

National Research Ethics
Service


Health Research Authority

NRES Committee East of England - Cambridge Central

Annual Report

01 April 2013 – 31 March 2014

Part 1 – Committee Membership and Training

Name of REC:	NRES Committee East of England - Cambridge Central
Type of REC:	Recognised to review CTIMPS in healthy volunteers - type i Recognised to review CTIMPS in patients - type iii
Type of Flag:	Establishing Research Tissue Banks Establishing Research Databases Medical Device Study Phase 1 Studies in Healthy Volunteers Research Involving Adults Lacking Capacity
Chair:	Mrs Carolyn Read
Vice-Chair:	Dr Joseph Cheriyan
Alternate Vice-Chair:	Revd Dr Derek Fraser
Co-ordinator:	Miss Jessica Parfremment
PRSC Co-ordinator:	Miss Georgia Copeland
Assistant Co-ordinator:	Miss Georgia Copeland
Committee Address:	The Old Chapel Royal Standard Place Nottingham NG1 6FS
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Chair's overview of the past year:

The last 12 months have seen a period of much greater stability and growth for Cambridge Central REC. Meetings have all been quorate and there has been no reduction in the number of applications or queries. The committee has retained its' flagging's and continues to review a wide variety of studies. I am also pleased to announce that the Committee was given full accreditation for the next three years and would like to thank everyone who was involved in this. Over the year there have been some comings and goings. We have sadly said goodbye to Hamid Jalal, one of our longest serving members, but welcomed new members Moira Malfroy and Giselle Kerry.

The work of the committee continues unabated. We are very pleased to report that all full REC applications were reviewed within 60 days and that the average time to a final decision was 29 days.

Finally I would like to take this opportunity to thank all the committee members for their endless support. It is very much appreciated and understood that all contribute to the REC on a voluntary basis and the time commitment in busy lives is not underestimated

NRES Committee East of England - Cambridge Central Membership:

Name	Occupation	Expert or Lay	Dates	
			Appointed	Resigned
Dr Joseph Cheriyan	Consultant Physician	Expert	20/05/2011	
Ms Anita Chhabra	Clinical Trials Pharmacist	Expert	01/04/2011	
Revd Dr Derek Fraser	Chaplain	Lay Plus	01/04/2011	
Dr Adrian French	Retired General Practitioner	Expert	01/04/2011	
Dr Hamid Jalal	Consultant Medical Virologist	Expert	01/04/2011	01/11/2013
Mr Stuart Kent	Retired Consultant Surgeon	Expert	01/04/2011	
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	
Mrs Beth Midgley	Lay Member	Lay	04/01/2011	
Dr Nothando Buhlebenkosi Ngwenya	Research Associate	Expert	01/11/2012	
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 Carolyn Read	External liaison and Research Governance Officer	Lay Plus	01/04/2011	
Mrs Caroline Saunders	Nurse	Expert	01/04/2011	

NRES Committee East of England - Cambridge Central: Members' Declarations of

Name	Declaration of Interest	Date
Mrs Carolyn Read	Other activities or interests: Research Governance Office for the Clinical School at the University of Cambridge	13/12/2013
Dr Ian Nimmo-Smith	None	12/12/2013
Mr Stuart Kent	None	13/12/2013
Mr David Lewin	None	13/12/2013
Mrs Caroline Saunders	Head of Clinical Operational at Addenbrookes Clinical Research Centre with day to day contact with multiple researchers and protocols, some of which may be reviewed by the committee. However I am not noted as a co-investigator or research team member of any of the projects.	13/12/2013
Dr Nothando Buhlebenkosi Ngwenya	None	13/12/2013
Miss Giselle Kerry	conflict by research at the Wellcome Trust Sanger Institute	13/12/2013
Dr Adrian French	Chairman of Camrowers a none profit company that may seek funds for research on benefits of exercise in older people	13/12/2013
Ms Anita Chhabra	Day to day contact with researchers in oncology harmatology research committee	13/12/2013
Ms Moira Malfroy	member of primary immunodeficiency charity	13/12/2013
Dr Joseph Cheriyan	Dr Cheriyan is a fulltime employee of Cambrldge University Hospitals NHS Foundation Trust. The Trust receives reimbursement from GSK Clinical Unit Cambridge so that it is able to procure the services of Dr Cheriyan (for 50% of his time) as a Senior Clinical Pharmacologist for the Phase I/II unit on the hospital site. However Dr Cheriyan receives no employee financial benefits such as a dividend, employee bonus or share options. Dr Cheriyan is also a member of the Cambridge Clinical Trials Unit Management Board.	14/02/2014
Mrs Beth Midgley	None	14/02/2014
Revd Dr Derek Fraser	Vice Chair of Bereavement Services Association	20/02/2014
Dr Sumantra Ray	None	14/03/2014

