

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

**Annual Report**

**01 April 2015 - 31 March 2016**



## 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>	Miss Rebecca Morledge
<b>REC Assistant:</b>	Mr George R. Martin
<b>Committee Address:</b>	Royal Standard Place Nottingham NG1 6FS
<b>Telephone:</b>	0207 104 8104 / 0207 104 8103
<b>Email:</b>	<a href="mailto:NRESCommittee.EastofEngland-CambridgeCentral@nhs.net">NRESCommittee.EastofEngland-CambridgeCentral@nhs.net</a>

## Chair's overview of the past year:

April 2015- March 2016 has been a busy year for the Cambridge Central Committee, as usual. We review six applications each month, and many are often fairly complex studies. We have also had some turnover in staff and have been working with a relatively new manager and a new support member for the manager, and we have experience the new HRA reviews system.

Overall, we have a strong committee with exceptional expertise and dedication to the thorough review of applications. This enables us to keep up with the busy workload, although I think that the time frames for discussing the applications and meeting with the applicants (30 min timeslots) would benefit from review and flexibility based on complexity of the application. For simple and straightforward studies, this time frame is very reasonable; for very complex or inconsistently documented studies it is not. We routinely overrun by 30 minutes, but sometimes more if all six applications are complex, which is not uncommon.

The turnover in members has not been significant, and we have gained a member with paediatric expertise which has been of significant benefit. We also have a rotating 1 year post that is filled by a junior doctor, which works well. However, the process for recruiting, interviewing, and then starting new members is very slow, which results in the risk of having too few members to quorate and we have had to co-opt members for a number of meetings this year. If there is a way to support more rapid recruitment and start dates of committee members, I would be happy to do this.

With respect to committee composition, I have had some comments over the past year of insufficient medical expertise. As noted above we receive exceptionally complex medical applications and do require significant medical expertise on the committee. We have recently had more members with medical expertise join, however, recruitment to the committee does need focus on key expertise areas in order to maintain this fine balance, and it would be helpful to involve the chairs and committee members in the recruitment process.

With respect to training committee members have reported to me that they are finding it difficult to register for training due to all places being full even when they log into the training portal on the same day that they were informed of the training or that many of the locations are inconvenient. I have noticed that more training is currently being held in Cambridge, which is helpful. However, I wonder if review of prioritising member registration over non-member and having flexibility for adding additional places is possible. I faced a similar problem in trying to access new chair training. In addition, we are working within our committee to set up ethics discussion groups to support self-directed training.

I think it is important to note that I receive significant support from the Nottingham office. Linda, Jess, Andrea, and Rebecca are always very supportive and responsive to queries, which is tremendously helpful and make my duties significantly easier. Ann Tunley has also provided wonderful support throughout the year. I am a bit concerned about additional workloads placed on the REC managers and how this may affect the necessary and valuable support we receive from them.

## 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 Adrian French	Retired General Practitioner	Expert	01/04/2011	30/04/2015
Ms Fatima Hussain	Journalist	Lay Plus	07/04/2015	27/07/2015
Mr Stuart Kent	Retired Consultant Surgeon	Expert	01/04/2011	13/12/2015
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	
Dr Adam McGeoch	Academic Clinical Lecturer	Expert	17/02/2015	17/02/2016
Mrs Beth Midgley	Public Speaker	Lay	04/01/2011	
Dr Nothando Buhlebenkosi Ngwenya	Research Associate	Expert	01/11/2012	06/07/2015
Dr Ian Nimmo-Smith	Statistician	Expert	01/04/2011	
Ms Polly Page	Operations Director	Lay Plus	01/01/2012	
Dr Sumantra Ray	Senior Medical Advisor/Scientist	Expert	01/01/2012	
Mrs Caroline Saunders	Nurse	Expert	01/04/2011	
Dr Mary-Beth Sherwood	Research Governance Assistant	Lay	15/04/2014	

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

Name	Profession	Status	Meeting date attended
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 Shahira Amr	Pharmacist	Expert	11.12.2015
Mr Derek Butters	Industrial Pharmacy Consultant and Locum Pharmacist	Expert	08.01.2016
Rebecca Harmston	Scientific Officer	Lay Plus	14.08.2015
Dr Martin Hewitt	Consultant Paediatric Oncologist	Expert	11.09.2015
Dr Ian Skidmore	Retired Company Director	Lay Plus	11.09.2015 09.10.2015
Dr Nkiruka Umaru	Pharmacist	Expert	11.12.2015

