

**London - Camden & Kings Cross Research Ethics  
Committee**

**Annual Report**

**01 April 2015 - 31 March 2016**



## Part 1 – Committee Membership and Training

<b>Name of REC:</b>	London - Camden & Kings Cross Research Ethics Committee
<b>Type of REC:</b>	Authorised
<b>Type of Flag:</b>	Adults Lacking Capacity, Qualitative Research, Research involving Children
<b>Chair:</b>	Mrs Rosie Glazebrook
<b>Vice-Chair:</b>	Ms Heidi Chandler
<b>Alternate Vice-Chair:</b>	Ms Eleni Yerolaki
<b>REC Manager:</b>	Miss Christie Ord
<b>REC Assistant:</b>	Ms Kirstie Penman
<b>Committee Address:</b>	HRA Jarrow Jarrow Business Centre Rolling Mill Road Jarrow NE32 3DT
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## Chair's overview of the past year:

Our committee strives to be friendly, hardworking and fair. We have received positive feedback from a number of research teams who commented on our efficiency, constructive approach and helpful advice. We make every effort to support researchers and want to make sure there is an open and honest discussion and key points are covered.

Members of our committee have wide-ranging expertise. We have lay and clinical members who have skills and experience in medical law and ethics, paediatrics, primary and secondary care, mental health, research management, and voluntary, public and private sector organisations. The committee has expertise, in particular, on reviewing research involving children, and involving participants subject to Mental Capacity Act considerations and qualitative research and we are currently flagged in these areas alongside the standard caseload.

The quality of most of the research studies we see is good, well-considered and well presented. The changes we most often ask for are ones more to do with the information provided to potential participants: and mainly to make it more likely they will agree to take part. There is often room for improvement and it would be helpful if research teams had earlier input from patients/members of the public in developing materials for potential participants, particularly in studies involving children and those with learning difficulties.

Our committee continues to work well and our members are very committed and put in a lot of work in preparation for meetings, sub-committee meetings and the proportionate review caseload. Those researchers who attend our meetings see us for only a short time, but they rapidly realise that we have looked at their applications very carefully and focus on the ethical issues from a participants' perspective.

We are delighted to welcome Julia Crenian, Petra Shroff and Beverley Taylor to our committee as new members. We are sorry to say goodbye to Dr Sati Ariyanayagam, Catherine Max, Fran Percival and Dr Joseph Hayes and thank them for their hard work and contribution.

## London - Camden & Kings Cross Research Ethics Committee Membership

Name	Profession	Expert or Lay	Dates	
			Appointed	Left
Dr Afia Ali	Psychiatrist	Expert	01/10/2011	
Dr Sati Ariyanayagam	Retired Consultant Physician	Expert	01/07/2011	01/09/2015
Ms Heidi Chandler	Deputy Research Delivery Manager	Lay	24/07/2008	
Mrs Julia Crenian	Volunteer with Home-Start	Lay Plus	01/10/2015	
Dr Sangeeta Dave	Senior Clinical Research Associate	Expert	01/10/2011	
Mrs Rosie Glazebrook	Consumer Marketing	Lay	01/01/2013	
Dr Joseph Hayes	Psychiatrist	Expert	08/07/2014	29/02/2016
Miss Jessica Hughes	Director, Corporate Public Policy	Lay Plus	01/09/2014	
Ms Catherine Max	Independent Consultant (sustainability, health and social care).	Lay	12/06/2013	31/12/2015
Dr Jacqueline Maxmin	Retired GP	Expert	01/05/2013	
Mrs Frances Percival	Professional & Scientific Consultant	Expert	18/04/2011	28/04/2015
Dr Andy Petros	Consultant Paediatric Intensivist	Expert	01/09/2011	
Ms Petra Shroff	Paediatric Nurse	Expert	06/05/2015	
Mr Jonathan Simons	Investment Manager	Lay Plus	07/03/2013	
Mrs Beverley Taylor	Lawyer	Lay Plus	06/05/2015	
Ms Mary Watkinson	Teacher	Lay Plus	06/02/2013	28/10/2015
Ms Eleni Yerolaki	Specialist Counsellor	Lay	20/06/2006	

## London - Camden & Kings Cross Research Ethics Committee: Deputy Members

None.