Meetings for Full Ethical Review 01 April 2013 - 31 March 2014:

Month	Date	Number of Members Present at Meeting
April	12/04/2013	10
May	10/05/2013	10
June	14/06/2013	11
August	09/08/2013	12
September	13/09/2013	11
October	11/10/2013	11
November	08/11/2013	8
December	13/12/2013	11
January	10/01/2014	11
February	14/02/2014	11
March	14/03/2014	11

11 full committee meetings were held during the reporting period.

Proportionate Review Sub Committee Meetings held during 01 April 2013 - 31 March 2014:

Month	Date	Number of Members Present at Meeting
July	24/07/2013	3
August	28/08/2013	3
September	25/09/2013	4
October	23/10/2013	4
November	27/11/2013	3
December	18/12/2013	3
January	17/01/2014	3
March	21/03/2014	3

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

Attendance of Members: 01 April 2013 – 31 March 2014:

Name	Number of Meetings Attended
Mrs Carolyn Read	11
Ms Anita Chhabra	10
Mr David Lewin	10
Mr Stuart Kent	9
Dr Adrian French	9
Dr Ian Nimmo-Smith	9
Mrs Caroline Saunders	8
Revd Dr Derek Fraser	8
Mrs Beth Midgley	7
Dr Nothando Buhlebenkosi Ngwenya	7
Miss Giselle Kerry	6
Dr Joseph Cheriyan	6
Dr Sumantra Ray	6
Ms Moira Malfroy	6
Ms Polly Page	3
Dr Hamid Jalal	2

**Attendance of Members at proportionate review sub-committee meetings:
01 April 2013 – 31 March 2014:**

Name	Number of Meetings Attended
Mrs Carolyn Read	6
Dr Adrian French	4
Mr Stuart Kent	3
Mrs Beth Midgley	2
Dr Sumantra Ray	2
Mr David Lewin	2
Revd Dr Derek Fraser	2
Dr Ian Nimmo-Smith	1
Dr Joseph Cheriyan	1
Mrs Caroline Saunders	1
Ms Anita Chhabra	1
Ms Moira Malfroy	1

Training 01 April 2013 – 31 March 2014:

