

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

**Annual Report**

**01 April 2016 - 31 March 2017**



## 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>	Jarrow Business Centre Rolling Mill Road Jarrow NE32 3DT
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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.

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, 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 Dr Emily Cadman, Rosalind Jones, Elizabeth Landers and Lorraine Ludman to our committee as new members. We are sorry to say goodbye to Dr Afia Ali and Jessica Hughes 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	18/07/2016
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	
Dr Sangeeta Dave	Senior Clinical Research Associate	Expert	01/10/2011	
Mrs Rosie Glazebrook	Consumer Marketing	Lay	01/01/2013	
Miss Jessica Hughes	Director, Corporate Public Policy	Lay Plus	01/09/2014	01/03/2017
Ms Rosalind Jones	Retired Mental Health Nurse	Lay	11/05/2016	
Mrs Elizabeth Landers	Tutor	Lay Plus	24/03/2017	
Dr Lorraine Ludman	Chartered Psychologist	Lay	13/05/2016	
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	
Mrs Beverley Taylor	Lawyer	Lay Plus	06/05/2015	
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 Rhona Bratt	Retired Multimedia Project Manager	Lay Plus	15/11/2016
Dr Sheila Fisher	Retired Maxillofacial Surgeon/Clinical Research Fellow	Expert	15/11/2016

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

<b>Name</b>	<b>Declaration of Interest</b>	<b>Date</b>
Dr Emily Cadman	2016-17 - None	31/03/2017
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)	31/03/2017
Mrs Julia Crenian	Volunteer for Home-Start Richmond, a charity which could potentially be involved in research.	31/03/2017
Mrs Rosie Glazebrook	Non-executive Advisory Board Member, Public Health England Non-executive Board Member, Food Standards Agency Council Member, General Optical Council	31/03/2017
Ms Rosalind Jones	None	31/03/2017
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.	31/03/2017
Dr Lorraine Ludman	None	31/03/2017
Dr Jacqueline Maxmin	None declared	31/03/2017
Dr Andy Petros	None	31/03/2017
Ms Petra Shroff	Employee at GOSH NHS Trust so has involvement in local research	31/03/2017
Mr Jonathan Simons	None	31/03/2017
Mrs Beverley Taylor	None	20/05/2016
Ms Eleni Yerolaki	None	31/03/2017

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

Month	Date	Number of Members Present at Meeting
April	25/04/2016	8
May	23/05/2016	10
June	27/06/2016	8
July	18/07/2016	12
September	19/09/2016	12
October	31/10/2016	11
November	21/11/2016	6
November	21/11/2016	7
January	23/01/2017	12
February	27/02/2017	11
March	20/03/2017	10

10 full committee meetings were held during the reporting period.

### Proportionate Review Sub-Committee Meetings held during 01 April 2016 - 31 March 2017:

Month	Date	Number of Members Present at Meeting
April	08/04/2016	3
May	10/05/2016	3
June	08/06/2016	3
July	12/07/2016	3
September	13/09/2016	3
October	17/10/2016	3
November	15/11/2016	3
December	14/12/2016	3
January	16/01/2017	3
February	16/02/2017	3

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

### Sub-Committee Meetings held during 01 April 2016 - 31 March 2017:

Month	Date	Number of Members Present at Meeting
April	06/04/2016	2
April	13/04/2016	2
April	20/04/2016	2
April	28/04/2016	3
May	06/05/2016	3
May	11/05/2016	2
May	18/05/2016	2
June	01/06/2016	2
June	02/06/2016	2
June	15/06/2016	2

June	16/06/2016	2
June	29/06/2016	2
July	13/07/2016	2
July	27/07/2016	2
August	10/08/2016	2
August	24/08/2016	2
September	07/09/2016	2
September	21/09/2016	2
October	05/10/2016	2
October	19/10/2016	2
November	02/11/2016	2
November	07/11/2016	3
November	16/11/2016	2
November	30/11/2016	2
December	13/12/2016	2
December	22/12/2016	2
January	05/01/2017	2
January	20/01/2017	2
February	03/02/2017	2
February	16/02/2017	2
February	17/02/2017	2
March	03/03/2017	2
March	10/03/2017	2
March	14/03/2017	2
March	17/03/2017	2
March	31/03/2017	2

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

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

Date	Reason	Action taken
21/11/2016*	Last minute apologies received	Arranged a teleconference at the end of the meeting with two co-opted members to ratify decisions.