## London - Camden & Kings Cross Research Ethics Committee: Co-opted Members

Name	Profession	Status	Meeting date attended
Dr Lorraine Ludman	Chartered Psychologist	Lay	25/01/2016
Dr Ralph White	Pharmacist	Expert	07/09/2015
Dr Jan Downer	Consultant Anaesthetist	Expert	05/10/2015

**London - Camden & Kings Cross Research Ethics Committee: Members' Declarations of Interest:**

<b>Name</b>	<b>Declaration of Interest</b>	<b>Date</b>
Dr Afia Ali	None declared,	31/03/2016
Ms Heidi Chandler	Seconded to the NIHR Clinical Research Network as a deputy research delivery manager. ROle is involved with the setting up of clinical research in the NHS. Lay reviewer of funding applications for the NIHRs Health Technology Assessment funding stream	27/01/2016
Mrs Julia Crenian	Volunteer for Home-Start UK and assisted with fundraising for Cancer Research UK (once a year).	31/03/2016
Dr Sangeeta Dave	None declared.	31/03/2016
Mrs Rosie Glazebrook	Non-Executive Director of Public Health England Non-Executive Director of Human Tissue Authority Board Member of General Optical Council	31/03/2016
Miss Jessica Hughes	Work full time for GSK as director of corporate public policy. hold shares in GSK	17/02/2016
Dr Jacqueline Maxmin	None	17/02/2016
Dr Andy Petros	None	17/02/2016
Ms Petra Shroff	Research undertaken on NICU/PICU @ GOSH	24/02/2016
Mr Jonathan Simons	None declared.	31/03/2016
Mrs Beverley Taylor	None	31/03/2016
Ms Eleni Yerolaki	None declared.	27/01/2016

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

Month	Date	Number of Members Present at Meeting
April	27/04/2015	12
June	01/06/2015	11
June	29/06/2015	10
September	07/09/2015	9
October	05/10/2015	8
November	02/11/2015	9
November	30/11/2015	10
January	25/01/2016	11
February	29/02/2016	11
March	21/03/2016	10

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	14/04/2015	3
May	12/05/2015	3
June	18/06/2015	3
July	16/07/2015	3
August	24/08/2015	3
November	24/11/2015	3
December	15/12/2015	3
January	19/01/2016	3
February	15/02/2016	3
March	15/03/2016	3

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

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

Month	Date	Number of Members Present at Meeting
April	02/04/2015	2
April	17/04/2015	2
May	01/05/2015	2
May	15/05/2015	2
May	29/05/2015	2
June	12/06/2015	2
June	26/06/2015	2
July	10/07/2015	2
July	24/07/2015	2
August	06/08/2015	2
August	21/08/2015	2
September	04/09/2015	2

September	18/09/2015	2
October	01/10/2015	3
October	14/10/2015	2
October	27/10/2015	2
November	13/11/2015	2
December	04/12/2015	2
December	18/12/2015	2
January	08/01/2016	2
January	27/01/2016	2
February	24/02/2016	2
March	08/03/2016	2
March	23/03/2016	2

24 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>
Mrs Rosie Glazebrook	9
Miss Jessica Hughes	8
Dr Jacqueline Maxmin	8
Mrs Beverley Taylor	8
Ms Eleni Yerolaki	8
Ms Heidi Chandler	7
Mr Jonathan Simons	7
Dr Afia Ali	6
Mrs Julia Crenian	6
Dr Joseph Hayes	6
Ms Catherine Max	6
Ms Petra Shroff	6
Dr Andy Petros	5
Dr Sangeeta Dave	3
Dr Sati Ariyanayagam	2
Ms Mary Watkinson	2
Mrs Frances Percival	1

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

<b>Name</b>	<b>Number of Meetings Attended</b>
Mrs Rosie Glazebrook	5
Ms Heidi Chandler	4
Dr Andy Petros	4
Mr Jonathan Simons	3
Dr Sangeeta Dave	2
Miss Jessica Hughes	2
Dr Jacqueline Maxmin	2
Ms Eleni Yerolaki	2
Dr Afia Ali	1
Dr Sati Ariyanayagam	1
Ms Catherine Max	1
Mr Paddy Stevenson	1
Mrs Beverley Taylor	1
Ms Mary Watkinson	1



