

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

Annual Report

01 April 2017 - 31 March 2018



Part 1 – Committee Membership and Training

Name of REC:	London - Camden & Kings Cross Research Ethics Committee
Type of REC:	Authorised
Type of Flag:	Adults Lacking Capacity Qualitative Research Research involving Children
Chair:	Mrs Rosie Glazebrook
Vice-Chair:	Ms Heidi Chandler
Alternate Vice-Chair:	Ms Eleni Yerolaki
REC Manager:	Miss Christie Ord
REC Assistant:	Miss Kirstie Penman (until June 2017) Miss Rheanneon Fuller (until February 2018) Ms Jane Harker (from April 2018)
Committee Address:	NHSBT Newcastle Blood Donor Centre Holland Drive Newcastle upon Tyne NE2 4NQ
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Chair's overview of the past year:

Camden and Kings Cross Research Ethics Committee strives to be friendly, hardworking and fair. We have received positive feedback from 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. We now meet at our new location of Friends House, Euston Road which is convenient for researchers and our members.

Members of our committee have wide-ranging expertise. We have lay and clinical members who have skills and experience in law, paediatrics, primary and secondary care, mental health, research management, and voluntary, public and private sector organisations. The committee has expertise, in particular, in 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. It is noticeable how helpful it is to student researchers to be accompanied by their supervisor at the meeting where their research is discussed.

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 Joelle Mak, Julia King, Georgia Mannion-Krase and Julie Taberer to our committee as new members. We are sorry to say goodbye to Beverley Taylor, Rosalind Jones and Ashley Stratton-Powell 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 Emily Cadman	Senior Registrar	Expert	01/09/2016	
Ms Heidi Chandler	Deputy Research Delivery Manager	Lay	24/07/2008	
Mrs Julia Crenian	Volunteer with Home-Start	Lay Plus	01/10/2015	
Mrs Rosie Glazebrook	Consumer Marketing	Lay	01/01/2013	
Ms Rosalind Jones	Retired Mental Health Nurse	Lay	11/05/2016	19/10/2017
Mrs Elizabeth Landers	Tutor	Lay Plus	24/03/2017	
Dr Lorraine Ludman	Chartered Psychologist	Lay	13/05/2016	
Ms Joelle Mak	Research Fellow	Lay Plus	03/01/2018	
Mrs Georgia Mannion-Krase	Data Manager	Expert	01/09/2017	
Dr Jacqueline Maxmin	Retired GP	Expert	01/05/2013	
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	
Mr Ashley Stratton-Powell	PhD Student in Mechanical Engineering	Lay Plus	07/11/2017	15/01/2018
Mrs Julie Taberer	Senior Solicitor	Lay Plus	07/03/2018	
Mrs Beverley Taylor	Lawyer	Lay Plus	06/05/2015	08/04/2017
Ms Eleni Yerolaki	Specialist Counsellor	Lay	20/06/2006	

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

Name	Profession	Status	Meeting date attended
Mrs Julia King	Consultant in human rights	Lay	19/03/2018 , 15/01/2018 & 20/11/2017

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

Name	Profession	Status	Meeting date attended
Ms Monika Temple	Civil Servant (Retired)	Lay	24/07/2017
Ms Fanny Mitchell	Retired NHS Manager	Lay Plus	24/07/2017
Mr Ashley Stratton-Powell	PhD Student in Mechanical Engineering	Lay Plus	30/10/2017
Dr Alexandros Chatziagorakis	Consultant Psychiatrist	Expert	15/01/2018

