

**London - City Road & Hampstead Research Ethics
Committee**

Annual Report

01 April 2015 - 31 March 2016



Part 1 – Committee Membership and Training

Name of REC:	London - City Road & Hampstead Research Ethics Committee
Type of REC:	Authorised REC
Type of Flag:	Research Tissue Bank
Chair:	Dr David Slovick
Vice-Chair:	Mr Hari Jayaram (Break in Service 15/09/2014-31/03/2016) Mr David Burbidge (Acting Vice-Chair 15/09/2014-31/03/2016)
Alternate Vice-Chair:	Mr David Burbidge (upto 15/09/2014) Dr Koula Asimakopoulou (Acting Alternate Vice-Chair 15/09/2014-31/03/2016)
REC Manager:	Maeve Groot Bluemink (01/01/2015 – 31/10/2015) Mr Rajat Khullar (31/10/2015 – 31/3/2016)
REC Assistant:	Mr Wai Yeung (31/10/2015 – 31/3/2016)
Committee Address:	Level 3, Block B Whitefriars Lewins Mead Bristol BS1 2NT
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Chair's overview of the past year:

The London - City Road and Hampstead REC closed on 01/04/2016 and we are very grateful to the Chair, officers and members of the REC for the excellent service they provided over the last few years to the research community.

Regards

Tom Lucas

Regional Manager for Bristol

Health Research Authority

London - City Road & Hampstead Research Ethics Committee Membership

Name	Profession	Expert or Lay	Dates	
			Appointed	Left
Dr Koula Asimakopoulou	Reader in Health Psychology	Expert	01/07/2011	
Mr Sam Booth	Research Nurse	Expert	01/09/2015	
Mr David Burbidge	Communications/Marketing Development Officer (Retired)	Lay Plus	01/03/2013	
Mr Thomas Dowe	Tissue Collection Officer	Lay	14/10/2014	
Mrs Ros Goldfarb	Immigration Judge (Retired)	Lay Plus	01/08/2009	
Miss Hattie Ismail	Divisional Governance Coordinator	Lay	01/04/2013	07/10/2015
Dr Imran Jawaid	General Practitioner	Expert	01/09/2014	
Mr Hari Jayaram	Academic Clinical Lecturer in Ophthalmology	Expert	01/07/2007	
Professor Diana Kornbrot	Professor of Mathematical Psychology	Expert	30/09/2008	
Miss Jennifer Lawson	Trials Manager	Lay	01/05/2015	
Mr Alex Shortt	MRC Clinical Research Fellow	Expert	13/01/2015	28/10/2015
Dr David Slovic	Consultant Physician	Expert	21/03/2007	
Dr Seetal Snoek	Anaesthetic Registrar	Expert	01/03/2014	
Mr Thomas Weijburg	Lead Complementary Therapist	Lay	04/07/2013	

London - City Road & Hampstead Research Ethics Committee: Deputy Members

Name	Profession	Status	Meeting date attended
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London - City Road & Hampstead Research Ethics Committee: Co-opted Members

Name	Profession	Status	Meeting date attended
Mr John Richardson	Retired Director of COREC: former Ecumenical Officer for Churches Together in South London	Lay Plus	11/11/2015, 21/11/2015
Mrs Sally Gordon-Boyd	Medical Ethicist	Lay Plus	16/09/2015
Ms Stephanie Ellis	Civil Servant (Retired)	Lay Plus	16/09/2015, 27/01/2016
Ms Jane Batchelor	Centre Administrator, Advanced Cardiovascular Imaging	Lay Plus	11/11/2015, 21/11/2015
Ms Ann Malkin	Consultant Psychologist	Expert	10/06/2015
Mr Roger Maran	Barrister	Lay Plus	11/11/2015, 21/11/2015
Reverend Catherine	Vicar	Lay	13/01/2016, 27/01/2016

McBride			
Mr Roy Sinclair	Pharmacist	Lay	11/11/2015, 21/11/2015
Mr Evan Stone QC	Retired Queen's Counsel	Lay	15/07/2016
Mrs Elizabeth Reeves	Clinical Trials Training Executive	Lay	13/01/2016, 27/01/2016

