

**East of England - Cambridge Central Research  
Ethics Committee**

**Annual Report**

**01 April 2016 - 31 March 2017**



## Part 1 – Committee Membership and Training

<b>Name of REC:</b>	East of England - Cambridge Central Research Ethics Committee
<b>Type of REC:</b>	RECs recognised to review CTIMPS in healthy volunteers - type i, RECs recognised to review CTIMPS in patients - type iii
<b>Type of Flag:</b>	Establishing Research Databases, Establishing Research Tissue Banks, Medical Device Study, Phase 1 Studies in Healthy Volunteers, Research Involving Adults Lacking Capacity
<b>Chair:</b>	Dr Lydia Drumright
<b>Vice-Chair:</b>	Dr Joseph Cheriyan
<b>Alternate Vice-Chair:</b>	Revd Dr Derek Fraser
<b>REC Manager:</b>	Ms Carolyn Halliwell
<b>REC Assistant:</b>	Miss Teagan Allen
<b>Committee Address:</b>	Royal Standard Place Nottingham NG1 6FS
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<b>Email:</b>	NRESCommittee.EastofEngland-CambridgeCentral@nhs.net

## Chair's overview of the past year:

April 2016 - March 2017 has, as in previous years, been very busy for the Cambridge Central Committee. We review six applications each month, and many are often fairly complex studies. We have seen a change in a handful of committee members, as well as the manager and manager's assistant.

Overall, we have a well-balanced committee with exceptional expertise and insightful lay input. The mix on the committee is good and leads to significant and focused ethical discussions. This enables us to rise to the challenge of the complexity of our studies, although the time frames for discussing the applications and meeting with the applicants (30 min timeslots) can be a challenge with increasing complexity of the application or inconsistent documents.

The turnover in members has not been substantial, and we have gained members with fresh perspectives, although we have yet to replace our statistician and this is sometime a concern for the committee. We have a rotating 1 year post that is filled by a junior doctor, which works well. The junior doctors often bring considerable medical expertise that is appreciated by the committee. This is very welcomed, as at times some members have commented that considerable medical expertise is necessary for many studies that we review, and they like to feel confident that there will be an expert in the room.

With respect to training, the HRA online training has been a very welcomed addition to the available courses, and some members have commented that the courses are 'terrific'. We have also been circulating the papers from the regional chairs meeting for self-study, and there are some excellent and thought provoking topics to explore. Regional meeting information is also very relevant to the Committee and they very much appreciate a short discussion at the meeting following these.

The new manager and manager's assistant are excellent. They have significant experience and expertise and are incredibly efficient and accurate. We receive significant support from the central office from Linda, Catherine, Jess and Andrea as well, which is very much appreciated.

Additionally, it has been very rewarding to see applicants in passing or at academic events who often extend thanks and appreciation for the review of their applications. I have received comments about how much they appreciate the thought provoking discussions and respect with which their applications are handled. The Committee's thorough reviews are receiving much appreciation and I am hopeful that all members of the Committee know how much the work that they do is appreciated by the applicants.

## East of England - Cambridge Central Research Ethics Committee Membership

Name	Profession	Expert or Lay	Dates	
			Appointed	Left
Dr Gusztav Belteki	Consultant Neonatologist	Expert	07/01/2016	
Dr Joseph Cheriyan	Consultant Physician	Expert	20/05/2011	
Ms Anita Chhabra	Clinical Trials Pharmacist	Expert	01/04/2011	
Dr Lydia Drumright	University Lecturer in Clinical Informatics	Expert	01/09/2014	
Revd Dr Derek Fraser	Chaplain	Lay Plus	01/04/2011	
Dr James Goodman	Registrar in clinical pharmacology and general medicine	Expert	01/10/2016	
Miss Giselle Kerry	Data Access and Regulatory Support Officer	Lay	12/07/2013	
Mr David Lewin	Retired Research Officer	Expert	01/04/2011	
Ms Moira Malfroy	Retired Senior Research Nurse/Clinical Trial Manager	Lay	12/06/2013	
Miss Emma McManus	Research Associate in Health Economics and Health Technology Assessment	Lay Plus	03/05/2016	
Mrs Beth Midgley	Public Speaker	Lay	04/01/2011	
Ms Polly Page	Operations Director	Lay Plus	01/01/2012	30/09/2016
Professor Sumantra Ray	Senior Medical Advisor/Scientist	Expert	01/01/2012	
Mrs Viona Rundell	Research Coordinator/Assistant	Lay	14/10/2016	
Mrs Caroline Saunders	Nurse	Expert	01/04/2011	
Dr Mary-Beth Sherwood	Research Governance Assistant	Lay	15/04/2014	
Dr Ian Smith	Consultant Respiratory and Sleep Physician, Clinical Director for Research and Development,	Expert	01/04/2011	08/04/2016

## East of England - Cambridge Central Research Ethics Committee: Deputy Members

None

**East of England - Cambridge Central Research Ethics Committee: Co-opted Members**

<b>Name</b>	<b>Profession</b>	<b>Status</b>	<b>Meeting date attended</b>
Dr Niki Bannister	Retired Hospital Doctor	Expert	13/05/2016
Dr Alan Lamont	Consultant Oncologist	Expert	13/05/2016
Dr Gerry Kamstra	Retired Solicitor	Lay Plus	10/06/2016
Dr Ted Barker	Reader in Developmental Psychopathology	Lay Plus	09/09/2016
Dr Ian Skidmore	Retired Company Director	Lay Plus	14/10/2016