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

<b>Name</b>	<b>Number of Meetings Attended</b>
Mrs Julia Crenian	10
Mrs Rosie Glazebrook	10
Ms Heidi Chandler	9
Dr Lorraine Ludman	9
Mr Jonathan Simons	9
Dr Emily Cadman	7
Ms Rosalind Jones	7
Dr Jacqueline Maxmin	7
Dr Andy Petros	7
Ms Petra Shroff	7
Ms Eleni Yerolaki	6
Miss Jessica Hughes	5
Mrs Beverley Taylor	5
Dr Afia Ali	3
Dr Sangeeta Dave	3

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

<b>Name</b>	<b>Number of Meetings Attended</b>
Ms Eleni Yerolaki	5
Ms Heidi Chandler	4
Dr Sangeeta Dave	3
Mrs Julia Crenian	2
Mrs Rosie Glazebrook	2
Miss Jessica Hughes	2
Dr Lorraine Ludman	2
Dr Jacqueline Maxmin	2
Dr Andy Petros	2
Ms Petra Shroff	2
Dr Afia Ali	1
Ms Rosalind Jones	1
Mr Jonathan Simons	1
Mrs Beverley Taylor	1

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

<b>Name</b>	<b>Number of Meetings Attended</b>
Ms Eleni Yerolaki	16



Mrs Rosie Glazebrook	15
Ms Heidi Chandler	12
Dr Sangeeta Dave	5
Mrs Julia Crenian	4
Miss Jessica Hughes	3
Dr Lorraine Ludman	3
Dr Andy Petros	3
Ms Petra Shroff	3
Ms Rosalind Jones	2
Dr Jacqueline Maxmin	2
Mr Jonathan Simons	2
Mrs Beverley Taylor	2
Dr Afia Ali	1
Dr Emily Cadman	1
Mr Richard Tomlin	1

**Training 01 April 2016 - 31 March 2017**

<b>Name of Member</b>	<b>Date</b>	<b>Event(s) attended</b>
Dr Emily Cadman	14/03/2017	Committee Members Induction
Ms Heidi Chandler	16/02/2017	National Members Training Day
Mrs Julia Crenian	31/03/2017	Self Directed Learning Log 2016-17
Mrs Rosie Glazebrook	01/12/2016	National Chairs Day
Ms Rosalind Jones	06/12/2016	Induction
Dr Lorraine Ludman	16/02/2017	National Members Training Day
Dr Jacqueline Maxmin	16/02/2017	National Members Training Day
Dr Andy Petros	16/02/2017	National Members Training Day
Ms Petra Shroff	01/08/2016	Equality and Diversity
Mrs Beverley Taylor	10/03/2017	E-Consent in Research Training
Ms Eleni Yerolaki	20/04/2016	Researcher Training Day
Mr Jonathan Simons	31/03/2017	SDL 2016-17

## 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	1
Number of applications withdrawn prior to the meeting	0
Number of student applications reviewed	18
Number of paediatric applications reviewed	17
Number of device applications reviewed	2
Number of prisoner applications reviewed	0
Number of applications involving adults unable consent reviewed	11
Number of applications reviewed that are funded by the US DHHS	0
Number of qualitative applications reviewed	11

**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	6	10.53
Favourable Opinion with Additional Conditions	11	19.30
Unfavourable Opinion	4	7.02
Provisional Opinion	36	63.16
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	27	47.37
Further Information Favourable Opinion with Additional Conditions	7	12.28
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	6	10.53
Favourable Opinion with Additional Conditions	11	19.30
Unfavourable Opinion	3	5.26
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>22</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	9
Number of studies withdrawn prior to the meeting	0
Number of student applications reviewed	10
Number of paediatric applications reviewed	0
Number of device applications reviewed	0
Number of qualitative applications reviewed	2