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

Name	Declaration of Interest	Date
Dr Emily Cadman	Currently actively involved in the identifying of eligible participants and consenting of parents for a double blinded RCT looking at treatment of community acquired pneumonia.	31/03/2018
Ms Heidi Chandler	Lay reviewer for Cochrane Member of the R&D Forum Registered Member of the Institute of Clinical Research Work for the NIHR (Clinical Research Network)	07/02/2018
Mrs Rosie Glazebrook	Non-executive Advisory Board Member, Public Health England Non-executive Board Member, Food Standards Agency Council Member, General Optical Council	05/02/2018
Mrs Julia King	Paid part-time consultancy for GlaxoSmithKline plc, advising on policy and implementation on human rights issues, specialising in supply chain labour rights. I am a shareholder of GSK and AstraZeneca as a result of periods of employment at these companies. I am discussing the potential to provide consultancy support, free of charge, for INGA Wellbeing which is a start-up business providing clothing for patients which allows easy access during medical examinations and treatments.	20/11/2017
Mrs Elizabeth Landers	I am tutor for the Boarding School Association. The BSA runs courses and undertakes some research on all aspects of pastoral care for children relevant to a residential education setting. The BSA also advises government bodies on issues concerning the pastoral care of children who are in residential education settings.	07/04/2017
Dr Lorraine Ludman	None	20/02/2018
Ms Joelle Mak	Employed by London School of Hygiene and Tropical Medicine. As part of her work, she conducts research in the social sciences though usually overseas and routinely seek ethical approval internally at LSHTM and in the country in which the research is conducted.	05/02/2018
Mrs Georgia Mannion-Krase	Data Manager at MRC CTU at UCL	09/08/2017
Dr Jacqueline Maxmin	None declared	20/06/2017
Dr Jacqueline Maxmin	None declared	31/03/2018
Dr Andy Petros	None	31/03/2018
Ms Petra Shroff	Employee at Great Ormond Street Children's NHS Trust and has involvement with local research.	20/06/2017
Mr Jonathan Simons	None	12/03/2018
Mrs Julie Taberer	None	19/03/2018
Ms Eleni Yerolaki	RESPOND - Forensic Service Manager	31/03/2018

Meetings for Full Ethical Review 01 April 2017 - 31 March 2018:

Month	Date	Number of Members Present at Meeting
April	24/04/2017	9
May	22/05/2017	10
June	26/06/2017	10
July	24/07/2017	9
September	18/09/2017	9
October	30/10/2017	10
November	20/11/2017	11
January	15/01/2018	11
February	26/02/2018	12
March	19/03/2018	11

10 full committee meetings were held during the reporting period.

Proportionate Review Sub-Committee Meetings held during 01 April 2017 - 31 March 2018:

Month	Date	Number of Members Present at Meeting
April	20/04/2017	3
May	25/05/2017	3
June	22/06/2017	3
July	26/07/2017	3
September	14/09/2017	3
October	24/10/2017	3
November	24/11/2017	3
December	15/12/2017	3
January	19/01/2018	3
February	16/02/2018	3

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

Sub-Committee Meetings held during 01 April 2017 - 31 March 2018:

Month	Date	Number of Members Present at Meeting
April	14/04/2017	2
April	26/04/2017	2
April	28/04/2017	2
May	12/05/2017	2
May	26/05/2017	2
June	09/06/2017	2
June	23/06/2017	2
July	07/07/2017	2
July	10/07/2017	2
July	21/07/2017	2
August	04/08/2017	2

August	16/08/2017	2
August	18/08/2017	2
September	15/09/2017	2
September	29/09/2017	2
October	13/10/2017	2
October	27/10/2017	2
November	10/11/2017	2
November	23/11/2017	2
November	24/11/2017	2
December	07/12/2017	2
December	12/12/2017	2
December	12/12/2017	3
December	21/12/2017	2
January	19/01/2018	2
February	02/02/2018	2
February	16/02/2018	2
March	02/03/2018	2
March	16/03/2018	2
March	29/03/2018	2