London - City Road & Hampstead Research Ethics Committee: Members' Declarations of

Name	Declaration of Interest	Date
Dr Koula Asimakopoulou	None	31/03/2016
Mr Sam Booth	Current employment as a clinical trials research nurse	16/09/2015
Mr David Burbidge	Member, National Health Education England North Central and East London Local Education Board. Co Chair of the Board of Directors, Tower Hamlets Health Watch. Director, Rainbow Hamlets.	23/04/2015
Mr Thomas Dowe	Tissue Collection Officer for the Bart's Gynae Tissue Bank of Queen Mary, University of London	31/03/2016
Mrs Ros Goldfarb	None	31/03/2016
Miss Hattie Ismail	None	27/04/2015
Dr Imran Jawaid	Expert Reviewer of Potential Research Topics at the NIHR	16/09/2015
Mr Hari Jayaram	None	31/03/2016
Professor Diana Kornbrot	University of Hertfordshire Emeritus Professor as well as some consulting/research/teaching work Connection with BPS Ethics Committee and BPS Division of Health Psychology Committee	25/04/2015
Miss Jennifer Lawson	None	31/03/2016
Mr Alex Shortt	Review of grant applications for the MRC, Wellcome Trust and BBSRC. Expert advisor for the European Medicines Agency. Receives payment for education talks sponsored by the pharmaceutical company Thea Pharmaceuticals.	23/04/2015
Dr David Slovick	None	31/03/2016
Dr Seetal Snoek	None	31/03/2016
Mr Thomas Weijburg	Contribution towards a publication of a clinical study managed by himself	31/03/2016

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

Month	Date	Number of Members Present at Meeting
April	15/04/2015	8
June	10/06/2015	8
July	15/07/2015	9
September	16/09/2015	9
October	14/10/2015	7
November	11/11/2015	6
November	21/11/2015	7
December	16/12/2015	6
January	08/01/2016	7
January	13/01/2016	6
January	27/01/2016	7

11 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	15/04/2015	3
May	13/05/2015	3
June	10/06/2015	3
July	15/07/2015	3
October	14/10/2015	3
January	13/01/2016	3

6 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	10/04/2015	2
April	17/04/2015	2
April	24/04/2015	2
May	08/05/2015	2
May	15/05/2015	2
June	19/06/2015	2
June	26/06/2015	3
July	03/07/2015	2
July	10/07/2015	2
July	17/07/2015	2
July	24/07/2015	3
August	07/08/2015	3
August	14/08/2015	2

September	04/09/2015	2
September	04/09/2015	2
September	18/09/2015	2
October	09/10/2015	2
October	12/10/2015	3
October	26/10/2015	3
November	09/11/2015	2
December	04/12/2015	2
December	22/12/2015	2
December	23/12/2015	2
December	23/12/2015	2
January	11/01/2016	3
January	22/01/2016	3
February	01/02/2016	3
February	15/02/2016	2
February	22/02/2016	2
February	29/02/2016	2
March	10/03/2016	2
March	24/03/2016	2

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

Details of inquorate meeting held:01 April 2015 - 31 March 2016

Date	Reason	Action taken
11/11/2015	Less than 7 members present	A subsequent quorate meeting was held on 21/11/2015 to consider the applications reviewed at the original meeting and to agree the ethical decision for each application.
16/12/2015	Less than 7 members present	A subsequent quorate meeting was held on 08/01/2016 to consider the applications reviewed at the original meeting and to agree the ethical decision for each application.
27/01/2016	Less than 7 members present	A subsequent quorate meeting was held on 27/01/2016 to consider the applications reviewed at the original meeting and to agree the ethical decision for each application.