**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	02/02/2016
Dr Joseph Cheriyan	Employed by Cambridge University Hospitals NHS Trust but 50% secondment to GSK Clinical Trials Unit Cambridge. No Shares/dividends/bonuses from GSK. Member/Head of Cambridge Cardiovascular Clinical Trials Office, Cambridge Clinical Trials Unit	31/12/2015
Ms Anita Chhabra	None Declared	01/01/2016
Dr Lydia Drumright	University Lecturer in Clinical Informatics University of Cambridge (Medicine). Peer Reviewer for MRC. Member of the University REC (Cambridge)	31/12/2015
Revd Dr Derek Fraser	UKBHC – board for healthcare chaplaincy	31/12/2015
Miss Giselle Kerry	None Declared	31/12/2015
Mr David Lewin	None Declared	31/12/2015
Ms Moira Malfroy	Has shares in Astra Zeneca and GSK, member of the charity primary Immunodeficiency	31/12/2015
Dr Adam McGeoch	None Declared	31/12/2015
Mrs Beth Midgley	None Declared	04/01/2016
Dr Ian Nimmo-Smith	None Declared	31/12/2015
Ms Polly Page	MRC HNR internal research review board, Chair	31/12/2015
Mrs Caroline Saunders	NHS Employee - CUH. Head of Clinical Operations for Addenbrookes Clinical research centre which supports 250 clinical research studies in patients and healthy patients. Some of the studies/PI conducted at the unit will be known to her.b Some studies will have been peer reviewed by the Scientific Advisory board of which she is a member	31/12/2015
Dr Mary-Beth Sherwood	Research Governance Assistant CPFT	31/12/2015
Dr Sumantra Ray	None Declared	31/12/2015

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

Month	Date	Number of Members Present at Meeting
April	10/04/2015	10
May	08/05/2015	8
June	12/06/2015	11
August	14/08/2015	8
September	11/09/2015	12
October	09/10/2015	12
December	11/12/2015	13
January	08/01/2016	11
February	12/02/2016	12
March	11/03/2016	9

10 full committee meetings were held during the reporting period.

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

Month	Date	Number of Members Present at Meeting
April	24/04/2015	3
May	27/05/2015	3
July	07/07/2015	3
August	24/08/2015	3
September	29/09/2015	3
October	23/10/2015	3
December	01/12/2015	3
December	22/12/2015	3
March	30/03/2016	3

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

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

Month	Date	Number of Members Present at Meeting
April	03/04/2015	2
April	17/04/2015	2
April	23/04/2015	2
May	11/05/2015	2
May	25/05/2015	2
June	05/06/2015	2
June	22/06/2015	2
July	06/07/2015	2
July	17/07/2015	2
July	27/07/2015	2
August	11/08/2015	2
August	24/08/2015	2

September	04/09/2015	2
September	21/09/2015	2
October	08/10/2015	2
October	21/10/2015	2
November	09/11/2015	2
November	25/11/2015	2
December	15/12/2015	2
December	21/12/2015	3
January	11/01/2016	2
January	22/01/2016	2
February	05/02/2016	2
February	19/02/2016	2
March	07/03/2016	2
March	18/03/2016	2

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

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

Date	Reason	Action taken
None		

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

Name	Number of Meetings Attended
Dr Gusztav Belteki	2
Dr Joseph Cheriyan	5
Ms Anita Chhabra	6
Dr Lydia Drumright	9
Revd Dr Derek Fraser	5
Rebecca Harmston	1
Mr Stuart Kent	5
Miss Giselle Kerry	7
Mr David Lewin	9
Ms Moira Malfroy	9
Dr Adam McGeoch	7
Mrs Beth Midgley	7
Dr Nothando Buhlebenkosi Ngwenya	1
Dr Ian Nimmo-Smith	8
Ms Polly Page	4
Dr Sumantra Ray	5
Mrs Caroline Saunders	5
Dr Mary-Beth Sherwood	9

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

Name	Number of Meetings Attended
Dr Joseph Cheriyan	2
Ms Anita Chhabra	1
Dr Lydia Drumright	3
Revd Dr Derek Fraser	4
Mr Stuart Kent	2
Miss Giselle Kerry	1
Mr David Lewin	3
Ms Moira Malfroy	1
Mrs Beth Midgley	1
Dr Ian Nimmo-Smith	1
Dr Sumantra Ray	1
Mrs Caroline Saunders	3
Dr Mary-Beth Sherwood	3

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

<b>Name</b>	<b>Number of Meetings Attended</b>
Mr John Aldridge	4
Dr Gusztav Belteki	1
Dr Joseph Cheriyan	3
Ms Anita Chhabra	1
Dr Lydia Drumright	10
Revd Dr Derek Fraser	10
Dr Adrian French	1
Miss Giselle Kerry	2
Mr David Lewin	4
Ms Moira Malfroy	3
Dr Adam McGeoch	1
Mrs Beth Midgley	1
Dr Nothando Buhlebenkosi Ngwenya	1
Dr Ian Nimmo-Smith	3
Dr Sumantra Ray	3
Mrs Caroline Saunders	4
Dr Mary-Beth Sherwood	1