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

Details of inquorate meeting held:01 April 2017 - 31 March 2018

None

Attendance of Members at full committee meetings: 01 April 2017 - 31 March 2018

Name	Number of Meetings Attended
Mrs Elizabeth Landers	10
Ms Heidi Chandler	9
Mrs Rosie Glazebrook	9
Dr Emily Cadman	8
Mrs Julia Crenian	8
Mr Jonathan Simons	8
Dr Lorraine Ludman	7
Dr Jacqueline Maxmin	7
Ms Petra Shroff	7
Ms Eleni Yerolaki	7
Mrs Georgia Mannion-Krase	5
Dr Andy Petros	4
Ms Rosalind Jones	3
Mrs Julia King	3
Mr Ashley Stratton-Powell	2
Ms Joelle Mak	1
Mrs Julie Taberer	1

Attendance of Members at proportionate review sub-committee meetings: 01 April 2017 - 31 March 2018

Name	Number of Meetings Attended
Dr Andy Petros	6
Ms Heidi Chandler	4
Dr Emily Cadman	3
Mrs Rosie Glazebrook	3
Dr Lorraine Ludman	3
Ms Eleni Yerolaki	3
Mrs Julia Crenian	2
Mr Jonathan Simons	2
Ms Rosalind Jones	1
Mrs Elizabeth Landers	1
Dr Jacqueline Maxmin	1
Ms Petra Shroff	1

Attendance of Members at sub-committee meetings: 01 April 2017 - 31 March 2018

Name	Number of Meetings Attended
Mrs Rosie Glazebrook	15

Ms Heidi Chandler	11
Ms Eleni Yerolaki	6
Mrs Julia Crenian	5
Dr Andy Petros	5
Ms Petra Shroff	5
Mr Jonathan Simons	5
Dr Emily Cadman	3
Dr Lorraine Ludman	3
Dr Jacqueline Maxmin	2
Mrs Elizabeth Landers	1

Training 01 April 2017 - 31 March 2018

Name of Member	Date	Event(s) attended
Dr Emily Cadman	16/11/2017	GCP
Ms Heidi Chandler	10/01/2018	GCP
Dr Alexandros Chatziagorakis	08/02/2018	Research involving adults lacking capacity
Dr Alexandros Chatziagorakis	08/02/2018	Confidentiality and information governance considerations in research
Dr Alexandros Chatziagorakis	06/03/2018	Reviewing the research design of Clinical Trials
Dr Alexandros Chatziagorakis	06/03/2018	Medical Devices
Mrs Julia Crenian	29/05/2017	Online Induction
Mrs Julia Crenian	29/05/2017	Equality and Diversity
Mrs Julia Crenian	12/12/2017	National Members Training Day
Mrs Rosie Glazebrook	05/02/2018	2017/18 SDL - mentoring new members in their application to a REC and 6 hours worth of reading associated with ethics in Palliative Care.
Mrs Elizabeth Landers	22/05/2017	Online Committee Members Induction
Mrs Elizabeth Landers	12/10/2017	Training - Human Tissue Act (Use of Human Samples in Research) - An Introductory Level
Dr Lorraine Ludman	22/04/2017	Equality and Diversity
Dr Lorraine Ludman	12/12/2017	National Members Training Day
Ms Joelle Mak	06/02/2018	Equality and Diversity
Mrs Georgia Mannion-Krase	06/10/2017	Equality and Diversity
Mrs Georgia Mannion-Krase	06/10/2017	Online Induction
Mrs Georgia Mannion-Krase	16/11/2017	Committee Members Induction
Mrs Georgia Mannion-Krase	13/03/2018	Ethical Issues of Research Involving Children
Dr Jacqueline Maxmin	12/12/2017	National Members Training Day
Dr Jacqueline Maxmin	13/02/2018	The Ethical Issues of Research Involving Children
Dr Jacqueline Maxmin	27/02/2018	Genetic and Genomic Research
Ms Fanny Mitchell	04/12/2017	HARP Member Portal Training
Ms Fanny Mitchell	13/03/2018	Confidentiality Consent/assent Research on children Medical devices Drug development Blinding Role of CAG Law and Ethics Compassionate & Innovative treatment of children Caldecott/ Fraser
Dr Andy Petros	01/06/2017	Equality and Diversity
Ms Petra Shroff	20/04/2017	SDL 2016-2017 - Equality and Diversity online training and 10 hours worth of reading surrounding ethical issues
Ms Petra Shroff	22/07/2017	E&D HRA Online