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

<b>Name</b>	<b>Number of Meetings Attended</b>
Mrs Rosie Glazebrook	14
Ms Heidi Chandler	9
Ms Eleni Yerolaki	6
Dr Afia Ali	4
Dr Sangeeta Dave	2
Dr Joseph Hayes	2
Miss Jessica Hughes	2
Ms Catherine Max	2
Dr Jacqueline Maxmin	2
Mr Jonathan Simons	2
Mrs Beverley Taylor	2
Dr Sati Ariyanayagam	1
Dr Andy Petros	1

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

<b>Name of Member</b>	<b>Date</b>	<b>Event(s) attended</b>
Dr Afia Ali	26/11/2015	Regional Training Day
Dr Sati Ariyanayagam	16/04/2015	Quantitative Research Methods & Statistics
Ms Heidi Chandler	01/09/2015	Equality & Diversity
Ms Heidi Chandler	26/11/2015	Regional Training Day
Mrs Julia Crenian	10/02/2016	Committee Members Induction
Mrs Rosie Glazebrook	10/10/2015	Equalit and Diversity
Ms Catherine Max	26/11/2015	Regional Training Day
Dr Jacqueline Maxmin	12/10/2015	Training - Complex Cases
Dr Jacqueline Maxmin	26/11/2015	Regional Training Day
Dr Andy Petros	31/03/2016	2015-16 SDL
Ms Petra Shroff	24/09/2015	Training - Committee Members Induction
Ms Petra Shroff	19/10/2015	The Ethical Issues of Research Involving Children
Mrs Beverley Taylor	15/06/2015	Members Induction
Ms Mary Watkinson	07/10/2015	Introduction to Phase 1 Research - Trials & Regulation.
Ms Eleni Yerolaki	21/09/2015	Researcher Training Day
Ms Eleni Yerolaki	04/02/2016	Researcher 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	57	100.00
<b>Total Applications Reviewed</b>	<b>57</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	21
Number of paediatric applications reviewed	12
Number of device applications reviewed	2
Number of prisoner applications reviewed	0
Number of applications involving adults unable consent reviewed	16
Number of applications reviewed that are funded by the US DHHS	0
Number of qualitative applications reviewed	9

**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	2	3.51
Favourable Opinion with Additional Conditions	10	17.54
Unfavourable Opinion	2	3.51
Provisional Opinion	43	75.44
Provisional Opinion Pending Consultation with Referee	0	0.00
<b>Total</b>	<b>57</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**

<b>Status of applications at date of generation of report</b>	<b>Number</b>	<b>%</b>
Further Information Favourable Opinion with Standard Conditions	21	36.84
Further Information Favourable Opinion with Additional Conditions	19	33.33
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	2	3.51
Favourable Opinion with Additional Conditions	10	17.54
Unfavourable Opinion	2	3.51
Provisional Opinion	2	3.51
Provisional Opinion Pending Consultation with Referee	0	0.00
Further Information response not complete	0	0.00
No decision entered on system	0	0.00
Number of studies withdrawn after the meeting	1	1.75
<b>Total</b>	<b>57</b>	<b>100</b>

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

<b>Total Applications Reviewed</b>	<b>28</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	13
Number of studies withdrawn prior to the meeting	2
Number of student applications reviewed	10
Number of paediatric applications reviewed	4
Number of device applications reviewed	1
Number of qualitative applications reviewed	4

**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	17	60.71
Favourable Opinion with Additional Conditions	3	10.71
No Opinion transfer to full committee for review	4	14.29
Provisional Opinion	3	10.71
Unfavourable Opinion	1	3.57
<b>Total</b>	<b>28</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>	5.70
<b>Number of completed applications for full ethical review</b>	56
<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>	2
<b>Number of completed applications over 40 days as a % of total</b>	3.51%
<b>Number of days taken to final decision – average (mean)</b>	28
<b>Number of completed proportionate review applications for ethical review</b>	24
<b>Number of completed proportionate review applications for ethical review over 14 days</b>	0
<b>Number of completed proportionate review applications over 14 days as a % of total</b>	0.00%
<b>Number of SSAs (non-Phase 1) reviewed</b>	7
<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>	70
<b>Number of completed substantial amendments over 35 days</b>	0
<b>Number of completed substantial amendments over 35 days as a % of total substantial amendments</b>	0.00%
<b>Number of completed substantial amendments over 28 days</b>	4
<b>Number of completed substantial amendments over 28 days as a % of total substantial amendments</b>	5.71%
<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 minor amendments received</b>	61
<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>	43
<b>Number of safety reports received</b>	0
<b>Number of Serious Adverse Events received</b>	14