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

Name	Number of Meetings Attended
Dr Koula Asimakopoulou	7
Mr Sam Booth	1
Mr David Burbidge	10
Mr Thomas Dowe	6
Mrs Ros Goldfarb	3
Miss Hattie Ismail	2
Dr Imran Jawaid	7
Professor Diana Kornbrot	9
Miss Jennifer Lawson	6
Mr Alex Shortt	3
Dr David Slovic	8
Dr Seetal Snoek	2

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

Name	Number of Meetings Attended
Dr Koula Asimakopoulou	3
Mr David Burbidge	3
Mr Thomas Dowe	1
Mrs Ros Goldfarb	1
Miss Hattie Ismail	1
Professor Diana Kornbrot	2
Miss Jennifer Lawson	2
Mr Alex Shortt	1
Dr David Slovic	2
Dr Seetal Snoek	2

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

Name	Number of Meetings Attended
Dr Koula Asimakopoulou	13
Dr Jo Brooke	1
Mr David Burbidge	17
Mr Thomas Dowe	2
Mrs Ros Goldfarb	2
Miss Hattie Ismail	3
Dr Imran Jawaid	1
Ms Carol Jones	2

Professor Diana Kornbrot	11
Miss Jennifer Lawson	2
Mrs Fran McMillan	1
Mr Alex Shortt	4
Dr David Slovic	10
Dr Seetal Snoek	4

Training 01 April 2015 - 31 March 2016

Name of Member	Date	Event(s) attended
Dr Koula Asimakopoulou	14/10/2015	Local Training Day - London - City Road & Hampstead (3hours, 45minutes)
Dr Koula Asimakopoulou	14/01/2016	Training for New REC Chairs
Mr David Burbidge	14/10/2015	Local training day - 3hours, 45minutes
Mrs Ros Goldfarb	14/10/2015	Local Training Day - London - City Road & Hampstead (3hours, 45minutes)
Miss Hattie Ismail	13/04/2015	Clinical Research involving infants, children and young people: an update for researchers - 40 mins
Miss Hattie Ismail	13/04/2015	Clinical Research Involving Infants, Children and Young People: an Update for Researchers and Ethics Committees
Dr Imran Jawaid	14/10/2015	Local training day - 3hrs, 45mins
Professor Diana Kornbrot	22/04/2015	E&D Training
Miss Jennifer Lawson	29/06/2015	Researcher Training Day (5.5 hours)
Miss Jennifer Lawson	24/09/2015	Committee Members Induction
Miss Jennifer Lawson	14/10/2015	Local training day (3hrs, 45mins)
Mr Alex Shortt	17/06/2015	Committee Members Induction (6 hours)
Dr David Slovick	14/10/2015	Local Training Day - London - City Road & Hampstead (3hours, 45minutes)
Dr Seetal Snoek	08/04/2015	Meeting - Ethics & GCP Forum ICR (7 hours)
Mr Thomas Weijburg	14/10/2015	Local training day - 3hours, 45minutes

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)	2	5.41
Research Database (including renewals)	0	0.00
Others	35	94.59
Total Applications Reviewed	37	100

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

Number of applications made invalid by the REC Manager	0
Number of applications withdrawn prior to the meeting	0
Number of student applications reviewed	12
Number of paediatric applications reviewed	6
Number of device applications reviewed	1
Number of prisoner applications reviewed	0
Number of applications involving adults unable consent reviewed	0
Number of applications reviewed that are funded by the US DHHS	0
Number of qualitative applications reviewed	3

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	0	0.00
Favourable Opinion with Additional Conditions	4	10.81
Unfavourable Opinion	1	2.70
Provisional Opinion	32	86.49
Provisional Opinion Pending Consultation with Referee	0	0.00
Total	37	100
Number of studies sent back to full committee meeting for final opinion	8	

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	30	81.08
Further Information Favourable Opinion with Additional Conditions	2	5.41
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	0	0.00
Favourable Opinion with Additional Conditions	4	10.81
Unfavourable Opinion	1	2.70
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	37	100

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

Total Applications Reviewed	10
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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	14
Number of studies withdrawn prior to the meeting	0
Number of student applications reviewed	3
Number of paediatric applications reviewed	2
Number of device applications reviewed	0
Number of qualitative applications reviewed	3

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	2	20.00
Favourable Opinion with Additional Conditions	1	10.00
No Opinion transfer to full committee for review	4	40.00
Provisional Opinion	3	30.00
Unfavourable Opinion	0	0.00
Total	10	100