Ms Petra Shroff	12/10/2017	Training - Human Tissue Act (Use of Human Samples in Research) - An Introductory Level
Mr Jonathan Simons	08/06/2017	Equality and Diversity
Mr Jonathan Simons	08/06/2017	Online Committee Members Induction
Mrs Julie Taberer	13/03/2018	Online Induction
Ms Monika Temple	11/04/2017	Local Training Day - London - Harrow
Ms Monika Temple	12/12/2017	Training - National Members Training Day
Ms Eleni Yerolaki	01/08/2017	Equality and Diversity
Ms Eleni Yerolaki	24/11/2017	HRA National Chairs' Day and Policy Event
Ms Eleni Yerolaki	29/11/2017	Regional 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:

Applications for full ethical review – Study Type	Number	%
Clinical Trial of Investigational Medicinal Product	0	0.00
Phase 1	0	0.00
Gene Therapy	0	0.00
Research Tissue Bank (including renewals)	0	0.00
Research Database (including renewals)	1	1.85
Others	53	98.15
Total Applications Reviewed	54	100

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	29
Number of paediatric applications reviewed	13
Number of device applications reviewed	4
Number of prisoner applications reviewed	0
Number of applications involving adults unable consent reviewed	12
Number of applications reviewed that are funded by the US DHHS	0
Number of qualitative applications reviewed	17

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	6	11.11
Favourable Opinion with Additional Conditions	16	29.63
Unfavourable Opinion	7	12.96
Provisional Opinion	24	44.44
Provisional Opinion Pending Consultation with Referee	1	1.85
Total	54	100
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	22	40.74
Further Information Favourable Opinion with Additional Conditions	1	1.85
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	6	11.11
Favourable Opinion with Additional Conditions	16	29.63
Unfavourable Opinion	7	12.96
Provisional Opinion	2	3.70
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	54	100

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

Total Applications Reviewed	25
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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	1
Number of student applications reviewed	11
Number of paediatric applications reviewed	2
Number of device applications reviewed	3
Number of qualitative applications reviewed	4

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	12	48.00
Favourable Opinion with Additional Conditions	4	16.00
No Opinion transfer to full committee for review	3	12.00
Provisional Opinion	5	20.00
Unfavourable Opinion	1	4.00
Total	25	100

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

Average number of applications reviewed per full meeting	5.40
Number of completed applications for full ethical review	54
Number of completed applications for full ethical review over 60 days	0
Number of completed applications over 60 days as a % of total	0.00%
Number of days taken to final decision – average (mean)	31
Number of completed proportionate review applications for ethical review	22
Number of completed proportionate review applications for ethical review over 21 days	0
Number of completed proportionate review applications over 21 days as a % of total	0.00%
Number of SSAs (non-Phase 1) reviewed	6
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	78
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 modified amendments reviewed	1
Number of completed modified amendments over 14 days	0
Number of completed modified amendments over 14 days as a % of total modified amendments	0.00%
Number of non substantial amendments received	86
Number of substantial amendments received for information	0
Number of substantial amendments received for new sites/PIs	0
Number of annual progress reports received	39
Number of safety reports received	0
Number of Serious Adverse Events received	1
Number of final reports received	25