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

<b>Name of Member</b>	<b>Date</b>	<b>Event(s) attended</b>
Dr Gusztav Belteki	28/04/2015	E&D
Dr Joseph Cheriyan	24/04/2015	E&D
Dr Joseph Cheriyan	25/09/2015	Members Regional Training Day
Mr David Lewin	01/04/2015	Advisory panel on the Testing Treatments Interactive Website;
Mr David Lewin	16/04/2015	Quantitative Research Methods and Statistics
Mr David Lewin	21/11/2015	Research Skills for Clinicians Course
Mr David Lewin	04/01/2016	Academic reading
Mr David Lewin	04/02/2016	Researcher Training Day
Mr David Lewin	05/02/2016	Frontier Issues of the Mental Capacity Act
Ms Moira Malfroy	30/04/2015	E&D
Ms Moira Malfroy	25/09/2015	Members Regional Training Day
Dr Nothando Buhlebenkosi Ngwenya	01/05/2015	E&D
Dr Ian Nimmo-Smith	17/12/2015	Joint RSS-HRA meeting for REC Statisticians
Mrs Caroline Saunders	12/05/2015	Mental Capacity Act self-directed learning
Mrs Caroline Saunders	20/05/2015	Online IRAS training
Mrs Caroline Saunders	08/03/2016	SDL submitted
Dr Mary-Beth Sherwood	02/07/2015	(Treating People with Respect) which includes E&D

## 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	6	11.11
Phase 1	1	1.85
Gene Therapy	0	0.00
Research Tissue Bank (including renewals)	5	9.26
Research Database (including renewals)	1	1.85
Others	41	75.93
<b>Total Applications Reviewed</b>	<b>54</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	10
Number of paediatric applications reviewed	8
Number of device applications reviewed	8
Number of prisoner applications reviewed	0
Number of applications involving adults unable consent reviewed	4
Number of applications reviewed that are funded by the US DHHS	0
Number of qualitative applications reviewed	3

**Table 3: Decisions given at meetings held within the reporting period**

<b>Decisions taken at meetings following review of applications</b>	<b>Number</b>	<b>%</b>
Favourable Opinion with Standard Conditions	1	1.85
Favourable Opinion with Additional Conditions	4	7.41
Unfavourable Opinion	2	3.70
Provisional Opinion	47	87.04
Provisional Opinion Pending Consultation with Referee	0	0.00
<b>Total</b>	<b>54</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	39	72.22
Further Information Favourable Opinion with Additional Conditions	5	9.26
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	1	1.85
Favourable Opinion with Additional Conditions	4	7.41
Unfavourable Opinion	2	3.70
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	1	1.85
<b>Total</b>	<b>54</b>	<b>100</b>

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

<b>Total Applications Reviewed</b>	<b>27</b>
------------------------------------	-----------

**Table 6: Breakdown of PRS applications and other activity during reporting period:**

Number of applications made invalid by the REC Manager	4
Number of studies withdrawn prior to the meeting	0
Number of student applications reviewed	5
Number of paediatric applications reviewed	5
Number of device applications reviewed	0
Number of qualitative applications reviewed	5

**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	5	18.52
Favourable Opinion with Additional Conditions	3	11.11
No Opinion transfer to full committee for review	5	18.52
Provisional Opinion	14	51.85
Unfavourable Opinion	0	0.00
<b>Total</b>	<b>27</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>	5.40
<b>Number of completed applications for full ethical review</b>	53
<b>Number of completed applications for full ethical review over 60 days</b>	1
<b>Number of completed applications over 60 days as a % of total</b>	1.85%
<b>Number of completed applications for full ethical review over 40 days</b>	25
<b>Number of completed applications over 40 days as a % of total</b>	46.30%
<b>Number of days taken to final decision – average (mean)</b>	41
<b>Number of completed proportionate review applications for ethical review</b>	22
<b>Number of completed proportionate review applications for ethical review over 14 days</b>	0
<b>Number of completed proportionate review applications over 14 days as a % of total</b>	0.00%
<b>Number of SSAs (non-Phase 1) reviewed</b>	12
<b>Number of completed applications for SSA review over 25 days</b>	0
<b>Number of completed applications for SSA review over 25 days as % of all non- Phase 1 SSAs</b>	0.00%
<b>Number of SSAs (Phase 1) reviewed</b>	1
<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>	137
<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>	11
<b>Number of completed substantial amendments over 28 days as a % of total substantial amendments</b>	8.03%
<b>Number of modified amendments reviewed</b>	8
<b>Number of completed modified amendments over 14 days</b>	0
<b>Number of completed modified amendments over 14 days as a % of total modified amendments</b>	0.00%
<b>Number of minor amendments received</b>	108
<b>Number of substantial amendments received for information</b>	0
<b>Number of substantial amendments received for new sites/PIs</b>	7
<b>Number of annual progress reports received</b>	157