<b>Number of final reports received</b>	7
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**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/0611	Adjustment to Care in Dementia: An Intervention Feasibility Study v0.1	30
15/LO/0660	Coagulation in Critical Care	25
15/LO/0670	Use of Video Technology to assist Occupational Therapists with discharging stroke patients	28
15/LO/0674	VOLUME 6	26
15/LO/0933	Diagnosing and monitoring infection in critical illness	38
15/LO/0944	ACtiF - Adherence to treatment in adults with Cystic Fibrosis 2.1C	28
15/LO/0953	Development of an informative patient resource for medical education	30
15/LO/1010	Attachment and mentalization as predictors of family therapy outcome	29
15/LO/1061	The association between hyperactivity and ITW	30
15/LO/1346	EURObservational Cardiomyopathy and Myocarditis Registry	35
15/LO/1518	Cardiac amyloid imaging using 18F-florbetapir (CARDIFF)	29
15/LO/1809	Aqueous Dynamics and Glaucoma Surgery	28
15/LO/1875	Experience of mood episodes for people diagnosed with bipolar disorder	30
15/LO/1967	Mindfulness meditation for chronic pelvic pain management	48
16/LO/0095	Time intensive CBT for a Specific Phobia of Vomiting - Version 1	26
16/LO/0214	G-PATH SUPPORT:Gastrostomy feeding and psychosocial support	29
16/LO/0253	Use of PET/MRI in assessing treatment response for cervix cancer.	27
16/LO/0393	Sleep and learning in childhood tic disorders	41
16/LO/0454	LUNG COOL TRIAL	36
16/LO/0465	Longitudinal Investigation of FTD and associated disorders (LIFTD)	31
16/LO/0471	Creativity and Forensic Mental Health v1.0	36

<b>Further Information Favourable Opinion with Additional Conditions</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
15/LO/0658	Hilotherm therapy following surgical wisdom tooth removal Version 1.1	31
15/LO/0688	Adaptation of measures for adolescents with ID	28
15/LO/1004	The unfolding movement in therapeutic conversations with families	23
15/LO/1067	Scleral vs Corneal RGP contact lenses in irregular cornea disorders	25
15/LO/1098	Evaluation of the response to wide diameter dental implants 1	27
15/LO/1099	Evaluation of the response to wide diameter dental implants 2	27
15/LO/1355	Questionnaire study in Xeroderma Pigmentosum	31



15/LO/1395	Interview study in Xeroderma Pigmentosum	30
15/LO/1442	Investigation of the revised Wessex head Injury Matrix (WHIM-II)	29
15/LO/1568	Bio-TBI	29
15/LO/1764	Mr. Burns (Metabolic Rate in Burns)	33
15/LO/1802	Designing a digital intervention to help when choosing contraception	30
15/LO/1804	Exercise for adults with crohn's disease trial	25
15/LO/1810	Pilot Study - Primary glaucoma surgery for patients of African Descent	34
15/LO/1949	Early Development in Tuberous Sclerosis (EDiTS)	29
15/LO/1960	ECLIPSE Study 9: Implementation of Remediation into EI Services	23
16/LO/0096	PET in HIV Study	24
16/LO/0099	Plasma oncotic pressure as a predictor of renal failure	30
16/LO/0320	A study of refugee and asylum-seeker experiences of NET for PTSD	32

#### 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
15/LO/1955	Unified high-dimensional modelling in stroke patients v1.0	22
16/LO/0094	Evaluating provision for children with Down syndrome	22

#### Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
15/LO/0950	PREDICTORS 5.0 - Stability Study	18
15/LO/0974	Copper Impact on Venous Insufficiency and Lipodermatosclerosis	18
15/LO/1071	Primary Radiotherapy And DIEP flAp reconstruction (PRADA) study	20
15/LO/1605	Haemodynamics after coarctation repair during isometric exercise	23
15/LO/1811	Multimodal MRI scanning of NHS patients referred from clinics for brain disorders	22
15/LO/1931	The prognostic implication of coronary wave intensity analysis	22
16/LO/0054	Melanoma in HIV	22
16/LO/0078	Impact of art therapy on sense of self in individuals with psychosis	22
16/LO/0328	Can latent tuberculosis be treated effectively in primary care?	25
16/LO/0455	Health communication and people with learning disabilities	28