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
17/LO/0598	Experience of receiving a positive HIV test result from primary care	35
17/LO/0659	EPICC-ID Randomised Controlled Trial	39
17/LO/0689	The role of dopaminergic therapy in Parkinson's disease	44
17/LO/0832	Service-User Views: Receiving a BPD Diagnosis in Specialist Services	36
17/LO/0854	What enables discharge for people requiring palliative care?	37
17/LO/0855	Personal accounts of the dementia assessment process (v.1)	41
17/LO/0878	Child Psychotherapy in a GP practice Baby Clinic	45
17/LO/0993	Understanding Early Mothering in Women with Postpartum Psychosis	34
17/LO/1036	Intraoperative radiotherapy for pelvic cancer	33
17/LO/1182	The CARMA Study	34
17/LO/1477	The feasibility of VR with PLWD	43
17/LO/1586	InGaP: Understanding interface between Geriatrics & Palliative Care	31
17/LO/1713	Exploring how people with dementia are supported to live independently	31
17/LO/1734	Monitoring quality of dementia care	35
17/LO/1742	FAITH study	46
17/LO/1901	The Grown Up Peanut Immunotherapy study (GUPI)	56
17/LO/1927	Effect of aspirin on endogenous fibrinolysis in patients with CAD	41
17/LO/1963	Mood in later life	32
17/LO/1965	PASS - Piloting the Pharmacist Asthma Support Study	34
18/LO/0007	Genetic and environmental contributions to cognitive outcome in glioma	39
18/LO/0331	Environmental impact on engagement in therapeutic activities (Ver.one)	41
18/LO/0418	Feeling and circumstance: Hallucinations in first episode psychosis.	46

Further Information Favourable Opinion with Additional Conditions		
REC Reference	Title	Number of Days on Clock
18/LO/0026	Evaluation of a Social Network Intervention for Severe Mental Illness	42

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
17/LO/1020	Fetal Alcohol Syndrome	24
17/LO/1058	The performance of the Mologic biomarker panel in infection	23
17/LO/1166	SysMedPD	25
17/LO/1200	Feasibility of training in nursing homes and mealtime experience.	25
18/LO/0010	Variation in health life expectancy Version 1.0	32
18/LO/0186	FICUBIOME – Tracking transmissible bacteria using faecal microbiome v2	24

Favourable Opinion with Additional Conditions		
REC Reference	Title	Number of Days on Clock
17/LO/0669	BOOST: Boosting Baby Behaviour and Bonding	28
17/LO/0688	Healing following root-end surgery, periapical radiographs vs CBCT	28
17/LO/0786	Experience of Discharge from an MSU	28
17/LO/0856	Smart Wheelchair Study	28
17/LO/0981	BUILD: BAF complex & related genes underlying intellectual disability	22
17/LO/1215	Young People's Experiences of Receiving a Diagnosis of ASD - Version 2	24
17/LO/1430	Feasibility of monitoring sedative use in palliative care	22
17/LO/1434	Cryoablation (8 seconds) for the Management of Barrett's Oesophagus	22
17/LO/1466	MOVement Control After Stroke (MOCAS)	22
17/LO/1486	The Psychosocial Impact of Psychiatric Medication in Psychosis	23
17/LO/1807	Evaluation of efficacy of novel LGX probe for S. aureus detection	25
17/LO/1885	INSigHT	28
17/LO/1971	SHAPED-TF	28
18/LO/0266	Novel multimodality imaging for navigation in skull base surgery	28
18/LO/0315	MISTER	33
18/LO/0489	Perceived autonomy in low secure forensic services	29

Unfavourable Opinion		
REC Reference	Title	Number of Days on Clock
17/LO/0599	Infant nutrition and brain development	24
17/LO/0843	Young People's Experiences of Receiving a Diagnosis of ASD - Version 1	28
17/LO/1000	Cryoablation (8 seconds) for the Management of Barrett's Oesophagus	23
17/LO/1138	The emergency department and patients with mental health conditions	24

17/LO/1378	Attachment and mentalization in anorexia nervosa & community controls	22
17/LO/1738	Child Psychotherapy In A Paediatric Out-Patient Setting	25
18/LO/0293	The maternal response to sepsis. Version 4	24