<b>Number of safety reports received</b>	21
<b>Number of Serious Adverse Events received</b>	8
<b>Number of final reports received</b>	19

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

<b>Further Information Favourable Opinion with Standard Conditions</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
15/EE/0109	Music Therapy, learning disabilities, self harm:the caring process	42
15/EE/0128	Cog-Train feasibility and acceptability trial	41
15/EE/0133	Returning to work after stroke	34
15/EE/0143	Glycosaminoglycan-Remodeling Effects of Na+ Depletion and Equilibrium	37
15/EE/0146	Relief II Study	40
15/EE/0158	REACT RCT	42
15/EE/0165	Dyslexia biomarkers study in newborn infants	42
15/EE/0166	SOUND: Study of auditory function and newborn brain development	41
15/EE/0173	Therapeutic Hypothermia and eArly Waking (THAW)	36
15/EE/0192	BARTS CANCER INSTITUTE BREAST TISSUE BANK	39
15/EE/0202	Comparison of SLP to X-Ray and Lung Function in Cystic Fibrosis	44
15/EE/0212	Action awareness in obsessive compulsive disorder	39
15/EE/0260	C-Optimise	60
15/EE/0270	The GOLDeN Study (version 1)	57
15/EE/0278	Closed-loop in Pregnancy Day & Night Home Feasibility Study (CLIP24/7)	37
15/EE/0280	Technique development in MR scanning of volunteers inhaling Xe gas	39
15/EE/0281	MRI of carotid atheroma inflammation	40
15/EE/0286	IBD Bioresource	52
15/EE/0309	FAST-Diary v1.0	57
15/EE/0318	Whole-genome sequencing of multidrug-resistant organisms in ICU	41
15/EE/0320	Blood and Genes in Acute Coronary Syndrome	59
15/EE/0328	The TREATment of severe Atopic eczema Trial (TREAT)	34
15/EE/0356	Ex-vivo normothermic perfusion in DCD kidney transplantation	39
15/EE/0357	The PolyBalm Study Version 1.0	33
15/EE/0368	COMPARE ABSORB	46
15/EE/0370	4216: SUSTAIN-7 semaglutide vs dulaglutide in type 2 diabetes	44
15/EE/0432	Improve Care Now (Cambridge)	61
15/EE/0454	Study to assess PK of HTL0009936 in 5 oral MR formulations (QCL117192)	42
16/EE/0001	Social economics in HD	51
16/EE/0003	Barts Cancer Institute Breast Metastatic Tissue Bank	55
16/EE/0004	The Cambridge Ultrasound Siblings and Parents (CUSP) Study	52
16/EE/0005	The Peak PlasmaBlade in DIEP free flap dissection	33

16/EE/0009	An open-label study of tivozanib versus sorafenib in renal cell cancer	55
16/EE/0010	Archival genito-urinary tissue, blood, urine and saliva collection, v1	39
16/EE/0014	Prognostic markers in kidney transplantation	40
16/EE/0041	Visionscope Hip & Knee	39
16/EE/0043	Leukaemia Model in Humanized Mice Version 1	43
16/EE/0072	Care pathway for survivors with severe disability after stroke	35
16/EE/0084	7Tesla MRI Scanning in Healthy Controls	50

#### Further Information Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
15/EE/0179	Social touch and neonatal development	43
15/EE/0297	African / Caribbean Experience of Accessing Mental Health Services	47
15/EE/0351	Prognostic markers in liver transplantation	54
16/EE/0006	Bedside measurement of brain activity in disorders of consciousness	38
16/EE/0067	Understanding the biology of human embryos and stem cells-v1	39

#### Further Information Unfavourable Opinion

REC Reference	Title	Number of Days on Clock
None		

#### Favourable Opinion with Standard Conditions

REC Reference	Title	Number of Days on Clock
15/EE/0186	Using surplus tissue for wound healing and surgical techniques R&D	23

#### Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
15/EE/0169	Efficacy of a Combination Hearing Aid and Sound Generator for tinnitus	28
15/EE/0445	Sleep in HD - Version 1.0	25
15/EE/0450	Proof of concept study of vagus nerve stimulation	25
16/EE/0086	The POSTCARD Study Version 1.0	32

<b>Unfavourable Opinion</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
15/EE/0170	Affective Disorders Research Database	28
15/EE/0449	Platelet Rich Plasma with Hyaluronic Acid in Knee Osteoarthritis	27

<b>Provisional Opinion</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
15/EE/0413	Breast Cancer Now Tissue Bank v1	n/a
16/EE/0091	Stem cell models of neurodevelopmental conditions	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>None</b>		

<b>Withdrawn after the meeting</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
15/EE/0354	First time in human study of oral anti-Serum Amyloid P (GSK3039294)	32