**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	12	54.55
Favourable Opinion with Additional Conditions	5	22.73
No Opinion transfer to full committee for review	1	4.55
Provisional Opinion	4	18.18
Unfavourable Opinion	0	0.00
<b>Total</b>	<b>22</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>	5.60
<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>	5
<b>Number of completed applications over 40 days as a % of total</b>	8.77%
<b>Number of days taken to final decision – average (mean)</b>	30
<b>Number of completed proportionate review applications for ethical review</b>	21
<b>Number of completed proportionate review applications for ethical review over 14 days (Please note, the timeline for the review of PR applications was extended from 14 to 21 calendar days in December 2016)</b>	3
<b>Number of completed proportionate review applications for ethical review over 21 days</b>	0
<b>Number of completed proportionate review applications over 21 days as a % of total</b>	0.00%
<b>Number of SSAs (non-Phase 1) reviewed</b>	11
<b>Number of completed applications for SSA review over 25 days</b>	2
<b>Number of completed applications for SSA review over 25 days as % of all non- Phase 1 SSAs</b>	18.18%
<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>	78
<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>	5.13%
<b>Number of modified amendments reviewed</b>	0
<b>Number of completed modified amendments over 14 days</b>	0
<b>Number of completed modified amendments over 14 days as a % of total modified amendments</b>	0.00%
<b>Number of non substantial amendments received</b>	109

<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>	53
<b>Number of safety reports received</b>	0
<b>Number of Serious Adverse Events received</b>	1
<b>Number of final reports received</b>	11

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

<b>Further Information Favourable Opinion with Standard Conditions</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
16/LO/0482	Safety of sedatives in hypothermic ICU patients v4	27
16/LO/0621	Care of patients experiencing hip fracture & confusion: PERFECTED CRCT	42
16/LO/0652	PRotect after depression: a randomised pilot trial	35
16/LO/0719	Lower limb afferent nerve function in relation to childbirth	30
16/LO/0869	Childhood trauma, emotion dysregulation and psychosis.	37
16/LO/0922	Biomarkers for FRDA	15
16/LO/1020	Assessing excessive and avoidance behaviours in depression v1.0	43
16/LO/1028	Morality in OCD	32
16/LO/1117	Mobile technology health solutions for psychosis	36
16/LO/1217	Delirium and Population Health Informatics Cohort (DELPHIC) Study	32
16/LO/1259	KLOX PERIO-1 Gel as adjunct to routine scaling in periodontal patients	30
16/LO/1281	Predicting Infant Extubation Using Diaphragm Surface Electromyography	42
16/LO/1305	ResolveD-CAP v1.0	37
16/LO/1445	An exploration of the attachment process in dementia	25
16/LO/1595	Familial genetic studies in people with diabetes	31
16/LO/1639	Disclosure of Smoking in Adolescents with Asthma	28
16/LO/1689	Re/imaginings in art psychotherapy for girls & young women.	32
16/LO/1918	Shared Decision Making in Risk Assessments and Risk Management.	31
16/LO/1943	Sexuality Following Breast Cancer - Version 1	40
16/LO/2009	Study to assess inhaled drug distribution in the lung	35
17/LO/0043	Experiences of sensory rooms on secure, forensic psychiatric wards	45
17/LO/0061	The PROMISE Study CLP 9508.B	40
17/LO/0077	VOICE Study	28
17/LO/0112	A website to help choose contraception - a pilot trial	26
17/LO/0158	Preparing patients and families for cancer chemotherapy	31
17/LO/0267	Individuals Experiences of Sacral Neuromodulation	37
17/LO/0357	Better Conversations with Primary Progressive Aphasia (BCPPA)	36

<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/0920	Advances in group-based falls rehabilitation	18



16/LO/1029	Harnessing resources from the internet (HaRI)	34
16/LO/2010	A feasibility cluster RCT of the AMBER care bundle	26
17/LO/0109	ABCaP: Anaerobic Bacteria and Prostate cancer.	32
17/LO/0118	Maternal Moments	43
17/LO/0149	(duplicate) What matters to older breast cancer patients?	40
17/LO/0175	Acupuncture for treatment of delay in labour	38

#### Further Information Unfavourable Opinion

REC Reference	Title	Number of Days on Clock
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#### Favourable Opinion with Standard Conditions

REC Reference	Title	Number of Days on Clock
16/LO/0551	MULTIPLEX STI AND NEONATE PATHOGEN TEST CLINICAL VALIDATION	24
16/LO/0887	Infants with CDH:Determining the Appropriate Level of Volume Guarantee	14
16/LO/1121	Quality of Life in Families of Children with Batten Disease	28
16/LO/1946	Improved Legionella Urinary Antigen Test	28
17/LO/0397	QUEST Follow-up Study Wave 3	22
17/LO/0458	Receipt of welfare benefits before and after renal transplantation	22

#### Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
16/LO/0870	A qualitative study investigating outcomes of orthodontic treatment	18
16/LO/1068	Analysis of COPD environmental exposure driven exacerbations	28
16/LO/1299	Developing a Psychoeducation Tool for Anxiety in Autism	24
16/LO/1606	Peer Supported Open Dialogue	22
16/LO/1618	INHALE Work Package 2	22
16/LO/1769	ASTAR	28
16/LO/1938	StigmaSurveyUK - YP	22
16/LO/1999	A comparison of CBTi and usual treatment for tinnitus related insomnia	22
16/LO/2014	WMC 75/UK/15	22
17/LO/0244	Exploring patients' experiences of nutrition after liver transplant	28
17/LO/0318	Pilot Study for The Tight-K Study	28

<b>Unfavourable Opinion</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
16/LO/0775	Re/imaginings in art psychotherapy for girls & young women	14
16/LO/1314	Evaluating the Effectiveness of a Therapeutic Parent and Toddler Group	23
16/LO/1958	Optimal: reduction in readmissions by using discharge co-ordinators	28

<b>Provisional Opinion</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
17/LO/0325	High Functioning Autistic Disorders in MSUs - Pathways & Co-morbidity	n/a
17/LO/0487	Origins of Theory of Mind in deaf children	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>
16/LO/0624	Chronic Kidney Disease Patient Digital Resource Design v1	14

**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>
16/LO/0650	WHISTL:ER. Follow up of hip arthroplasty long term:Effect on Revision	14
16/LO/0655	SHARE-D (version 2)	13
16/LO/1119	Patient enactment of delayed prescribing of antibiotics	16
16/LO/1899	Evaluation of a culture free CBT based Thirdwave Therapy Manual	14

<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>
16/LO/0644	Living with a stoma - wellbeing and fitness - a patient survey	12
16/LO/0899	Smoking in Pregnancy 1	14
16/LO/0911	Triggers for Vocal Cord Dysfunction and Asthma	13
16/LO/1109	Southwark: Trialling Letters for Diabetes Prevention Program uptake	11
16/LO/1110	Derivation and study of organoids from cancer patients	12
16/LO/1320	Kinematics Before and After Joint Replacement	11
16/LO/1351	Investigating the mechanisms underlying osteoarthritis	10
16/LO/1705	Fertility after prostate brachytherapy	12
16/LO/1712	Core outcome set for bronchiectasis	12
16/LO/2054	Compassion Focused Therapy (CFT) group for persistent pain	14
17/LO/0116	Meniscal Tear Outcome Cohort (MenTOC)	14
17/LO/0136	COPD Microenvironment Study	15

<b>Favourable Opinion with Additional Conditions</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
16/LO/1317	FUSCHIA STUDY	11
16/LO/1698	Personality trait and tinnitus habituation	14
16/LO/1920	The Molecular Genetics of Carpal Tunnel Syndrome, Version 1	9
16/LO/2238	Flavour programming	12
17/LO/0320	Impact of Severity of Nausea Affecting Pregnant Women (iSNAP)	20

### **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
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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>
09/H0722/46/AM07	GBS PCR Concordance study	SA4	21/10/2016	18
10/H0722/14/AM09	Chronic Depression (Version Two 10/HO722/14)	SA3	22/02/2016	31
11/LO/2016/AM04	EpiPGX	Substantial Amendment 4	30/06/2016	28
12/LO/0141/AM03	Genetic study of inherited retinal disease	SA3	10/10/2016	21
12/LO/1176/AM08	Streamline C	Substantial Amendment 7	06/09/2016	10
12/LO/1177/AM06	Streamline L	Substantial Amendment 6	06/09/2016	10
13/LO/0091/AM05	MRS assay of glutamate-GABA in autism	Substantial Amendment 5, 29/04	20/05/2016	13
13/LO/0495/AM03	Comparison of MBCT, relaxation and waiting list in tinnitus management	Substantial Amendment 2	28/07/2016	10
13/LO/0728/AM02	How do co-inherited blood conditions affect malaria protection? V1	SA2	08/02/2017	12
13/LO/1309/AM04	Shared decision making in mild to moderate dementia.	Substantial Amendment 4	28/11/2016	14
13/LO/1546/AM07	TRACERx	Substantial Amendment 6	08/06/2016	8
13/LO/1868/AM01	A pilot qualitative study after bariatric surgery	SA1	02/03/2016	28
14/LO/0107/AM07	CORE: Crisis Team Optimisation and Relapse Prevention - Phase 4	SA3	15/03/2016	21
14/LO/0612/AM13	Care of Late Stage Parkinsonism (CLaSP)	SA3	02/02/2017	22
14/LO/1136/AM05	Non-invasive diagnostic testing for Gastro-intestinal disease	SA2	10/10/2016	15
14/LO/1136/AM07	Non-invasive diagnostic testing for Gastro-intestinal disease	SA3	12/01/2017	8
14/LO/1150/AM05	SERENADE	Substantial Amendment 4	25/04/2016	9
14/LO/1150/AM09	SERENADE	SA5	28/09/2016	29
14/LO/1698/AM02	Home based health promotion for vulnerable older people	Substantial Amendment 2,	25/05/2016	7