Name of Member	Date	Event(s) attended
Dr Adrian French	01/04/2013 - 01/04/2013	Sanger Institute online questionnaire
Ms Polly Page	05/06/2013 - 05/06/2013	Equality & Diversity, MRC
Mr David Lewin	02/10/2013 - 02/10/2013	Researcher Training Day , HRA
Ms Moira Malfroy	24/09/2013 - 24/09/2013	Cambridge Members training day , Jess and Andrea
Mrs Beth Midgley	24/09/2013 - 24/09/2013	Regional training day , HRA
Dr Ian Nimmo-Smith	04/10/2013 - 04/10/2013	Regional training day , HRA
Dr Nothando Buhlebenkosi Ngwenya	24/09/2013 - 24/09/2013	Regional training day , HRA
Miss Giselle Kerry	24/09/2013 - 24/09/2013	Regional training day , HRA
Mrs Carolyn Read	16/05/2013 - 16/05/2013	MRC Research and Governance and Human Tissue, Work
Mrs Carolyn Read	27/11/2013 - 27/11/2013	Research presentation to junior doctors, Work
Mrs Carolyn Read	18/06/2013 - 18/06/2013	NREAP Meeting, HRA
Mrs Caroline Saunders	24/02/2014 - 24/02/2014	Speaker at NIHR regional clinical research nurse day, Work
Mrs Caroline Saunders	01/01/2014 - 01/01/2014	Coach Education & training manager with ethics training sessions for clinicians research skills cour
Mrs Caroline Saunders	28/02/2014 - 28/02/2014	Written article with national colleagues about research education and training for clinical research, work
Revd Dr Derek Fraser	06/02/2014 - 06/02/2014	designing and providing ethics at end of life training, Work
Revd Dr Derek Fraser	03/03/2014 - 03/03/2014	designing and providing ethics at end of life training, work

Part 2: REC workload and activity during the reporting period.

Table 1: Applications assigned to a full committee meeting held within the reporting period:

Applications for full ethical review – Study Type	Number	%
Clinical Trial of Investigational Medicinal Product	9	16.07
Phase 1	1	1.79
Gene Therapy	0	0.00
Research Tissue Bank	4	7.14
Research Database	1	1.79
Others	41	73.21
Total Applications Reviewed	56	100

Table 2: Other REC activity during the reporting period:

Number of applications made invalid by co-ordinator	10
Number of studies withdrawn prior to the meeting	7
Number of student applications reviewed	11
Number of paediatric applications reviewed	7
Number of device applications reviewed	2
Number of prisoner applications reviewed	0
Number of applications involving adults unable consent reviewed	9
Number of applications reviewed funded by the US DHHS	0

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

Decisions taken at meetings following review of applications	Number	%
Favourable Opinion with Standard Conditions	15	26.79
Favourable Opinion with Additional Conditions	13	23.21
Unfavourable Opinion	1	1.79
Provisional Opinion	26	46.43
Invalid	0	0.00
No Opinion Pending Consultation with Referee	0	0.00
Provisional Opinion Pending Consultation with Referee	1	1.79
Not Requiring Review by NHS REC	0	0.00
Total	56	100
Number of studies sent back to full committee meeting for final opinion	1	

Table 4: Summary of current status of applications reviewed during the reporting period:

Status of applications at date of generation of report	Number	%
Further Information Favourable Opinion with Standard Conditions	13	23.21
Further Information Favourable Opinion with Additional Conditions	7	12.50
Further Information Unfavourable Opinion	1	1.79
Favourable Opinion with Standard Conditions	15	26.79
Favourable Opinion with Additional Conditions	13	23.21
Unfavourable Opinion	2	3.57
Provisional Opinion	4	7.14
Provisional Opinion Pending Consultation with Referee	0	0.00
Invalid	0	0.00
No Opinion Pending Consultation with Referee	0	0.00
Further Information response not complete	0	0.00
Not Requiring Review by NHS REC	0	0.00
No decision entered on RED	1	1.79
Number of studies withdrawn after the meeting	0	0.00
Total	56	100

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

Total Applications Reviewed	14
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Table 6: Decisions given at proportionate review sub-committee meetings held within the reporting period:

Decisions taken at proportionate review sub-committee meetings	Number	%
Favourable Opinion with Standard Conditions	5	35.71
Favourable Opinion with Additional Conditions	1	7.14
No Opinion transfer to full committee for review	5	35.71
Provisional Opinion	2	14.29
Unfavourable Opinion	1	7.14
Total	14	100

Table 7: Other Management Information for the reporting period:

Average number of applications reviewed per full meeting	4.67
Number of applications for full ethical review over 60 days	0
Number of applications over 60 days as a % of total	0.00%
Number of days taken to final decision - average	28
Number of days taken to final decision - mode	21
Number of SSAs (non-Phase 1) reviewed	10
Number of applications for SSA review over 25 days	0
Number of applications for SSA review over 25 days as % of all non-Phase 1 (SSAs)	0.0%
Number of SSAs (Phase 1) reviewed	0
Number of applications for SSA review over 14 days	0
Number of applications for SSA review over 14 days as % of all Phase 1 (SSAs)	0%
Number of substantial amendments reviewed	162
Number of substantial amendments over 35 days	1
Number of substantial amendments over 35 days as a % of total substantial amendments	0.6%
Number of Section 30 applications reviewed	0
Number of Section 30 applications over 60 days	0
Number of Section 30 applications over 60 days as a % of total Section 30 applications	0%
Number of modified amendments reviewed	4
Number of modified amendments over 14 days	0
Number of modified amendments over 14 days as a % of total modified amendments	0.0%
Number of proportionate review applications for ethical review over 14 days*	0
Number of proportionate review applications over 14 days as a % of total	0.0%

Table 8: Breakdown of current status of all applications reviewed within the reporting period:

Further Information Favourable Opinion with Standard Conditions		
REC Reference	Application Short Title	Number of Days on Clock
13/EE/0080	EVAS I Study CP-0008 Rev. 02	29
13/EE/0088	Vestibular function in Stickler Syndrome	30
13/EE/0104	Neuroimaging of Inflammation in MemoRy and Other Disorders (NIMROD) v1	31
13/EE/0152	Detection of Hepatorenal Syndrome by Magnetic Resonance Elastography	31
13/EE/0154	Factors that predict compression outcome in lymphoedema	31
13/EE/0236	Assessment of CR8020, a monoclonal antibody, against influenza A	52
13/EE/0257	K-5172+ MK-8742+ Ribavirin in Treating Subjects with Genotype 2,4,5, a	22
13/EE/0258	Blood Glucose Performance Test (ADC-PMS-GLU-12014), version 1.0	32
13/EE/0319	Preop CPET testing and exercise training in colorectal patients	24
13/EE/0391	Deep Brain Stimulation for patients with Dementia with Lewy Bodies	28
13/EE/0408	Dipole Density Mapping in Supraventricular Tachycardia (CL-SVT-002)	24
13/EE/0435	The role of microRNAs in Kidney Disease (version 1)	12
14/EE/0004	Fun and Fit Norfolk (Version 1)	47
14/EE/0007	Barts Cardiovascular Tissue Bank	29
14/EE/0013	Lycopene following aneurysmal subarachnoid haemorrhage (LASH)	19
14/EE/0065	MAD, Safety, PK&PD of multiple doses of CHN438 in adults & elderlies	25
Further Information Favourable Opinion with Additional Conditions		
REC Reference	Application Short Title	Number of Days on Clock
13/EE/0096	Blood flow and oxygenation following subarachnoid haemorrhage	30
13/EE/0226	The GSTT/KCL BioResource	26
13/EE/0293	CIGMA (Concentrated IgM for Application) Study	29
13/EE/0329	Midwives' and mothers' views of requested C-Section and the care given	24
13/EE/0339	COMPASS (BAY 59-7939/15786)	29
13/EE/0362	Service Evaluation for Cambridgeshire Telehealth and Telecare Service	26
13/EE/0392	Acute Symptomatic Infectious Hepatitis in Hospitalised Children	14
14/EE/0003	Oxygen consumption in critical illness	19
14/EE/0019	The VISION study	52
14/EE/0052	LINKED	28

Further Information Unfavourable Opinion		
REC Reference	Application Short Title	Number of Days on Clock
13/EE/0083	Vitamin D in Breast Milk from Women in Britain (version 1)	59
14/EE/0090	The Influence of Vestibular Processing on Human Cognition	30