**Table 9.2: Breakdown of current status of all PRS applications reviewed within the reporting period**

<b>Further Information Favourable Opinion with Standard Conditions</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
15/EE/0183	Flow variations through Continuous Flow Ventricular Assist Devices	14
15/EE/0224	Women's experiences of being "overdue" in pregnancy	12
15/EE/0340	HEalth Check TRial (HECTR) 1	9
15/EE/0381	Approaches to the communication of Alzheimer's disease risk (ACAR)	7

15/EE/0383	Impaired awareness of hypoglycaemia: a national prevalence study	14
15/EE/0453	PDCS Parkinson's Disease Composite Scale	14
15/EE/0455	Metabonome & Microbiome Variability & Differential Risk in PBC	12
15/EE/0479	Rotational osteotomy outcome	14
15/EE/0480	Cognitive/behavioural barriers towards optimal glucose control in T1DM	14
16/EE/0138	Encouraging South Asians to consider hepatitis testing	14
16/EE/0139	Oxalobacter formigenes – Risk factor for Kidney stone formation in CF	9

#### Further Information Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
15/EE/0487	BB Quick- Study to Create a QC Panel in Patients with AATD	14
16/EE/0140	IGF-I in the newborn	14

#### Further Information Unfavourable Opinion

REC Reference	Title	Number of Days on Clock
None		

#### Favourable Opinion with Standard Conditions

REC Reference	Title	Number of Days on Clock
15/EE/0219	Pilot study to determine the effect of dialysis on intestinal biome	12
15/EE/0228	PROGRess	11
15/EE/0338	FLU07E-Enhanced passive safety surveillance of Vaxigrip and Intanza 15	8
15/EE/0382	Oxytocin in CDI. Version 1.	7
15/EE/0461	Differentiation between ranibizumab IVT and PFS	12

#### Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
15/EE/0287	Case Series - Egg Allergic Children Able to Tolerate Duck Egg	14
15/EE/0290	A non-interventional study on effectiveness of Eylea in RAP lesions	14
15/EE/0404	Daily Disposable Contact Lens Satisfaction Variability Survey	14

<b>Unfavourable Opinion</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
None		

<b>Provisional Opinion</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
15/EE/0384	Fetal cardiac function in early-onset fetal growth restriction	n/a

<b>Further information response not complete</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
None		

<b>Withdrawn after the meeting</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
None		

**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>
01/358/AM06	Fabry Outcome Survey (FOS)	28.05.2015	28/05/2015	20
02/172/AM06	Clinicopathological and Molecular Genetic Analysis of Retinal Detachme	4	12/12/2015	6
03/018/AM13	Evaluation of biomarkers in urological diseases	Substantial Amendment 12	03/06/2015	22
03/302/AM11	Risk patterns and processes for affective psychopathology	9	16/06/2015	21
04/Q0108/44/AM23	The Cambridge BioResource	26	08/10/2015	8
04/Q0108/44/AM24	The Cambridge BioResource	25 18/11/15	18/11/2015	28
04/Q0108/44/AM28	The Cambridge BioResource	Amendment 29	03/03/2016	26
04/Q0108/99/AM08	Derivation of stem cells from surplus human embryos	8	17/03/2015	15
05/Q0108/262/AM12	The time-course and determinants of arterial stiffening	Amendment 7	19/08/2015	26
05/Q0108/365/AM13	RAPPER	14	10/06/2015	13
05/Q0108/365/AM14	RAPPER	15	07/01/2016	21
07/Q0108/3/AM08	Clinical Unit Cambridge Volunteer Panel DNA Repository Study	3	18/02/2016	8
08/H0308/128/AM01	Modelling cell behaviour in normal and malignant tissues	2	19/03/2015	10
08/H0308/128/AM02	Modelling cell behaviour in normal and malignant tissues	3	01/05/2015	19
08/H0308/128/AM03	Modelling cell behaviour in normal and malignant tissues	4 24/11/15	27/11/2015	18
08/H0308/153/AM29	Genes and Phenotypes in Type 1 Diabetes	29	31/03/2015	30
08/H0308/153/AM30	Genes and Phenotypes in Type 1 Diabetes	30	15/06/2015	16
08/H0308/153/AM32	Genes and Phenotypes in Type 1 Diabetes	31	07/08/2015	22
08/H0308/267/AM03	Immunohistological Research in Primary Systemic Vasculitis (IRVAS)	1	26/10/2015	28
08/H0308/281/AM04	Regulation of neutrophil apoptosis by phosphoinositide 3-kinases	23/08/15	19/11/2015	25
08/H0308/281/AM05	Regulation of neutrophil apoptosis by phosphoinositide 3-kinases	amendment 7	22/01/2016	19
08/H0308/310/AM33	Addiction Endophenotypes	29	08/01/2016	19