**East of England - Cambridge Central Research Ethics Committee: Members' Declarations of Interest:**

<b>Name</b>	<b>Declaration of Interest</b>	<b>Date</b>
Dr Gusztav Belteki	None declared	14/12/2016
Dr Joseph Cheriyan	Dr Cheriyan is a full time employee of Cambridge University Hospitals NHS Foundation Trust, and part of his contract stipulates a 50% secondment to GSK's Clinical Unit Cambridge – a Phase ½ research unit on the hospital campus. He receives no shares/dividends/bonuses/employee benefits as a result of this connection to GSK. He is a Board member of the Cambridge Clinical Trials Unit Steering Committee and Management group	14/12/2016
Ms Anita Chhabra	Support Cambridge University Hospital NHS Foundation Trust R&D. Cambridge Clinical Trials Unit. Cambridge Cancer Trials Unit. Cambridge Ethics Committee Psychology Research	13/12/2016
Dr Lydia Drumright	University Lecturer - Uni of Cambridge, Chair of Board of Scrutiny Member of UREC - Uni of Cambridge, Member of Cambridge Big Data SRI: Deputy head Cambridge Infectious Diseases IRC: Fellow of Hughes Hall Fellow of Hughes Hall - this is a Cambridge College, which is a charity. Being a Fellow means that she is on the Governing Body. Hughes Hall may do health research University Lecturer in the Department of Medicine, Uni of Cambridge - as part of job, actively seeks out research funding in order to conduct health related research. The University is a charity Member of UREC	14/12/2016
Revd Dr Derek Fraser	Chair of UKBHC – board for healthcare chaplaincy	13/12/2016
Dr James Goodman	none declared	13/12/2016
Miss Giselle Kerry	none declared	13/01/2017
Mr David Lewin	none declared	13/12/2016
Ms Moira Malfroy	Has shares in Astra Zeneca and GSK, member of the charity primary Immunodeficiency	13/12/2016
Miss Emma McManus	Member of Tuberous Sclerosis Association Research Committee – Methodologist (since April 2016)	14/12/2016
Mrs Beth Midgley	None declared	13/01/2017
Professor Sumantra Ray	Honorary: Founding Chair and Executive Director* of the NNEdPro** Global Centre for Nutrition and Health (affiliated with Cambridge University Health Partners and Wolfson College at the University of Cambridge and the British Dietetic Association)**Director and Company Secretary of not-for-profit legal entity*NNEdProTM – The Need for Nutrition Education/Innovation Programme and Cambridge Research Education and Training Enterprise Medical Research Council – Senior Medical Advisor & Senior Clinician Scientist (Volunteer Studies and Clinical Services Facility & Vascular Studies Platform)   Lead Clinician (UK	28/12/2016

	National Diet and Nutrition Survey) – MRC Elsie Widdowson Laboratory, Cambridge, UK Honorary Consultant in Nutrition, Public Health England Co-Chair of the Healthcare Specialism Working Group, Registration Committee, Association for Nutrition, UK Governing Body Fellow of Wolfson College at the University of Cambridge Visiting Professor, Ulster University Visiting Professor, Imperial College London Adjunct Professor, University of Waterloo Adjunct Senior Research Fellow, Griffith University Medical Research Council Reviewer/Advisor National Institute of Health Research Reviewer/Advisor	
Mrs Viona Rundell	None declared	13/12/2016
Mrs Caroline Saunders	Head of Clinical operations at Addenbrookes clinical research centre - conducts 250 clinical research protocols in patients.	13/12/2016
Mary-Beth Sherwood	work in CPFT as a Research Governance Assistant	14/12/2016

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

Month	Date	Number of Members Present at Meeting
April	08/04/2016	8
May	13/05/2016	9
June	10/06/2016	9
August	12/08/2016	8
September	09/09/2016	9
October	14/10/2016	9
December	09/12/2016	10
January	13/01/2017	12
February	10/02/2017	10
March	10/03/2017	9

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	27/04/2016	3
May	31/05/2016	3
June	29/06/2016	3
August	02/08/2016	4
August	30/08/2016	3
September	26/09/2016	3
October	28/10/2016	3
November	29/11/2016	3
January	27/01/2017	3
February	24/02/2017	3
March	24/03/2017	3

11 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	04/04/2016	2
April	20/04/2016	2
April	29/04/2016	2
May	13/05/2016	2
June	02/06/2016	2
June	10/06/2016	2
June	24/06/2016	2
June	27/06/2016	2
July	08/07/2016	2
July	22/07/2016	2



August	05/08/2016	2
August	19/08/2016	2
September	05/09/2016	2
September	16/09/2016	2
October	07/10/2016	2
October	28/10/2016	2
November	21/11/2016	2
November	29/11/2016	2
December	13/12/2016	2
January	13/01/2017	2
January	27/01/2017	2
February	10/02/2017	2
February	24/02/2017	2
March	10/03/2017	3
March	24/03/2017	2
March	27/03/2017	2