		24/05		
14/LO/1832/AM01	Tissue metabolism and blood flow in critically ill patients	SA1	28/04/2016	7
14/LO/2098/AM02	QUEST Follow-Up Study	SA2	11/02/2016	17
14/LO/2216/AM07	COPD Exacerbations and Environmental Exposure Modelling	SA5	22/03/2016	22
14/LO/2217/AM05	Risk Factors Leading to Hospital Infection	Substantial Amendment 2	12/07/2016	14
14/LO/2235/AM09	Trial of Electronic Cigarettes (TEC)	Substantial Amendment 2	11/05/2016	15
15/LO/0085/AM05	Development and Validation of the ACB	SA4	26/07/2016	8
15/LO/0431/AM03	MELODY	SA2	16/12/2016	16
15/LO/0480/AM01	Real time adverse event reporting by patients using a smart phone app	Substantial Amendment 1	01/06/2016	19
15/LO/0482/AM01	Co-producing personalised care solutions	SA1	15/12/2016	3
15/LO/0511/AM06	E-Compared (version 1.11)	Substantial Amendment 2	26/07/2016	14
15/LO/0511/AM09	E-Compared (version 1.11)	SA3	26/01/2017	21
15/LO/0611/AM02	Adjustment to Care in Dementia: An Intervention Feasibility Study v0.1	SA1	12/12/2016	22
15/LO/0933/AM01	Diagnosing and monitoring infection in critical illness	SA1	06/11/2015	18
15/LO/1071/AM01	Primary Radiotherapy And DIEP flAp reconstruction (PRADA) study	AM1604/10	01/06/2016	21
15/LO/1568/AM01	Bio-TBI	SA1	09/11/2016	35
15/LO/1809/AM01	Aqueous Dynamics and Glaucoma Surgery	Substantial Amendment 1	01/08/2016	8
15/LO/1810/AM01	Pilot Study - Primary glaucoma surgery for patients of African Descent	SA1	11/01/2017	20
15/LO/1811/AM01	Multimodal MRI scanning of NHS patients referred from clinics for brain disorders	SA1	23/02/2017	22
15/LO/1949/AM05	Early Development in Tuberous Sclerosis (EDiTS)	amendment 5	05/09/2016	24
15/LO/1960/AM01	The CIRCUITS Study: Implementation of Remediation into EI Services	SA1	17/02/2016	17
15/LO/1960/AM03	The CIRCUITS Study: Implementation of Remediation into EI Services	Substantial Amendment 2	25/07/2016	15
15/LO/1960/AM04	The CIRCUITS Study: Implementation of Remediation into EI Services	Substantial Amendment 3	31/08/2016	7
15/LO/1960/AM08	The CIRCUITS Study: Implementation of Remediation into EI	SA4	01/12/2016	13