09/H0308/124/AM02	Endurant Stent Graft Natural Selection Global Postmarket Registry	1.0	02/11/2015	14	
09/H0308/127/AM10	Heart Outcomes Prevention Evaluation (HOPE) - 3 (version 1.6.1)	7	25/06/2015	7	
09/H0308/134/AM03	Assessing nociception in patients with congenital indifference to pain	3	12/05/2015	20	
09/H0308/2/AM18	study investigating hippocampal function in Huntingdon's disease (HD)	18	28/08/2015	19	
10/H0308/50/AM04	Cambridge Centre for Ageing and Neuroscience (Cam-CAN) study	4	14/10/2015	17	
10/H0308/71/AM16	Evaluation of a Non-Endoscopic Device for Barrett's Oesophagus-BEST 2	14	06/05/2015	33	
11/EE/0037/AM10	Validation of Structured Light Plethysmography against spirometry	6	11/03/2015	21	
11/EE/0037/AM13	Validation of Structured Light Plethysmography against spirometry	7	12/05/2015	27	
11/EE/0068/AM05	The Cambridge Baby Growth Study II	5	04/06/2015	20	
11/EE/0068/AM06	The Cambridge Baby Growth Study II	6	07/01/2016	21	
11/EE/0210/AM11	CL002_168 ANCA-Associated Renal Vasculitis	8	22/07/2015	20	
11/EE/0210/AM13	CL002_168 ANCA-Associated Renal Vasculitis	10	09/10/2015	12	
11/EE/0278/AM03	Influence of Cortisol Levels on Cognitive Function in Psychosis	3	20/02/2015	20	
11/EE/0347/AM02	The 2nd European Carotid Surgery Trial	2	03/09/15	27/11/2015	19
11/EE/0421/AM03	A genomic study in Ghana, Kenya and Nigeria	3	29/09/2015	21	
11/EE/0458/AM09	An Investigation of the neural correlates of avoidance learning in OCD	4	24/12/2015	24	
11/EE/0463/AM03	Interrogating Energy Metabolism in the Human Brain	2	25/06/2015	13	
11/EE/0463/AM04	Interrogating Energy Metabolism in the Human Brain	3	07/08/2015	27	
11/H0308/9/AM02	Investigation of Lymphoproliferative and Plasma Cell Disorders (Ver.1)	1	24/02/2016	13	
12/EE/0096/AM07	TransEUro Transplant Study	7	07/07/2015	19	
12/EE/0096/AM08	TransEUro Transplant Study	8	24/08/2015	16	
12/EE/0206/AM06	STH Research Database for Diabetes, Endocrinology & Retinal Screening	2	11/09/2015	27	
12/EE/0250/AM08	U-Change v1.0	6	20/04/2015	20	
12/EE/0253/AM06	Assessment of donor pancreas quality: suitability for	5	17/06/2015	22	

	transplantation			
12/EE/0355/AM05	Dynamics of free cortisol during surgical and medical stress v1.0	Amendment 6	12/02/2015	28
12/EE/0475/AM03	PIPPIN Study	1	20/10/2015	21
12/EE/0491/AM01	Mechanisms of IFN Induced Depression in Hepatitis-C	1	19/10/2015	24
12/EE/0516/AM03	Stratification of patients with kidney cancer	3	21/05/2015	14
12/EE/0523/AM10	HGS1006-C1100 Phase 3 - Belimumab for Maintenance of Remission in AAV	10	28/04/2015	22
13/EE/0012/AM03	Approaches to earlier detection & intervention in lung cancer-Study1a	3	13/04/2015	19
13/EE/0012/AM04	Approaches to earlier detection & intervention in lung cancer-Study1a	4	24/08/2015	28
13/EE/0018/AM05	Closed Loop in Pregnancy Overnight Home Feasibility Study (CLIP_03)	3	18/05/2015	21
13/EE/0026/AM01	Archival colorectal tissue, blood and urine collection	1	01/02/2016	21
13/EE/0065/AM03	Clinical trial for elderly patients with Multiple Diseases (CHROMED)V1	2	19/10/2015	29
13/EE/0104/AM06	Neuroimaging of Inflammation in MemoRy and Other Disorders (NIMROD) v1	3	11/05/2015	10
13/EE/0104/AM07	Neuroimaging of Inflammation in MemoRy and Other Disorders (NIMROD) v1	4	23/11/2015	22
13/EE/0104/AM08	Neuroimaging of Inflammation in MemoRy and Other Disorders (NIMROD) v1	5	22/01/2016	13
13/EE/0161/AM02	The UCL BioResource version 1	1	03/08/2015	18
13/EE/0161/AM04	The UCL BioResource version 1	2	18/02/2016	22
13/EE/0169/AM02	Mesobank	2	04/01/2016	21
13/EE/0226/AM06	The GSTT/KCL BioResource	5	22/05/2015	23
13/EE/0226/AM07	The GSTT/KCL BioResource	6	19/06/2015	20
13/EE/0226/AM09	The GSTT/KCL BioResource	7	23/07/2015	28
13/EE/0226/AM10	The GSTT/KCL BioResource	8	28/08/2015	22
13/EE/0321/AM03	Closing the loop in adults with type 1 diabetes	3	27/11/2015	18
13/EE/0339/AM16	COMPASS (BAY 59-7939/15786)	Amendment 009	19/10/2015	21
13/EE/0421/AM01	Contrast enhanced MRI of carotid atheroma: MRCON Study (2013)	1	23/03/2015	18
13/EE/0429/AM10	BET116183: GSK525762 in Subjects with Haematologic Malignancies	3.1	15/06/2015	35