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

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

None

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

<b>Name</b>	<b>Number of Meetings Attended</b>
Dr Gusztav Belteki	3
Dr Joseph Cheriyan	3
Ms Anita Chhabra	8
Dr Lydia Drumright	10
Revd Dr Derek Fraser	5
Dr James Goodman	4
Miss Giselle Kerry	6
Mr David Lewin	6
Ms Moira Malfroy	8
Miss Emma McManus	6
Mrs Beth Midgley	7
Ms Polly Page	2
Professor Sumantra Ray	4
Mrs Viona Rundell	4
Mrs Caroline Saunders	4
Mary-Beth Sherwood	7
Dr Ian Smith	1

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

<b>Name</b>	<b>Number of Meetings Attended</b>
Dr Gusztav Belteki	2
Dr Joseph Cheriyan	3
Ms Anita Chhabra	1
Dr Lydia Drumright	3
Revd Dr Derek Fraser	5
Miss Giselle Kerry	2
Mr David Lewin	4
Ms Moira Malfroy	4
Mrs Beth Midgley	2
Polly Page	2
Dr Sumantra Ray	1
Mrs Caroline Saunders	2
Mary-Beth Sherwood	2

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

<b>Name</b>	<b>Number of Meetings Attended</b>
Dr Gusztav Belteki	1
Dr Joseph Cheriyan	4
Ms Anita Chhabra	4
Dr Lydia Drumright	12
Revd Dr Derek Fraser	10
Miss Giselle Kerry	2
Mr David Lewin	5
Ms Moira Malfroy	2
Mrs Beth Midgley	4
Dr Sumantra Ray	3
Mary-Beth Sherwood	5

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

<b>Name of Member</b>	<b>Date</b>	<b>Event(s) attended</b>
Dr Joseph Cheriyan	22/03/2017	National Members Training Day
Ms Anita Chhabra	01/05/2016	Mental Capacity Act training
Ms Anita Chhabra	01/06/2016	1:2:1 teaching non-medical member of staff ,REC and MHRA requirements of IRAS application for a CTIMP trial
Ms Anita Chhabra	16/02/2017	National Members Training Day
Dr Lydia Drumright	03/06/2016	NREAP Chairs Meeting
Revd Dr Derek Fraser	10/05/2016	Equality & Diversity
Revd Dr Derek Fraser	01/06/2016	Taught Muslim students some of the ethical challenges that emerge in critical care
Revd Dr Derek Fraser	16/02/2017	National Members Training Day
Miss Giselle Kerry	31/10/2016	Reviewing the Research Design of Clinical Trials
Mr David Lewin	20/04/2016	Researcher Training Day
Mr David Lewin	23/09/2016	REC Member Training Day
Mr David Lewin	01/02/2017	Medical Devices Training
Mr David Lewin	08/03/2017	Handling Health Related Findings in Research
Ms Moira Malfroy	23/09/2016	REC Member Training Day
Ms Moira Malfroy	01/12/2016	New Member Buddy
Miss Emma McManus	26/05/2016	Equality & Diversity
Miss Emma McManus	26/05/2016	Online Member Induction
Miss Emma McManus	30/11/2016	Committee Members Induction
Miss Emma McManus	23/02/2017	Data Protection
Mrs Beth Midgley	23/09/2016	REC Member Training Day
Professor Sumantra Ray	01/06/2016	Organised and chaired the 2nd NNEdPro Summit in Medical Nutrition Education and Research (2 days) which was adjacent to the 1st NNEdPro Summer School and Certificate Course in Applied Human Nutrition
Mrs Viona Rundell	06/12/2016	Committee Member Induction
Mrs Viona Rundell	16/02/2017	National Members Training Day
Mrs Caroline Saunders	23/09/2016	REC Member Training Day
Mary-Beth Sherwood	23/09/2016	REC Member 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	8	14.29
Phase 1	2	3.57
Gene Therapy	0	0.00
Research Tissue Bank (including renewals)	1	1.79
Research Database (including renewals)	1	1.79
Others	44	78.57
<b>Total Applications Reviewed</b>	<b>56</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	21
Number of paediatric applications reviewed	7
Number of device applications reviewed	4
Number of prisoner applications reviewed	0
Number of applications involving adults unable consent reviewed	15
Number of applications reviewed that are funded by the US DHHS	0
Number of qualitative applications reviewed	4

**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	3.57
Favourable Opinion with Additional Conditions	0	0.00
Unfavourable Opinion	8	14.29
Provisional Opinion	46	82.14
Provisional Opinion Pending Consultation with Referee	0	0.00
<b>Total</b>	<b>56</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	34	60.71
Further Information Favourable Opinion with Additional Conditions	8	14.29
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	2	3.57
Favourable Opinion with Additional Conditions	0	0.00
Unfavourable Opinion	7	12.50
Provisional Opinion	3	5.36
Provisional Opinion Pending Consultation with Referee	0	0.00
Further Information response not complete	1	1.79
No decision entered on system	0	0.00
Number of studies withdrawn after the meeting	1	1.79
<b>Total</b>	<b>56</b>	<b>100</b>