Provisional Opinion

REC Reference	Title	Number of Days on Clock
18/LO/0296	Implementing the findings of the MemoryCare project on acute wards	n/a
18/LO/0345	The CHildren with COugh Randomised Controlled Trial (The CHICO RCT)	n/a

Provisional Opinion Pending Consultation with Referee

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
17/LO/1291	Functional Outcomes in Patients undergoing GI operations	20
17/LO/1294	A composite block is a replacement for routine control tissue.	15
17/LO/1833	Identifying the organisms associated with Denture Stomatitis.	20
17/LO/2124	The PitQoL Study	20
18/LO/0155	Population-based system for serological surveillance of influenza	20

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
17/LO/0664	ENABLE - Blackpool	20
17/LO/0667	CASPA: Cardiac sarcoidosis in Papworth	15
17/LO/0906	Self-management of Type 1 Diabetes During Prolonged Cycling	8
17/LO/1073	Readmission to an acute hospital Trust within 30 days of discharge	18
17/LO/1570	SmartObs v1.0	15
17/LO/1576	A self-management app for lung cancer survivors	13
17/LO/1583	Managing Achilles Pain - a pilot study; version 2.0	16
17/LO/1841	Clinician's perception of class 3 malocclusion using photographs	12
17/LO/2012	Women's perceptions of physical activity during pregnancy v1	21
18/LO/0164	SIGCO	15
18/LO/0301	In vitro platelet activation in Asian subjects	10
18/LO/0317	Diabetes Digital Coach	21

Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
17/LO/1281	VACcept Survey	16
17/LO/1286	Care4today System In-home Usability Test	16
18/LO/0297	International BPA registry	17
18/LO/0310	Occupational therapy on a chronic back PMP v1	11

Unfavourable Opinion

REC Reference	Title	Number of Days on Clock
17/LO/2126	Embedding the patient.	13

Provisional Opinion		
REC Reference	Title	Number of Days on Clock

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

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

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
11/LO/0706/AM04	Global coagulation assays in liver disease	SA2	13/05/2017	14
11/LO/0706/AM05	Global coagulation assays in liver disease	Substantial Amendment 3, 18/01/18	09/03/2018	17
12/LO/1176/AM11	Streamline C	Substantial Amendment 8, 03/03/18	20/03/2018	18
12/LO/1177/AM09	Streamline L	Substantial Amendment 7, 03/03/18	20/03/2018	18
13/LO/0728/AM03	How do co-inherited blood conditions affect malaria protection? V1	SA3	13/09/2017	13
13/LO/0728/AM04	How do co-inherited blood conditions affect malaria protection? V1	Substantial Amendment 4	13/02/2018	23
14/LO/0648/AM02	Tablet Cognitive Screening	SA1	06/05/2017	11
14/LO/1136/AM08	Non-invasive diagnostic testing for Gastro-intestinal disease	SA4	05/07/2017	7
14/LO/1136/AM09	Non-invasive diagnostic testing for Gastro-intestinal disease	SA5	24/11/2017	22
14/LO/1150/AM14	SERENADE	SA6 - protocol version 5	20/06/2017	12
14/LO/1150/AM17	SERENADE	SA7	24/08/2017	13
14/LO/1150/AM21	SERENADE	SA8 protocol V6.1	31/01/2018	19
14/LO/1517/AM06	SHAPED (v1.0)	SA4	16/06/2017	13
15/LO/0093/AM01	Linguistic markers of risk for future Alzheimer's Disease	SA1	10/03/2017	7
15/LO/0093/AM02	Linguistic markers of risk for future Alzheimer's Disease	SA2	22/05/2017	14
15/LO/0933/AM02	Diagnosing and monitoring infection in critical illness	SA2	30/05/2017	13
15/LO/1010/AM05	Attachment and mentalization as predictors of family therapy outcome	Amendment 4	31/03/2017	8
15/LO/1071/AM02	Primary Radiotherapy And DIEP flAp reconstruction (PRADA) study	AM1706-61	13/07/2017	10
15/LO/1140/AM01	Exhaled breath metabolite signals of disease and surgical	SA1	25/02/2017	8