13/EE/0429/AM11	BET116183: GSK525762 in Subjects with Haematologic Malignancies	4	24/08/2015	24
14/EE/0007/AM03	Barts Cardiovascular Tissue Bank	3	20/01/2016	13
14/EE/0064/AM01	Fast Optical Tomography On Neonates (FOTON)	1	28/01/2016	35
14/EE/0109/AM02	ECCO2R in AECOPD	2	07/12/2015	28
14/EE/0119/AM06	Safety, Tolerability and PK of MAD of ASP7962 in Healthy Subjects	3	19/05/2015	21
14/EE/0119/AM08	Safety, Tolerability and PK of MAD of ASP7962 in Healthy Subjects	4	06/07/2015	17
14/EE/0119/AM10	Safety, Tolerability and PK of MAD of ASP7962 in Healthy Subjects	5	28/08/2015	12
14/EE/0145/AM02	BEHOLD v1.0	Amendment 2	20/10/2015	21
14/EE/0149/AM01	Investigating the effects of cognitive training on attention	1	01/04/2015	18
14/EE/0149/AM02	Investigating the effects of cognitive training on attention	2	12/11/2015	26
14/EE/0172/AM02	Adolescent Asthma Study	1	15/05/2015	18
14/EE/0202/AM01	Imaging Oxytocin and Autism	1	15/04/2015	27
14/EE/0202/AM02	Imaging Oxytocin and Autism	2	29/07/2015	24
14/EE/0218/AM03	GLP-1 loading during elective PCI (GOLD-1-PCI)	1	23/07/2015	18
14/EE/1014/AM01	Pilot study of tremor disruption in Parkinson's Disease	1	28/04/2015	12
14/EE/1096/AM04	FABRY SRT MONO	003	23/07/2015	32
14/EE/1118/AM03	Retinal biomarkers for Alzheimer's disease in Down's syndrome	31.03.2015	31/03/2015	17
14/EE/1118/AM04	Retinal biomarkers for Alzheimer's disease in Down's syndrome	4	29/07/2015	14
14/EE/1118/AM05	Retinal biomarkers for Alzheimer's disease in Down's syndrome	5 03/11/15	03/11/2015	32
14/EE/1118/AM06	Retinal biomarkers for Alzheimer's disease in Down's syndrome	6	04/02/2016	18
14/EE/1138/AM02	PROCO	1	21/01/2016	12
14/EE/1144/AM04	Gen2 Hardware Submission for CL-SVT-002	31/03/2015	27/03/2015	13
14/EE/1144/AM05	Gen2 Hardware Submission for CL-SVT-002	19/05/2015	19/05/2015	24
14/EE/1164/AM04	Information and Risk Modification Trial (INFORM)	4	30/06/2015	17
14/EE/1172/AM01	Cambridge Prostate Biopsy Device: CAMPROBE	1	22/06/2015	13
14/EE/1178/AM01	The effect of walking on recovery following total hip replacement.	1	24/09/2015	21
14/EE/1224/AM02	SADAL: Selinexor and Dexamethasone in Aggressive	2	10/03/2015	18