<b>Unfavourable Opinion</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
15/LO/1036	Understanding Visual Snow Syndrome	22
15/LO/1615	High Functioning Autistic Disorders in MSUs - Pathways & Co-morbidity	23

<b>Provisional Opinion</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
16/LO/0313	Cytokine clearance in AKI (ClicAKI)	n/a
16/LO/0468	Reducing drug-related admissions from Care Homes, improving well-being	n/a

<b>Provisional Opinion Pending Consultation with Referee</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>
15/LO/0956	Do Parents Know What Children are Watching? Screen Time.	18

**Table 9.2: Breakdown of current status of all PRS 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/0912	Basophil activation test in pollen food syndrome-version 2	13
16/LO/0189	Bisphosphonates and oral health management in the community: version 1	11
16/LO/0504	IDEAL-PM	11

<b>Further Information Favourable Opinion with Additional Conditions</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>

<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>
15/LO/0709	Friendships of youth with Perinatally Acquired HIV (Version 2)	7
15/LO/0712	Routine assessment of frailty in older people - Frail Clinic	7
15/LO/1140	Exhaled breath metabolite signals of disease and surgical stress	12
15/LO/1270	Biomarkers predict response to XELOX and Avastin in mCRC- Version 1.0	11
15/LO/1303	The role of the tumour microenvironment in thyroid cancer.	9
15/LO/2076	Learning from exceptional general practices to improve quality of care	10
15/LO/2090	The salivary glycome as a novel diagnostic marker in oral cancer	9
15/LO/2104	A laboratory evaluation of a chlorhexidine surgical incise drape	9
15/LO/2186	What do people with chronic pain think about when they answer the TSK?	12
16/LO/0181	Predicting who benefits from injections for chronic low back pain v1.0	10
16/LO/0200	Cluster RCT of falls prevention Exergames for older adults	9
16/LO/0343	Pilot evaluation of low-intensity CBT in NI Version 1	8
16/LO/0344	EDACS - stability and associations with growth	13
16/LO/0345	DUOGLOBE	9
16/LO/0494	Therapy for digestive and bronchopulmonary neuroendocrine tumours	13
16/LO/0499	Impacts and Treatment of OLP	14
16/LO/0503	Treatment choices and outcomes in the National Lung Cancer Audit	13

<b>Favourable Opinion with Additional Conditions</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
15/LO/0702	Conjunctival blood flow during cardiac surgery	7
15/LO/1275	Perceptions and Attitudes of People undergoing LVA	11
15/LO/1521	Raynaud's Symptoms in Systemic Sclerosis Study	13

**Unfavourable Opinion**

REC Reference	Title	Number of Days on Clock
15/LO/2192	Automated ultrasound image analysis to assess cardiac function	11

**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
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**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>
10/H0722/79/AM18	Patient entered outcomes	Substantial Amendment 15, 05/0	26/03/2015	5
10/H0722/79/AM20	Patient entered outcomes	Substantial Amendment 16, 17/0	23/07/2015	14
10/H0722/79/AM21	Patient entered outcomes	Substantial Amendment 17	26/08/2015	20
11/H0722/8/AM07	Rapid Identification via Interferon Gamma test for Active Tuberculosis	Substantial Amendment 7 (AM07)	17/03/2015	14
11/LO/0908/AM06	Radiosurgery or Open Surgery for Epilepsy (ROSE) Trial	Substantial Amendment 6, 09/04	12/04/2015	24
12/LO/0141/AM02	Genetic study of inherited retinal disease	Substantial Amendment 2 - 7/6/	07/06/2015	27
12/LO/0988/AM05	CORE: Crisis Team Optimisation and Relapse Prevention - Phase 3	Substantial Amendment 3 - 1/7/	01/07/2015	20
12/LO/0988/AM06	CORE: Crisis Team Optimisation and Relapse Prevention - Phase 3	Substantial Amendment 4 - 19/11/2015	30/11/2015	18
12/LO/1176/AM07	Streamline C	Substantial Amendment 6, 27/08	27/08/2015	16
12/LO/1177/AM05	Streamline L	Substantial Amendment 5	26/06/2015	22
13/LO/0082/AM07	NIPT Implementation Study	Substantial Amendment 6 - 1/7/	01/07/2015	25
13/LO/0091/AM04	MRS assay of glutamate-GABA in autism	Substantial Amendment 4 - 2/6/	02/06/2015	28
13/LO/0495/AM01	Comparison of MBCT, relaxation and waiting list in tinnitus management	Substantial Amendment 1	01/07/2015	21
13/LO/0900/AM05	An investigation into the mechanisms of lung injury and repair.	Substantial	13/03/2015	30