	Services			
15/LO/1960/AM10	The CIRCUITS Study: Implementation of Remediation into EI Services	SA5	09/03/2017	21
15/LO/1967/AM02	Mindfulness meditation for chronic pelvic pain management	SA1	13/06/2016	11
15/LO/1967/AM04	Mindfulness meditation for chronic pelvic pain management	Substantial Amendment 2	02/09/2016	6
15/LO/1967/AM05	Mindfulness meditation for chronic pelvic pain management	SA3	28/09/2016	10
15/LO/1967/AM06	Mindfulness meditation for chronic pelvic pain management	SA4	27/10/2016	13
15/LO/1967/AM07	Mindfulness meditation for chronic pelvic pain management	SA5	22/12/2016	27
16/LO/0078/AM03	Impact of art therapy on sense of self in individuals with psychosis	SA1	08/08/2016	13
16/LO/0078/AM04	Impact of art therapy on sense of self in individuals with psychosis	SA2	21/11/2016	15
16/LO/0214/AM01	G-PATH SUPPORT:Gastrostomy feeding and psychosocial support	Substantial Amendment 1	18/08/2016	28
16/LO/0214/AM03	G-PATH SUPPORT:Gastrostomy feeding and psychosocial support	SA2	14/10/2016	13
16/LO/0214/AM07	G-PATH SUPPORT:Gastrostomy feeding and psychosocial support	SA3	06/02/2017	6
16/LO/0345/AM04	DUOGLOBE	SA1	15/10/2016	23
16/LO/0393/AM01	Sleep and learning in childhood tic disorders	SA1	01/06/2016	14
16/LO/0455/AM03	Health communication and people with learning disabilities	SA1	28/09/2016	9
16/LO/0465/AM01	Longitudinal Investigation of FTD and associated disorders (LIFTD)	Substantial Amendment 1	20/06/2016	13
16/LO/0465/AM02	Longitudinal Investigation of FTD and associated disorders (LIFTD)	Substantial Amendment 2	08/07/2016	37
16/LO/0468/AM02	Reducing drug-related admissions from Care Homes, improving well-being	SA1	10/10/2016	10
16/LO/0471/AM01	Creativity and Forensic Mental Health v1.0	SA1	27/02/2017	18
16/LO/0504/AM01	IDEAL-PM	Substantial Amendment 1	28/07/2016	7
16/LO/0621/AM01	Care of patients experiencing hip fracture & confusion: PERFECTED CRCT	Substantial Amendment 1	05/09/2016	25
16/LO/0621/AM02	Care of patients experiencing hip fracture & confusion: PERFECTED CRCT	Substantial Amendment 2	11/11/2016	19
16/LO/0621/AM06	Care of patients experiencing hip fracture & confusion:	SA3	08/02/2017	11

	PERFECTED CRCT			
16/LO/0621/AM07	Care of patients experiencing hip fracture & confusion: PERFECTED CRCT	SA04	08/03/2017	13
16/LO/0652/AM01	PRotect after depression: a randomised pilot trial	SA1	04/10/2016	14
16/LO/0922/AM01	Biomarkers for FRDA	SA1	06/12/2016	10
16/LO/1068/AM01	Analysis of COPD environmental exposure driven exacerbations	Substantial Amendment 1	23/06/2016	16
16/LO/1068/AM02	Analysis of COPD environmental exposure driven exacerbations	SA2	11/10/2016	19
16/LO/1110/AM02	Derivation and study of organoids from cancer patients	SA1	02/11/2016	9
16/LO/1110/AM03	Derivation and study of organoids from cancer patients	SA2	13/01/2017	20
16/LO/1110/AM04	Derivation and study of organoids from cancer patients	SA3	08/03/2017	20
16/LO/1119/AM02	Patient enactment of delayed prescribing of antibiotics	Substantial Amendment 1	22/08/2016	6
16/LO/1121/AM01	Quality of Life in Families of Children with Batten Disease	Substantial Amendment 1	15/09/2016	15
16/LO/1769/AM01	ASTAR	SA1	06/02/2017	14
16/LO/2010/AM01	A feasibility cluster RCT of the AMBER care bundle	SA1	10/01/2017	12
16/LO/2010/AM02	A feasibility cluster RCT of the AMBER care bundle	SA1	27/01/2017	23

#### Unfavourable opinion

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
14/LO/2241/AM03	Investigating migraine with novel MRI methods Version 1	SA2	24/01/2017	27

**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
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#### Unfavourable opinion timeline



<b>Amendment REC Reference</b>	<b>Title</b>	<b>Version</b>	<b>Date</b>	<b>Number of Days on Clock</b>
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**Table 11: Items exceeding timelines**

**Full applications for ethical review over 60 day timeline**

REC Reference	Title	Number of Days on Clock
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**Proportionate review applications for ethical review over 21 day timeline**

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

REC Reference	Title	Number of Days on Clock
16/LO/1160	A multi-centre, cluster random	26
16/LO/1162	A multi-centre, cluster random	26

**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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