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

<b>Total Applications Reviewed</b>	<b>33</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	3
Number of studies withdrawn prior to the meeting	0
Number of student applications reviewed	14
Number of paediatric applications reviewed	5
Number of device applications reviewed	2
Number of qualitative applications reviewed	6

**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	1	3.03
Favourable Opinion with Additional Conditions	4	12.12
No Opinion transfer to full committee for review	4	12.12
Provisional Opinion	24	72.73
Unfavourable Opinion	0	0.00
<b>Total</b>	<b>33</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>	5.09
<b>Number of completed applications for full ethical review</b>	55
<b>Number of completed applications for full ethical review over 60 days</b>	5
<b>Number of completed applications over 60 days as a % of total</b>	8.93%
<b>Number of completed applications for full ethical review over 40 days</b>	33
<b>Number of completed applications over 40 days as a % of total</b>	58.93%
<b>Number of days taken to final decision – average (mean)</b>	47

<b>Number of completed proportionate review applications for ethical review</b>	29
<b>Number of completed proportionate review applications for ethical review over 14 days (Please note, the timeline for ethical review of PR applications was extended from 14 to 21 calendar days in December 2016)</b>	13
<b>Number of completed proportionate review applications for ethical review over 21 days</b>	5
<b>Number of completed proportionate review applications over 14 days as a % of total</b>	44.83%

<b>Number of SSAs (non-Phase 1) reviewed</b>	10
<b>Number of completed applications for SSA review over 25 days</b>	1
<b>Number of completed applications for SSA review over 25 days as % of all non- Phase 1 SSAs</b>	10.00%

<b>Number of SSAs (Phase 1) reviewed</b>	3
<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>	123
<b>Number of completed substantial amendments over 35 days</b>	5
<b>Number of completed substantial amendments over 35 days as a % of total substantial amendments</b>	4.07%
<b>Number of completed substantial amendments over 28 days</b>	36
<b>Number of completed substantial amendments over 28 days as a % of total substantial amendments</b>	29.27%

<b>Number of modified amendments reviewed</b>	3
<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>	107
<b>Number of substantial amendments received for information</b>	1
<b>Number of substantial amendments received for new sites/PIs</b>	13
<b>Number of annual progress reports received</b>	115
<b>Number of safety reports received</b>	17
<b>Number of Serious Adverse Events received</b>	4
<b>Number of final reports received</b>	13

**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/EE/0087	Fatigue in Sarcoidosis: Treatment with Methylphenidate	58
16/EE/0100	Personalised Breast Cancer Program	57
16/EE/0101	Serotonin, Emotion, and Behaviour	59
16/EE/0112	OCT imaging of conjunctiva, adnexal structures & oral mucous membrane	58
16/EE/0131	The Genetics of Cholesteatoma	59
16/EE/0151	Mapping of cognitive function in diffuse low grade glioma surgery	34
16/EE/0170	Time to Delivery of Preterm Birth	59
16/EE/0182	Quantifying the support stroke survivors get with daily medication	51
16/EE/0201	Genetic risk factors for cerebral small vessel disease	49
16/EE/0210	Cortisol PD AD	55
16/EE/0230	PK study of LAS41008 120mg and Fumaderm 120mg in healthy subjects	54
16/EE/0249	NoSH Study	46
16/EE/0251	Executive function and QoL/Social cognition in BPD	48
16/EE/0255	Community Navigators Study	49
16/EE/0307	Exploring meaning of penetration in vaginismus	71
16/EE/0313	Effect of orthoses and underfoot vibration on balance in neuropathy	75
16/EE/0333	Apathy and outcome after stroke	52
16/EE/0337	Effectiveness and safety of lemborexant in patients with Insomnia	56
16/EE/0351	7Tesla MRI Scanning in AD and FTLD	46
16/EE/0358	CTBM100G2202, For patients with Non-Cystic Fibrosis Bronchiectasis	39
16/EE/0367	Extension Study for SMA patients who participated in ISIS396443 study	27
16/EE/0370	MesoTRAP pilot clinical trial and feasibility study	68
16/EE/0372	Asthma Monitoring Device- Methacholine Challenge Study	28
16/EE/0393	DIALIVE in ACLF	32
16/EE/0394	Investigating how childhood tumours and congenital disease develop	58
16/EE/0418	7T MRI study of brain changes in Dementia with Lewy bodies	79
16/EE/0526	CLOTFAST II	68
16/EE/0536	1363.2 BI443651 vs placebo in healthy volunteers, COPD and CF subjects	53
17/EE/0016	A Randomised Control Trial of SEEG Electrode Placement methods	42
17/EE/0025	NIHR BioResource	48
17/EE/0032	Cambridge GENFI v1	30
17/EE/0033	The MRC Brain Bank Genomic Database	28

17/EE/0084	Study to assess QCC374 in treatment of pulmonary arterial hypertension	47
17/EE/0096	Myocardial modelling and assessment using 2D TOE echocardiography	38

#### Further Information Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
16/EE/0118	Familial Cerebral Small Vessel Disease	43
16/EE/0178	Cochlear nerve monitoring study ver2	59
16/EE/0402	AMROA	60
16/EE/0412	Rexmyelocel-T to treat critical limb ischaemia in adults with diabetes	48
16/EE/0529	Tau Evaluation in Neurodegeneration and Dementia Research (TENDeR)	55
17/EE/0004	Lung Ultrasound in ECMO (LUS-ECMO)	39
17/EE/0048	Mitochondria and Synapses in the aging brain	40
17/EE/0055	ME-SOS study-Microcirculation of the Eyes in Severe OSA Syndrome	33