	stress			
15/LO/1270/AM01	Biomarkers predict response to XELOX and Avastin in mCRC- Version 1.0	SA1	16/11/2017	14
15/LO/1568/AM02	Bio-TBI	Protocol v4.1	10/05/2017	27
15/LO/1875/AM03	Experience of mood episodes for people diagnosed with bipolar disorder	SA1	20/12/2017	21
16/LO/0214/AM08	G-PATH SUPPORT:Gastrostomy feeding and psychosocial support	SA4	01/08/2017	18
16/LO/0214/AM09	G-PATH SUPPORT:Gastrostomy feeding and psychosocial support	SA5	02/10/2017	23
16/LO/0214/AM11	G-PATH SUPPORT:Gastrostomy feeding and psychosocial support	SA6	23/11/2017	23
16/LO/0343/AM01	Pilot evaluation of low-intensity CBT in NI Version 1	SA1	19/09/2017	22
16/LO/0504/AM03	IDEAL-PM	Substantial Amendment 2, 28/02/18	01/03/2018	35
16/LO/0621/AM08	Care of patients experiencing hip fracture & confusion: PERFECTED CRCT	SA5	03/05/2017	8
16/LO/0621/AM10	Care of patients experiencing hip fracture & confusion: PERFECTED CRCT	SA6	04/07/2017	19
16/LO/0920/AM01	Advances in group-based falls rehabilitation	SA1	06/07/2017	22
16/LO/1110/AM05	Derivation and study of organoids from cancer patients	Substantial Amendment 4 - 01/03/18	13/03/2018	20
16/LO/1217/AM02	Delirium and Population Health Informatics Cohort (DELPHIC) Study	1.2	19/04/2017	12
16/LO/1281/AM01	Predicting Infant Extubation Using Diaphragm Surface Electromyography	Substantial Amendment 1, 29/01/18	07/02/2018	13
16/LO/1299/AM02	Developing a Psychoeducation Tool for Anxiety in Autism	SA1	12/04/2017	14
16/LO/1606/AM01	Peer Supported Open Dialogue	1	24/03/2017	21
16/LO/1606/AM03	Peer Supported Open Dialogue	SA3	04/08/2017	13
16/LO/1618/AM02	INHALE Work Package 2	SA1	09/01/2018	14
16/LO/1769/AM03	ASTAR	SA2	26/10/2017	30
16/LO/1918/AM02	Shared Decision Making in Risk Assessments and Risk Management.	SA2	27/07/2017	20