		Amendment 4, March		
13/LO/0900/AM06	An investigation into the mechanisms of lung injury and repair.	Substantial Amendment 5	22/05/2015	21
13/LO/1124/AM05	Aerosure during six-minute walk tests in COPD	Amendment 2, 06.05.15	06/05/2015	10
13/LO/1269/AM01	Immunobiology of leprosy version 4	Substantial Amendment 1	01/05/2015	7
13/LO/1315/AM03	Biomarker identification in lymphoproliferative disorders	Substantial Amendment 2 - 10/7	10/07/2015	20
13/LO/1546/AM05	TRACERx	Substantial Amendment 4	28/07/2015	9
13/LO/1546/AM06	TRACERx	SA5	12/02/2016	9
13/LO/1901/AM07	Blood oxygen carrying capacity, iron, CPET and POMS - a pilot study	Substantial Amendment Protocol	26/05/2015	28
13/LO/1902/AM07	Oxygen carrying capacity in the clinical setting - a pilot	Substantial Amendment 2, 10/04	26/05/2015	21
14/LO/0107/AM05	CORE: Crisis Team Optimisation and Relapse Prevention - Phase 4	Substantial Amendment 2	03/08/2015	20
14/LO/0107/AM06	CORE: Crisis Team Optimisation and Relapse Prevention - Phase 4	Substantial Amendment 1	25/06/2015	29
14/LO/0266/AM02	Infection In Children Attending The Emergency Department (ICED)	Substantial Amendment 1	12/11/2015	28
14/LO/0303/AM02	The UK-AIH Cohort	Substantial Amendment 2: Proto	15/05/2015	17
14/LO/0303/AM04	The UK-AIH Cohort	SA 3	02/11/2015	14
14/LO/0505/AM02	Protective TB	Substantial Amendment 2, 02/02	30/03/2015	18
14/LO/0505/AM03	Protective TB	Substantial Amendment 4	09/08/2015	11
14/LO/0612/AM01	Care of Late Stage Parkinsonism (CLaSP)	Substantial Amendment 2,	26/03/2015	23

		25/02		
14/LO/0633/AM03	Decellularisation of tissues for use as scaffolds in ortho repair.	Substantial Amendment 3	14/08/2015	4
14/LO/0640/AM02	The Bluebelle Study: Phase A	Substantial Amendment 2, 16/06	03/07/2015	18
14/LO/1117/AM02	PICTURE BREAST - Longitudinal	2.0	20/05/2015	11
14/LO/1118/AM02	Keep Safe: feasibility of CBT groups for young people with ID & HSB	2	31/03/2015	10
14/LO/1136/AM03	Non-invasive diagnostic testing for Gastro-intestinal disease	Substantial Amendment 1	21/10/2015	20
14/LO/1150/AM02	SERENADE	Substantial Amendment 2, 24/03	17/04/2015	15
14/LO/1150/AM03	SERENADE	Substantial Amendment 3 - 16/7	16/07/2015	13
14/LO/1517/AM03	SHAPED (v1.0)	Substantial Amendment 3, 11/05	27/05/2015	15
14/LO/1684/AM01	Body composition, the brain and human life history v1.01	Substantial Amendment 1	14/09/2015	14
14/LO/1698/AM01	Home based health promotion for vulnerable older people	Substantial Amendment 1, 10/09	16/09/2015	8
14/LO/1901/AM02	Plaque Erosion Pilot Study (PEPS)	Substantial Amendment 1.14, 12	20/07/2015	15
14/LO/1912/AM01	Coping with chronic pain.	Substantial Amendment 1	05/01/2016	22
14/LO/2216/AM02	COPD Exacerbations and Environmental Exposure Modelling	Substantial Amendment 2, 26/05	27/05/2015	22
14/LO/2216/AM03	COPD Exacerbations and Environmental Exposure Modelling	Substantial Amendment 3, 15/06	16/06/2015	22
14/LO/2216/AM04	COPD Exacerbations and Environmental Exposure Modelling	Substantial	24/09/2015	7