#### 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/EE/0326	Can individuals with dementia live well in extra care?	54
96/129 - duplicate	XY Sex reversal Syndromes in Childhood a diagnostic study	16

#### Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
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#### Unfavourable Opinion

REC Reference	Title	Number of Days on Clock
16/EE/0193	Genetics and Cardiovascular Diseases (GenCAD)	34
16/EE/0250	Extra Care and its appropriateness for individuals with dementia	42
16/EE/0498	Effect of sugar intake on aggressive behaviour in dementia	33

16/EE/0511	ASPECTS - analysing trauma narratives in children and adolescents	33
17/EE/0060	Addiction Services Treatment Evaluation of Risk Cohort Study Pilot	22
17/EE/0085	Online services and support for those with early onset dementia	39
17/EE/0091	Music-sound linked autobiographical memory intervention in dementia.	32

#### Provisional Opinion

REC Reference	Title	Number of Days on Clock
17/EE/0002	Beneficial Effects of Inorganic Nitrates in Liver Steatosis	n/a
17/EE/0067	Rexmyelocel-T to treat ischaemic ulcers in diabetic adults(Category 5)	n/a
17/EE/0075	Interrogating Metabolism Kinetics in the Human Brain	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
17/EE/0011	SAMOA: Spatial Analytics through Mobile sensing of early AD	n/a

#### Withdrawn after the meeting

REC Reference	Title	Number of Days on Clock
16/EE/0435	st:art	45

**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
16/EE/0189	The evaluation of tailored electronic reminders on compliance	13
16/EE/0194	Family Based Support with parents and family carers	14
16/EE/0239	The role of mast cell in Eosinophilic esophagitis	15

16/EE/0240	Views on, and preferences for, a digital diabetes prevention programme	14
16/EE/0242	Human Reliability Analysis of transanal Total Mesorectal Excision	14
16/EE/0288	Knowledge & skills perinatal mental health - training needs analysis	14
16/EE/0330	Ovarian cancer and feeding into a vein	13
16/EE/0331	Kidney patients' views on questionnaires: a think-aloud study	16
16/EE/0332	PRODIGY	14
16/EE/0376	Bioavailability of beetroot compounds in older adults, 0.1	13
16/EE/0378	CapPPE	13
16/EE/0385	Developing a Programme Theory of Integrated Care	14
16/EE/0426	Cardiac Mechanics by Echocardiography in HER2+ Breast Cancer vr1.2	15
16/EE/0477	Thoracic MRI as a tool in diagnosis and follow up in COVID patients	6
16/EE/0539	PROMs in the Management of Endodontically Involved Teeth at LUDH	15
17/EE/0039	Investigating link between GAD, Stiff person syndrome and Type 1 DM	27
17/EE/0042	Exploring hidden mental illness within the farming community	22
17/EE/0043	Inspiratory muscle training for adults with CAP	20
17/EE/0047	Evaluation of a D-Dimer assay	19
17/EE/0087	Impact of chronic pain on the lives of adolescents	17
17/EE/0088	Survey of self-management in individuals with asthma	15
17/EE/0134	Right ventricular contractile reserve following lung resection	25

#### Further Information Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
16/EE/0429	ML30098 UK Breast Cancer Productivity and Utility Study	29

#### 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/EE/0377	Unilateral Congenital Myogenic Ptosis Observational Study v1	14

#### Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
16/EE/0191	Impact of counselling intervention on patients' knowledge of apixaban.	13
16/EE/0291	Understanding ELISA anti-TNF monitoring assays	14
16/EE/0293	Variations in our genes that increase the risk of having kidney stones	14
17/EE/0136	Improving utilisation of pulmonary rehabilitation v1	10

#### Unfavourable Opinion

REC Reference	Title	Number of Days on Clock
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#### Provisional Opinion

REC Reference	Title	Number of Days on Clock
17/EE/0135	A pilot of two rehabilitation programmes for scapholunate instability	n/a