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

Average number of applications reviewed per full meeting	3.36
Number of completed applications for full ethical review	37
Number of completed applications for full ethical review over 60 days	2
Number of completed applications over 60 days as a % of total	5.41%
Number of completed applications for full ethical review over 40 days	19
Number of completed applications over 40 days as a % of total	51.35%
Number of days taken to final decision – average (mean)	43
Number of completed proportionate review applications for ethical review	5
Number of completed proportionate review applications for ethical review over 14 days	0
Number of completed proportionate review applications over 14 days as a % of total	0.00%
Number of SSAs (non-Phase 1) reviewed	4
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	0
Number of completed substantial amendments over 35 days as a % of total substantial amendments	0.00%
Number of completed substantial amendments over 28 days	5
Number of completed substantial amendments over 28 days as a % of total substantial amendments	9.80%
Number of modified amendments reviewed	3
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 minor amendments received	30
Number of substantial amendments received for information	0
Number of substantial amendments received for new sites/PIs	0
Number of annual progress reports received	18

Number of safety reports received	0
Number of Serious Adverse Events received	0
Number of final reports received	19

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
15/LO/0549	Inherited Cardiac Disease: A clinical and genetic investigation	46
15/LO/0555	NITRATE-OCT	42
15/LO/0584	PSABRE	38
15/LO/0594	Change mechanisms for minority ethnic youth in multisystemic therapy	36
15/LO/0661	Migration of hip replacements using radiostereometric analysis v1	36
15/LO/0948	Inflammatory liver diseases biobank	46
15/LO/1009	Quality of Life in Elderly patients following pancreatic surgery	41
15/LO/1033	Predictors of treatment response in late-onset depression 1.0	48
15/LO/1038	Step Home Trial: Physical Activity in the Post-operative Setting	42
15/LO/1131	Mapping cholinesterase enzyme deficiencies within a family	42
15/LO/1185	STEP in PH	40
15/LO/1199	The Young Evaluators	57
15/LO/1539	ARISE - Losmapimod	28
15/LO/1549	Preventing Preterm Birth with Probiotics - Pilot Randomised Trial	26
15/LO/1557	The Cognitive Remediation in Bipolar (CRiB) Study: A Feasibility Trial	27
15/LO/1566	A study looking at a new walking intervention for stroke survivors	27
15/LO/1567	IMMUNET	29
15/LO/1862	VESTâ„¢ Long term FU clinical protocol	48
15/LO/1888	Measuring Biomarkers in Children with Inherited Cardiovascular Disease	34
15/LO/1894	Evaluating RE-IDentification. A vocational rehab ABI intervention.	42
15/LO/1898	Investigating maladaptive cognitive biases in patients with asthma	29
15/LO/2122	Early maladaptive schemas in diabetes and depression	41
15/LO/2127	BIORESOURCE BASED STUDIES OF THE DIGESTIVE SYSTEM IN CHILDREN & ADULTS	76
15/LO/2134	Predictors 5.1	55
15/LO/2140	STAR PACE	57
15/LO/2158	IPS Mental Health & Employment Support Evaluation v2.0	54
16/LO/0015	GAPS - Graduated compression as an Adjunct to Pharmacoprophylaxis in S	39
16/LO/0070	Care4Today Heart Failure Platform	49
16/LO/0071	Cognitive Bias Modification for Paranoia	45
16/LO/0073	5-2 Study	64

Further Information Favourable Opinion with Additional Conditions		
REC Reference	Title	Number of Days on Clock
15/LO/0651	Metabonomic Profiling in Deep Venous Thrombosis	44
15/LO/1188	Pilot walking intervention for people with severe mental illness	39

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

Favourable Opinion with Additional Conditions		
REC Reference	Title	Number of Days on Clock
15/LO/0789	Influence of dietary nitrate on vascular dysfunction and inflammation	27
15/LO/1039	Colonic Motility in Constipation and Ageing (version 2.0)	27
15/LO/1186	Lung Screen Uptake Trial v1.0	28
15/LO/1904	MROC: MR in Ovarian Cancer	27