		Amendment 4, 21/09		
14/LO/2217/AM01	Risk Factors Leading to Hospital Infection	Substantial Amendment 1, 24/04	04/06/2015	29
14/LO/2235/AM03	Trial of Electronic Cigarettes (TEC)	Substantial Amendment 1, 29/05	24/06/2015	19
15/LO/0048/AM02	Effect of maternal TB infection on infant response to BCG immunisation	Substantial Amendment 1	14/09/2015	14
15/LO/0048/AM03	Effect of maternal TB infection on infant response to BCG immunisation	SA2	08/03/2016	14
15/LO/0085/AM01	Development and Validation of the ACB	Substantial Amendment 1, 14/08	22/09/2015	7
15/LO/0085/AM02	Development and Validation of the ACB	SA2	23/11/2015	21
15/LO/0085/AM03	Development and Validation of the ACB	SA 4	27/01/2016	7
15/LO/0097/AM01	Parkinson's Families Project (PFP)	Substantial Amendment 1, 14/05	01/06/2015	32
15/LO/0125/AM01	Understanding variability in the phenotype of long QT syndrome	Substantial Amendment 1 - 1/7/	01/07/2015	19
15/LO/0156/AM01	After the Liverpool Care Pathway	SA1	07/12/2015	26
15/LO/0311/AM03	Handlebar Grip Related Injury Prevention (GRIP) Feasibility Study	Substantial Amendment 2	26/05/2015	17
15/LO/0431/AM01	MELODY	Substantial Amendment 1	02/11/2015	11
15/LO/0511/AM03	E-Compared (version 1.11)	SA1	25/02/2016	11
15/LO/0702/AM01	Conjunctival blood flow during cardiac surgery	1	24/02/2016	12
15/LO/0709/AM01	Friendships of youth with Perinatally Acquired HIV (Version 2)	Substantial Amendment 1	17/06/2015	21
15/LO/0944/AM01	ACtiF - Adherence to treatment in adults with Cystic Fibrosis 2.1C	Substantial Amendment 1	27/08/2015	21
15/LO/0944/AM03	ACtiF - Adherence to treatment in adults with Cystic Fibrosis 2.1C	Substantial Amendment 2	11/11/2015	24
15/LO/0944/AM04	ACtiF - Adherence to treatment in adults with Cystic Fibrosis 2.1C	Amendment 4	27/02/2016	7



15/LO/1010/AM01	Attachment and mentalization as predictors of family therapy outcome	Substantial Amendment 1	23/07/2015	14
15/LO/1355/AM01	Questionnaire study in Xeroderma Pigmentosum	SA1	12/02/2016	19
15/LO/1804/AM01	Exercise for adults with crohn's disease trial	Substantial Amendment 1 - 11/03/2016	11/03/2016	13
16/LO/0181/AM01	Predicting who benefits from injections for chronic low back pain v1.0	SA1	10/02/2016	12

#### Unfavourable opinion

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
06/Q0511/54/AM01	Assessment of hepatic fibrosis with FibroScan compared to liver biopsy	Substantial Amendment 1 - 20/08/2015	11/12/2015	18
14/LO/1353/AM01	Wellbeing in young people with neurological conditions	Substantial Amendment 1 - 15/7	15/07/2015	14
14/LO/2241/AM02	Investigating migraine with novel MRI methods Version 1	Substantial amendment 1	01/08/2015	18

**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/2241/AM02/1	Investigating migraine with novel MRI methods Version 1	Modified Amendment 2	22/10/2015	5

#### 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 14 day timeline**

REC Reference	Title	Number of Days on Clock
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**SSAs (non Phase 1) over 25 day timeline**

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

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

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
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**Modified Amendments over 14 day timeline**

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
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