#### 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>
01/149/AM08	A study to investigate the cell biological determinants of the develop	10	25/05/2016	28
01/358/AM09	Fabry Outcome Survey (FOS)	01/358	03/05/2016	16
01/358/AM14	Fabry Outcome Survey (FOS)	Substantial Amendment Protocol	29/06/2016	15
03/018/AM14	Evaluation of biomarkers in urological diseases	13	26/04/2016	23
03/288/AM03	The organisation and neural basis of semantic memory, and its interact	1	13/04/2016	29
04/Q0108/44/AM29	The Cambridge BioResource	30	20/05/2016	35
04/Q0108/44/AM35	The Cambridge BioResource	34	17/10/2016	26
05/Q0108/30/AM10	Bodily sample collection for use in method development	Substantial Amendment 10	11/01/2017	12
05/Q0108/365/AM15	RAPPER	16	16/05/2016	16
06/Q0108/281/AM06	Function and fate of human granulocytes	5	11/05/2016	28
06/Q0108/281/AM07	Function and fate of human granulocytes	6	02/11/2016	25
06/Q0108/84/AM18	Reference measurements for studies of metabolism	Substantial Amendment 16	05/10/2016	40
08/H0308/153/AM33	Genes and Phenotypes in Type 1 Diabetes	32	28/09/2016	21
08/H0308/281/AM06	Regulation of neutrophil apoptosis by phosphoinositide 3-kinases	Substantial Amendment #8	20/01/2017	10
09/H0308/118/AM11	Trimodal Imaging and Molecular Endpoints	8	27/04/2016	29
09/H0308/134/AM04	Assessing nociception in patients with congenital indifference to pain	5	17/08/2016	27
09/H0308/24/AM02	The study of Human Gut Hormones	2	02/06/2016	21
10/H0308/11/AM03	Lung shunt and VQ mismatch in adults	2	19/05/2016	35
10/H0308/18/AM03	TYM (Test Your Memory) testing version 2	3	26/04/2016	15
10/H0308/56/AM11	Cambridge Brain Bank a Division of Cambridge University NHS	4	10/08/2016	20

	Foundation			
11/EE/0037/AM14	Validation of Structured Light Plethysmography against spirometry	8	20/06/2016	32
11/EE/0037/AM15	Validation of Structured Light Plethysmography against spirometry	Substantial Amendment 9	12/12/2016	36
11/EE/0120/AM03	ATTOM version 1	Substantial Amendment 3	01/01/2017	21
11/EE/0202/AM17	CR UK Stratified Medicine Pilot study	11	21/03/2016	19
11/EE/0330/AM04	Phenotypes in Intellectual Disability	Amendment 3 18/03/2016	18/03/2016	19
11/EE/0330/AM05	Phenotypes in Intellectual Disability	4	23/11/2016	35
11/EE/0463/AM05	Interrogating Energy Metabolism in the Human Brain	4	18/08/2016	35
12/EE/0206/AM07	STH Research Database for Diabetes, Endocrinology & Retinal Screening	3	26/05/2016	28
12/EE/0250/AM10	U-Change v1.0	8	14/04/2016	26
12/EE/0349/AM06	BriTROC1: Sample collection study in recurrent HGSOc	5	21/03/2016	28
12/EE/0407/AM03	Research database for Cambridgeshire & Peterborough NHS FT (CPFT)	2	07/10/2016	18
12/EE/0475/AM04	PIPPIN Study	Substantial Amendment 2	01/10/2016	27
12/EE/0486/AM14	Genetic influences on pain perception in chronic pain states	7	11/05/2016	28
12/EE/0486/AM15	Genetic influences on pain perception in chronic pain states	8	18/10/2016	7
12/EE/0516/AM04	Stratification of patients with kidney cancer	4	13/05/2016	26
12/EE/0523/AM13	HGS1006-C1100 Phase 3 - Belimumab for Maintenance of Remission in AAV	12	09/08/2016	15
13/EE/0011/AM07	Uterine LMS study	Amendment 6	21/03/2016	30
13/EE/0047/AM04	Closed-loop insulin delivery in the general ward (ANGIE02)	4	02/06/2016	35
13/EE/0161/AM05	The UCL BioResource version 1	3	23/09/2016	29
13/EE/0161/AM07	The UCL BioResource version 1	4	12/01/2017	30
13/EE/0161/AM10	The UCL BioResource version 1	Substantial Amendment 5	01/03/2017	22
13/EE/0169/AM05	Mesobank	Substantial Amendment 3	03/02/2017	16
13/EE/0226/AM11	The GSTT/KCL BioResource	9	12/04/2016	28
13/EE/0226/AM13	The GSTT/KCL BioResource	10	26/05/2016	35
13/EE/0321/AM05	Closing the loop in adults with type 1 diabetes	Substantial	14/04/2016	16



