional Cardiovascular Anatomy System (3D-CAS)	19
16/LO/0324	REDUCER-I	16

**SSAs (non Phase 1) over 25 day timeline**

REC Reference	Title	Number of Days on Clock
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**SSAs (Phase 1) over 14 day timeline**

REC Reference	Title	Number of Days on Clock
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**Substantial Amendments over 35 day timeline**

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
14/LO/0677/AM04	Preterm birth and executive attention	4.0	04/12/2015	41
14/LO/1157/AM01	PRIME: PRostate Imaging for Margin Evaluation	1	09/11/2015	42
14/LO/1611/AM02	Cook IVC filter Study (12-018)	1	06/05/2015	44
14/LO/1662/AM02	THEPCA (V1)	2	06/11/2015	42

**Modified Amendments over 14 day timeline**

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
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