	Lymphoma			
14/EE/1224/AM05	SADAL: Selinexor and Dexamethasone in Aggressive Lymphoma	5	06/08/2015	28
14/EE/1224/AM07	SADAL: Selinexor and Dexamethasone in Aggressive Lymphoma	7	18/09/2015	19
14/EE/1273/AM01	Neutrophils distribution in lungs in health and COPD	SA#01	19/03/2015	14
14/EE/1273/AM03	Neutrophils distribution in lungs in health and COPD	2	22/05/2015	10
14/EE/1279/AM02	Latella-2	#1	13/07/2015	10
14/EE/1279/AM03	Latella-2	2	27/10/2015	21
14/EE/1279/AM04	Latella-2	3	24/11/2015	22
14/EE/1282/AM01	The ANSeR Clinical Investigation	1.0	03/02/2016	10
15/EE/0004/AM02	The modulatory role of serotonin in model-based and model-free choice	Amendment 1	11/02/2016	20
15/EE/0033/AM01	A new dementia screening test for people with Learning Disabilities	1	11/08/2015	26
15/EE/0073/AM01	HGUS Study	1	03/07/2015	15
15/EE/0090/AM01	First in human study of anti-OSM monoclonal antibody (GSK2330811)	1	08/01/2016	21
15/EE/0094/AM01	Measuring circulating tumour DNA in glioma patients	1	07/12/2015	29
15/EE/0146/AM01	Relief II Study	1	29/09/2015	20
15/EE/0158/AM01	REACT RCT	1	17/12/2015	25
15/EE/0165/AM01	Dyslexia biomarkers study in newborn infants	1	01/12/2015	15
15/EE/0165/AM02	Dyslexia biomarkers study in newborn infants	2	02/02/2016	19
15/EE/0166/AM01	SOUND: Study of auditory function and newborn brain development	1	16/09/2015	27
15/EE/0192/AM01	BARTS CANCER INSTITUTE BREAST TISSUE BANK	1	15/09/2015	26
15/EE/0192/AM02	BARTS CANCER INSTITUTE BREAST TISSUE BANK	2	19/11/2015	26
15/EE/0202/AM03	Comparison of SLP to X-Ray and Lung Function in Cystic Fibrosis	1	17/02/2016	20
15/EE/0212/AM01	Action awareness in obsessive compulsive disorder	1	09/12/2015	28
15/EE/0212/AM05	Action awareness in obsessive compulsive disorder	2	10/02/2016	10
15/EE/0224/AM02	Women's experiences of being "overdue" in pregnancy	1	13/01/2016	15
15/EE/0260/AM01	C-Optimise	1	06/11/2015	32
15/EE/0260/AM02	C-Optimise	2	12/01/2016	28
15/EE/0260/AM03	C-Optimise	2	24/11/2015	21
15/EE/0270/AM01	The GOLDeN Study (version 1)	Amendment	02/03/2016	27

		02/03/2016		
15/EE/0286/AM01	IBD Bioresource	1	26/02/2016	29
15/EE/0450/AM02	Proof of concept study of vagus nerve stimulation	1	11/02/2016	11
96/085/AM19	Invitro studies of postmortem human foetal neural tissue	13	20/11/2015	25

### Unfavourable opinion

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
04/Q0108/44/AM21	The Cambridge BioResource	24	15/05/2015	22
04/Q0108/99/AM10	Derivation of stem cells from surplus human embryos	9	21/10/2015	12
08/H0308/267/AM02	Immunohistological Research in Primary Systemic Vasculitis (IRVAS)	1	10/09/2015	13
10/H0308/50/AM03	Cambridge Centre for Ageing and Neuroscience (Cam-CAN) study	3	28/08/2015	35
12/EE/0250/AM09	U-Change v1.0	7	05/06/2015	24
13/EE/0226/AM05	The GSTT/KCL BioResource	3	16/03/2015	28
13/EE/0339/AM14	COMPASS (BAY 59-7939/15786)	7	24/03/2015	24
14/EE/1224/AM03	SADAL: Selinexor and Dexamethasone in Aggressive Lymphoma	3	12/03/2015	22
15/EE/0092/AM01	BIOMarkers in DEPRESSION (BIODEP)	1	07/08/2015	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
04/Q0108/44/AM21/1	The Cambridge BioResource	Modified Amendment 24	06/07/2015	12
11/EE/0210/AM10/2	CL002_168 ANCA-Associated Renal Vasculitis	7	31/03/2015	7
12/EE/0250/AM09/1	U-Change v1.0	7	17/08/2015	11
13/EE/0226/AM05/1	The GSTT/KCL BioResource	#4	20/04/2015	8
13/EE/0339/AM14/1	COMPASS (BAY 59-7939/15786)	008	23/04/2015	8

14/EE/0007/AM02/1	Barts Cardiovascular Tissue Bank	2	02/03/2015	0
14/EE/1224/AM03/1	SADAL: Selinexor and Dexamethasone in Aggressive Lymphoma	4	16/06/2015	8
15/EE/0092/AM01/1	BIOmarkers in DEPRESSION (BIODEP)	Modified Amendment 1	07/08/2015	11

<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>
<b>None</b>				

**Table 11: Items exceeding timelines****Full applications for ethical review over 60 day timeline**

REC Reference	Title	Number of Days on Clock
15/EE/0432	Improve Care Now (Cambridge)	61

**Proportionate review applications for ethical review over 14 day timeline**

REC Reference	Title	Number of Days on Clock
None		

**SSAs (non Phase 1) over 25 day timeline**

REC Reference	Title	Number of Days on Clock
None		

**SSAs (Phase 1) over 14 day timeline**

REC Reference	Title	Number of Days on Clock
None		

**Substantial Amendments over 35 day timeline**

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
None				

**Modified Amendments over 14 day timeline**

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
None				