		Amendment 4		
13/EE/0339/AM18	COMPASS (BAY 59-7939/15786)	10	18/06/2016	16
13/EE/0339/AM21	COMPASS (BAY 59-7939/15786)	Substantial Amendment #011	06/03/2017	14
13/EE/0395/AM02	The Research Tissue Bank, Huntingdon Life Sciences	2	13/05/2016	31
13/EE/0429/AM12	BET116183: GSK525762 in Subjects with Haematologic Malignancies	Substantial Amendment 5	04/05/2016	15
13/EE/0429/AM13	BET116183: GSK525762 in Subjects with Haematologic Malignancies	6	26/08/2016	7
13/EE/0429/AM17	BET116183: GSK525762 in Subjects with Haematologic Malignancies	07	24/02/2017	28
14/EE/0145/AM03	BEHOLD v1.0	3.0	07/11/2016	28
14/EE/0149/AM03	Investigating the effects of cognitive training on attention	3	25/05/2016	35
14/EE/0193/AM01	Adjuvant benefit of NMES to Supervised Exercise in IC	1.2	26/10/2015	22
14/EE/0218/AM05	GLP-1 loading during elective PCI (GOLD-PCI)	3	28/11/2016	12
14/EE/1096/AM06	FABRY SRT MONO	4	15/01/2016	21
14/EE/1138/AM03	PROCO	SA2	23/03/2016	22
14/EE/1224/AM12	SADAL: Selinexor and Dexamethasone in Aggressive Lymphoma	8	17/02/2017	26
14/EE/1278/AM01	The culture of healthcare	1	23/03/2016	19
14/EE/1279/AM07	Latella-2	4	07/06/2016	20
14/EE/1279/AM08	Latella-2	8	11/10/2016	26
15/EE/0092/AM03	BIOMarkers in DEPRESSION (BIODEP)	2	13/05/2016	10
15/EE/0092/AM04	BIOMarkers in DEPRESSION (BIODEP)	3	19/10/2016	8
15/EE/0143/AM01	Glycosaminoglycan-Remodeling Effects of Na <sup>+</sup> Depletion and Equilibrium	1	12/05/2016	20
15/EE/0146/AM02	Relief II Study	2	06/01/2017	23
15/EE/0158/AM02	REACT RCT	2	04/08/2016	27
15/EE/0158/AM04	REACT RCT	4	02/12/2016	11
15/EE/0192/AM03	BARTS CANCER INSTITUTE BREAST TISSUE BANK	3	25/11/2016	30
15/EE/0260/AM04	C-Optimise	4	25/05/2016	35
15/EE/0270/AM02	The GOLDeN Study (version 1)	2	19/04/2016	20
15/EE/0286/AM04	IBD Bioresource	2	12/10/2016	29
15/EE/0320/AM01	Blood and Genes in Acute Coronary Syndrome	1.0	28/04/2016	30
15/EE/0328/AM04	The TREATment of severe Atopic eczema Trial (TREAT)	3.0	17/10/2016	28
15/EE/0356/AM01	Ex-vivo normothermic perfusion in DCD kidney transplantation	1	11/08/2016	21

15/EE/0368/AM03	COMPARE ABSORB	1	05/07/2016	19
15/EE/0368/AM04	COMPARE ABSORB	2	02/03/2017	19
15/EE/0370/AM07	4216: SUSTAIN-7 semaglutide vs dulaglutide in type 2 diabetes	4	12/07/2016	20
15/EE/0370/AM08	4216: SUSTAIN-7 semaglutide vs dulaglutide in type 2 diabetes	5	31/10/2016	27
15/EE/0370/AM09	4216: SUSTAIN-7 semaglutide vs dulaglutide in type 2 diabetes	6	13/01/2017	31
15/EE/0382/AM01	Oxytocin in CDI. Version 1.	1	01/03/2016	17
15/EE/0445/AM01	Sleep in HD - Version 1.0	1	15/07/2016	17
15/EE/0450/AM03	Proof of concept study of vagus nerve stimulation	2	16/03/2016	22
15/EE/0450/AM04	Proof of concept study of vagus nerve stimulation	3	26/04/2016	23
15/EE/0479/AM01	Rotational osteotomy outcome	1	05/09/2016	29
16/EE/0004/AM01	The Cambridge Ultrasound Siblings and Parents (CUSP) Study	1	28/04/2016	19
16/EE/0006/AM01	Bedside measurement of brain activity in disorders of consciousness	1	27/05/2016	35
16/EE/0006/AM02	Bedside measurement of brain activity in disorders of consciousness	2.0	23/02/2017	15
16/EE/0009/AM01	An open-label study of tivozanib versus sorafenib in renal cell cancer	1	07/04/2016	29
16/EE/0009/AM03	An open-label study of tivozanib versus sorafenib in renal cell cancer	2	12/08/2016	21
16/EE/0009/AM07	An open-label study of tivozanib versus sorafenib in renal cell cancer	3	20/01/2017	34
16/EE/0010/AM01	Archival genito-urinary tissue, blood, urine and saliva collection, v1	1	08/09/2016	33
16/EE/0067/AM01	Understanding the biology of human embryos and stem cells-v1	1	18/10/2016	33
16/EE/0072/AM01	Care pathway for survivors with severe disability after stroke	1	12/05/2016	27
16/EE/0084/AM02	7Tesla MRI Scanning in Healthy Controls	1	27/10/2016	33
16/EE/0086/AM03	The POSTCARD Study Version 1.0	1	05/10/2016	27
16/EE/0100/AM01	Personalised Breast Cancer Program	1	06/10/2016	19
16/EE/0101/AM01	Serotonin, Emotion, and Behaviour	1	13/07/2016	28
16/EE/0118/AM01	Familial Cerebral Small Vessel Disease	1	13/12/2016	28
16/EE/0131/AM01	The Genetics of Cholesteatoma	1	02/09/2016	18
16/EE/0138/AM01	Encouraging South Asians to consider hepatitis testing	1	30/08/2016	28