Unfavourable Opinion		
REC Reference	Title	Number of Days on Clock
15/LO/1552	Do 16-19 year olds understand sex and consent? A qualitative study	20

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		
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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/0755	The SCIOaS Study- Phase 4	8
15/LO/0756	Clients perspectives around Psychologist/therapist self disclosure 1	11

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
15/LO/1840	Salivary cortisol and cortisone in healthy children	8
15/LO/1860	Exploring women's views on attendance for breast screening	4

Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
15/LO/0923	MyMOPS for Hips and Knees	6

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
15/LO/1112	Effect of Immunomodulatory molecules on HBV Infected Liver/Blood	8

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
05/Q0504/101/AM16	The MacTel Study	Protocol Version 4	23/06/2015	33
07/H0721/106/AM19	Argusâ„¢ II Retinal Stimulation System Feasibility Study	Substantial Amendment 18	10/04/2015	23
09/H0721/25/AM05	Patient derived hepatitis C replication.	Substantial Amendment 5	02/12/2015	10
10/H0721/79/AM05	Evaluation of Integrated Cardiac Imaging (EVINCI)	5 (AM05)	06/03/2016	18
11/LO/1433/AM02	Immune regulation in autoimmune rheumatic disease	Substantial amendment dated	11/01/2016	21
11/LO/1653/AM02	Protocol to Collect Volunteer Blood Samples for T-cell Research	Substantial amendment dated 12	12/02/2016	18
12/LO/0187/AM03	Cardiac and vascular changes with kidney transplantation	1.1	02/10/2015	4
12/LO/0496/AM04	AHEAD	CTAmendEC# 2 (08 May 2015)	08/05/2015	28
12/LO/0940/AM09	LiGHT: Laser-1st vs Drops-1st for Glaucoma and Ocular Hypertension 1.0	Protocol Amendment 3	20/05/2015	8
12/LO/1934/AM06	Managing cardiovascular risk in patients with SMI - The PRIMROSE trial	Amendment 7	08/06/2015	7
12/LO/1934/AM07	Managing cardiovascular risk in patients with SMI - The PRIMROSE trial	Substantial amendment dated 12	12/02/2016	15
13/LO/0296/AM02	Crosstalk between gut innate and adaptive immunity against infection	1	15/02/2016	9
13/LO/0598/AM02	Exercise physiology in Cardiovascular Disease	Amendment 2	19/08/2015	21
13/LO/0832/AM01	FES Cycling in SCI	Substantial Amendment 1	07/08/2015	28
13/LO/0960/AM02	Electronic alerting tool to help prevent Acute kidney injury	1.3	24/06/2015	8
13/LO/0974/AM03	Changes in Gastrointestinal Homeostasis in Critically Ill Children	Version 4	29/07/2015	22
13/LO/0974/AM04	Changes in Gastrointestinal Homeostasis in Critically Ill	5	10/11/2015	14

	Children			
13/LO/0981/AM23	The SCIN (Skin Care intervention in Nurses) Trial	Substantial Amendment 3	16/07/2015	28
13/LO/0981/AM29	The SCIN (Skin Care intervention in Nurses) Trial	Sunstantial amendment 4 dated	12/10/2015	15
13/LO/1442/AM05	Morbidity after paediatric cardiac surgery	Substantial Amendment 4	20/06/2015	9
13/LO/1442/AM06	Morbidity after paediatric cardiac surgery	5	06/10/2015	27
13/LO/1442/AM07	Morbidity after paediatric cardiac surgery	6 (AM07)	03/03/2016	8
13/LO/1895/AM01	Randomized bilateral study of trans-epithelial corneal cross-linking	1	18/08/2015	14
14/LO/0320/AM03	Subclinical semantic deficits in autoimmune conditions. Version 1	Amendment 3 25/06/2015	05/06/2015	14
14/LO/0360/AM02	Multi-Lead surface ECG Analysis of Inherited Cardiac Disease	1	01/02/2016	4
14/LO/0377/AM01	Using rewards to improve children's behaviour in the dental setting	1	10/07/2015	23
14/LO/0400/AM01	LV Endocardial Cardiac Resynchronisation Therapy	1	06/10/2015	4
14/LO/0554/AM02	Access to CBT and early diagnosis in dementia- version 1	Substantial Amendment 1	17/04/2015	19
14/LO/0662/AM02	HUMAN FEEDING STUDY OF BLOOD MONOCYTE RESPONSE TO DIETARY LIPID	04.01.16	04/01/2016	25
14/LO/1883/AM02	VOCAL - Virtual Online Consultations: Advantages and Limitations	1	23/02/2016	27
14/LO/1937/AM01	FACT	Substantial Amendment 1	08/04/2015	21
14/LO/1937/AM03	FACT	Substantial amendment dated 12	12/02/2016	18
15/LO/0060/AM01	Look at food and lose your fear	1	07/10/2015	6
15/LO/0070/AM01	Diabetic Foot Ulcer Prevention System (DFUPS)	amendment 1 02/3/2015	02/03/2015	23
15/LO/0154/AM01	DEUS pilot student study: Diet & Exercise in Uterine Cancer Survivors	Substantial Amendment v1	18/03/2015	29
15/LO/0154/AM02	DEUS pilot student study: Diet & Exercise in Uterine Cancer Survivors	Substantial Amendment 2	26/05/2015	19