16/LO/2010/AM03	A feasibility cluster RCT of the AMBER care bundle	SA3	30/03/2017	21
16/LO/2010/AM04	A feasibility cluster RCT of the AMBER care bundle	SA4	10/07/2017	11
16/LO/2010/AM05	A feasibility cluster RCT of the AMBER care bundle	SA5	29/09/2017	16
16/LO/2010/AM06	A feasibility cluster RCT of the AMBER care bundle	Substantial Amendment 6, 09/11/17	14/11/2017	29
16/LO/2014/AM01	WMC 75/UK/15	SA1	25/05/2017	21
16/LO/2054/AM01	Compassion Focused Therapy (CFT) group for persistent pain	1	18/05/2017	19
16/LO/2238/AM01	Flavour programming	SA1	19/06/2017	18
17/LO/0112/AM01	A website to help choose contraception - a pilot trial	SA1	26/09/2017	14
17/LO/0136/AM02	COPD Microenvironment Study	Substantial Amendment 1, 27/01/18	26/02/2018	25
17/LO/0158/AM02	Preparing patients and families for cancer chemotherapy	SA1	26/06/2017	22
17/LO/0175/AM01	Acupuncture for treatment of delay in labour	SA1	31/10/2017	24
17/LO/0318/AM01	Pilot Study for The Tight-K Study	1	06/04/2017	19
17/LO/0318/AM02	Pilot Study for The Tight-K Study	SA2	27/06/2017	10
17/LO/0320/AM01	Impact of Severity of Nausea Affecting Pregnant Women (iSNAP)	SA1	22/03/2017	7
17/LO/0357/AM01	Better Conversations with Primary Progressive Aphasia (BCPPA)	SA1	12/07/2017	31
17/LO/0357/AM02	Better Conversations with Primary Progressive Aphasia (BCPPA)	Substantial Amendment 2, 23/02/18	06/03/2018	34
17/LO/0397/AM01	QUEST Follow-up Study Wave 3	SA1	19/04/2017	28
17/LO/0397/AM03	QUEST Follow-up Study Wave 3	Substantial Amendment 2, 14/02/18	19/03/2018	19
17/LO/0458/AM01	Employment and receipt of welfare benefits before and after renal transplantation	SA1	14/07/2017	16
17/LO/0487/AM01	Origins of Theory of Mind in deaf children	SA1	22/08/2017	15
17/LO/0598/AM02	Experience of receiving a positive HIV test result from primary care	SA1	20/07/2017	15
17/LO/0598/AM03	Experience of receiving a positive HIV test result from primary care	SA2	09/10/2017	21
17/LO/0598/AM05	Experience of receiving a positive HIV test result from primary	SA3	30/10/2017	30

	care			
17/LO/0598/AM06	Experience of receiving a positive HIV test result from primary care	Substantial Amendment 4, 19/02/18	19/02/2018	17
17/LO/0659/AM04	EPICC-ID Randomised Controlled Trial	SA1	08/09/2017	13
17/LO/0659/AM05	EPICC-ID Randomised Controlled Trial	SA2	25/10/2017	10
17/LO/0659/AM06	EPICC-ID Randomised Controlled Trial	Substantial Amendment 3, 08/12/17	22/01/2018	14
17/LO/0669/AM01	BOOST: Boosting Baby Behaviour and Bonding	SA1	18/10/2017	19
17/LO/1166/AM01	SysMedPD	SA 1.1	04/10/2017	20
17/LO/1215/AM01	Young People's Experiences of Receiving a Diagnosis of ASD - Version 2	Amendment 1, Change of Academic Supervisor, 24.01.18	24/01/2018	13
17/LO/1486/AM01	The Psychosocial Impact of Psychiatric Medication in Psychosis	SA1	19/10/2017	26
17/LO/1576/AM01	A self-management app for lung cancer survivors	SA1	15/11/2017	6
17/LO/1576/AM02	A self-management app for lung cancer survivors	SA2	04/01/2018	15
17/LO/1742/AM01	FAITH study	Substantial Amendment 1, 14/02/18	27/02/2018	24
17/LO/1901/AM01	The Grown Up Peanut Immunotherapy study (GUPI)	Substantial Amendment 1, 02/02/18	19/02/2018	17
18/LO/0155/AM02	Population-based system for serological surveillance of influenza	Substantial Amendment 2, 27/02/18	27/02/2018	21

Unfavourable opinion				
Amendment REC Reference	Title	Version	Date	Number of Days on Clock
09/H0722/77/AM01	Early detection of HPB cancers using biomarkers	SA1	22/10/2017	21
15/LO/1010/AM06	Attachment and mentalization as predictors of family therapy outcome	5	21/04/2017	19
15/LO/1764/AM01	Mr. Burns (Metabolic Rate in Burns)	SA1 - Protocol 5.0	07/07/2017	33

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

Unfavourable opinion timeline				
Amendment REC Reference	Title	Version	Date	Number of Days on Clock
15/LO/1764/AM01/1	Mr. Burns (Metabolic Rate in Burns)	MA 5 SA1	07/11/2017	13

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
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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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