16/EE/0151/AM01	Mapping of cognitive function in diffuse low grade glioma surgery	1	09/12/2016	45
16/EE/0201/AM01	Genetic risk factors for cerebral small vessel disease	1	09/01/2017	22
16/EE/0210/AM01	Cortisol PD AD	1	08/08/2016	31
16/EE/0240/AM01	Views on, and preferences for, a digital diabetes prevention programme	1	17/08/2016	16
16/EE/0255/AM01	Community Navigators Study	1	30/11/2016	13
16/EE/0255/AM02	Community Navigators Study	2	09/02/2017	18
16/EE/0291/AM01	Understanding ELISA anti-TNF monitoring assays	1	14/10/2016	40
16/EE/0293/AM02	Variations in our genes that increase the risk of having kidney stones	1	02/12/2016	11
16/EE/0330/AM01	Ovarian cancer and feeding into a vein	1	26/01/2017	21
16/EE/0337/AM01	Effectiveness and safety of lemborexant in patients with Insomnia	1	25/10/2016	7
16/EE/0337/AM04	Effectiveness and safety of lemborexant in patients with Insomnia	03	20/01/2017	16
16/EE/0358/AM03	CTBM100G2202, For patients with Non-Cystic Fibrosis Bronchiectasis	3	05/01/2017	15
16/EE/0378/AM01	CapPPE	1	27/02/2017	21
16/EE/0393/AM01	DIALIVE in ACLF	1	19/12/2016	14
16/EE/0429/AM02	ML30098 UK Breast Cancer Productivity and Utility Study	2	22/02/2017	19
16/EE/0526/AM01	CLOTFAST II	1	24/01/2017	21
95/031/AM03	Longterm cognitive outcome following focal brain lesions	1	02/08/2016	35
96/129 - duplicate/AM01	XY Sex reversal Syndromes in Childhood a diagnostic study	5	07/03/2016	34

<b>Unfavourable opinion</b>				
<b>Amendment REC Reference</b>	<b>Title</b>	<b>Version</b>	<b>Date</b>	<b>Number of Days on Clock</b>
00/325/AM02	Cambridge Baby Growth Study	2	19/04/2016	39
10/H0308/71/AM20	Evaluation of a Non-Endoscopic Device for Barrett's Oesophagus-BEST 2	16	14/03/2016	32
12/EE/0368/AM10	Adrenal study	SA4	09/03/2016	23
13/EE/0395/AM03	The Research Tissue Bank, Huntingdon Life Sciences	3	04/10/2016	34
96/085/AM20	Invitro studies of postmortem human foetal neural tissue	14	15/07/2016	23

**Table 10.2: Breakdown of current status of all modified amendments reviewed within the reporting period**

<b>Favourable opinion timeline</b>				
<b>Amendment REC Reference</b>	<b>Title</b>	<b>Version</b>	<b>Date</b>	<b>Number of Days on Clock</b>
10/H0308/71/AM20/1	Evaluation of a Non-Endoscopic Device for Barrett's Oesophagus-BEST 2	17	19/04/2016	9
12/EE/0368/AM10/1	Adrenal study	Modified Amendment V2	29/06/2016	13
13/EE/0395/AM03/1	The Research Tissue Bank, Huntingdon Life Sciences	Amendment Number 4	14/11/2016	10

<b>Unfavourable opinion timeline</b>				
<b>Amendment REC Reference</b>	<b>Title</b>	<b>Version</b>	<b>Date</b>	<b>Number of Days on Clock</b>

**Table 11: Items exceeding timelines**

<b>Full applications for ethical review over 60 day timeline</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
16/EE/0307	Exploring meaning of penetration in vaginismus	71
16/EE/0313	Effect of orthoses and underfoot vibration on balance in neuropathy	75
16/EE/0370	MesoTRAP pilot clinical trial and feasibility study	68
16/EE/0418	7T MRI study of brain changes in Dementia with Lewy bodies	79
16/EE/0526	CLOTFAST II	68

<b>Proportionate review applications for ethical review over 14 day timeline (Please note, the timeline for ethical review of PR applications was extended in December 2016)</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
16/EE/0239	The role of mast cell in Eosinophilic esophagitis	15
16/EE/0331	Kidney patients' views on questionnaires: a think-aloud study	16
16/EE/0426	Cardiac Mechanics by Echocardiography in HER2+ Breast Cancer vr1.2	15
16/EE/0429	ML30098 UK Breast Cancer Productivity and Utility Study	29
16/EE/0539	PROMs in the Management of Endodontically Involved Teeth at LUDH	15
17/EE/0043	Inspiratory muscle training for adults with CAP	20
17/EE/0047	Evaluation of a D-Dimer assay	19
17/EE/0087	Impact of chronic pain on the lives of adolescents	17
17/EE/0088	Survey of self-management in individuals with asthma	15

<b>Proportionate review applications for ethical review over 21 day timeline (post December 2016)</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
17/EE/0039	Investigating link between GAD, Stiff person syndrome and Type 1 DM	27
17/EE/0042	Exploring hidden mental illness within the farming community	22
17/EE/0134	Right ventricular contractile reserve following lung resection	25

<b>SSAs (non Phase 1) over 25 day timeline</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
17/EE/0065	Efficacy and safety of semaglu	30

**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
00/325/AM02	Cambridge Baby Growth Study	2	19/04/2016	39
06/Q0108/84/AM18	Reference measurements for studies of metabolism	Substantial Amendment 16	05/10/2016	40
11/EE/0037/AM15	Validation of Structured Light Plethysmography against spirometry	Substantial Amendment 9	12/12/2016	36
16/EE/0151/AM01	Mapping of cognitive function in diffuse low grade glioma surgery	1	09/12/2016	45
16/EE/0291/AM01	Understanding ELISA anti-TNF monitoring assays	1	14/10/2016	40

**Modified Amendments over 14 day timeline**

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
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