15/LO/0154/AM03	DEUS pilot student study: Diet & Exercise in Uterine Cancer Survivors	3	04/09/2015	32
15/LO/0154/AM04	DEUS pilot student study: Diet & Exercise in Uterine Cancer Survivors	4.0	21/10/2015	19
15/LO/0196/AM01	Real vs. sham rTMS in severe and enduring AN	Substantial Amendment 1	10/06/2015	18
15/LO/0196/AM02	Real vs. sham rTMS in severe and enduring AN	2	30/11/2015	7
15/LO/0196/AM03	Real vs. sham rTMS in severe and enduring AN	4	24/02/2016	27
15/LO/0584/AM01	PSABRE	Substantial Amendment 1	29/02/2016	11
15/LO/0594/AM01	Change mechanisms for minority ethnic youth in multisystemic therapy	1	27/10/2015	10
15/LO/0755/AM01	The SCIOaS Study- Phase 4	Substantial Amendment 1	07/05/2015	18
15/LO/1557/AM01	The Cognitive Remediation in Bipolar (CRiB) Study: A Feasibility Trial	Substantial amendment dated 21	21/01/2016	32
15/LO/1557/AM02	The Cognitive Remediation in Bipolar (CRiB) Study: A Feasibility Trial	2 (AM02)	14/03/2016	14
15/LO/1566/AM01	A study looking at a new walking intervention for stroke survivors	1	11/12/2015	6
15/LO/1840/AM01	Salivary cortisol and cortisone in healthy children	Substantial amendment 1 dated	25/02/2016	28
16/LO/0015/AM01	GAPS - Graduated compression as an Adjunct to Pharmacoprophylaxis in S	Amendment 1 (AM01)	17/03/2016	12

Unfavourable opinion

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
13/LO/1434/AM04	Hyperthermia for Intermediate risk bladder cancer(HIVEC-II)	Substantial Amendment 2	26/02/2015	31
15/LO/1188/AM01	Pilot walking intervention for people with severe mental illness	Substantial amendment dated 19	28/10/2015	6

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
10/H0721/87/AM06/2	Using Genetics to Understand Parkinson's Disease	3/11/15	03/11/2015	5
13/LO/1434/AM04/1	Hyperthermia for Intermediate risk bladder cancer(HIVEC-II)	Modified Substantial Amendment	26/05/2015	8

Unfavourable opinion timeline				
Amendment REC Reference	Title	Version	Date	Number of Days on Clock
12/LO/1934/AM05/1	Managing cardiovascular risk in patients with SMI - The PRIMROSE trial	6: 23/03/2015	23/03/2015	11

Table 11: Items exceeding timelines

Full applications for ethical review over 60 day timeline

REC Reference	Title	Number of Days on Clock
15/LO/2127	BIORESOURCE BASED STUDIES OF THE DIGESTIVE SYSTEM IN CHILDREN & ADULTS	76
16/LO/0073	5-2 Study	64

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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