Favourable Opinion with Standard Conditions		
REC Reference	Application Short Title	Number of Days on Clock
13/EE/0119	PET Imaging of Inflammation following Brain Injury	25
13/EE/0161	The UCL BioResource version 1	22
13/EE/0244	The role of psychological factors in side effect reporting	9
13/EE/0251	Home testing of 24/7 closed-loop in young people with type 1 diabetes	49
13/EE/0259	AncestryDNA Human Genetic Diversity Project	21
13/EE/0282	Why does Clozapine cause weight gain?	24
13/EE/0316	Genetic and humoral factors predicting recurrence of IgA Nephropathy	14
13/EE/0321	Closing the loop in adults with type 1 diabetes	21
13/EE/0340	Controlled Study of Exhaled breath in type 1 diabetes	23
13/EE/0341	Measuring intraoperative electrically evoked vestibular function 1	54
13/EE/0420	Immunohistochemical Markers in Colorectal Cancer Assessment v1	21
13/EE/0421	Contrast enhanced MRI of carotid atheroma: MRCON Study (2013)	38
13/EE/0457	Privacy in Milk Expression Room	5
13/EE/0459	Pilot study of ultrasound in rheumatoid arthritis (version 1)	6
14/EE/0009	Learning about Breathlessness study (LaB)	38
14/EE/0031	Catheter ablation of typical right atrial flutter under MR guidance	18
14/EE/0041	Exploring the Subjective Experience of Nausea in Children with Cancer	10
14/EE/0064	Fast Optical Tomography On Neonates (FOTON)	21
14/EE/0085	COOL BRIDGE Study	21
14/EE/0086	NMES in Patients with Intermittent Claudication	21

Favourable Opinion with Additional Conditions		
REC Reference	Application Short Title	Number of Days on Clock
13/EE/0091	CoDem - Comorbidity and dementia	24
13/EE/0114	(May) Has electrical sinus translated effective remodelling (HESTER)	42

13/EE/0120	Multicentre closed-loop home study in young people with type1 diabetes	25
13/EE/0121	The Clinical and Research Database for Persistent Schizophrenia V1	25
13/EE/0169	Mesobank	25
13/EE/0227	Refametinib in combination with sorafenib in RAS mutant HCC	21
13/EE/0228	Refametinib in RAS mutant HCC	21
13/EE/0233	Cambridge Baby Growth Outcome Study	21
13/EE/0287	Oral PTH (1-34) in the treatment of hypoparathyroidism	24
13/EE/0361	VBI: Piloting Research Methods	9
13/EE/0368	Dietary n-3 PUFAs and the response to adalimumab in Crohn's disease	24
13/EE/0395	The Research Tissue Bank, Huntingdon Life Sciences	24
13/EE/0423	PET Qualification of MRI techniques in Alzheimer's disease	21
13/EE/0429	BET116183: GSK525762 in Subjects with Haematologic Malignancies	21

Unfavourable Opinion

REC Reference	Application Short Title	Number of Days on Clock
13/EE/0115	Blood Glucose Performance Test (ADC-PMS-GLU-12014), version 1.0	25
13/EE/0248	Does Your View of Yourself Affect Recovery From a Head Injury	9
13/EE/0267	Views of patients detained under Mental Health Act towards appealing	28

Provisional Opinion

REC Reference	Application Short Title	Number of Days on Clock
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Provisional Opinion Pending Consultation with Referee

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

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

REC Reference	Application Short Title	Number of Days on Clock
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Invalid Application

REC Reference	Application Short Title	Number of Days on Clock
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No Opinion Pending Consultation with Referee		
REC Reference	Application Short Title	Number of Days on Clock

Not Requiring Review by NHS REC		
REC Reference	Application Short Title	Number of Days on Clock

Table 9: Items exceeding timelines:

Full applications for ethical review over 60 day timeline			
REC Reference	Application Short Title	Number of Days on Clock	
Proportionate review applications for ethical review over 14 days timeline			
REC Reference	Application Short Title	Number of Days on Clock	
SSAs (non Phase 1) over 25 days timeline			
REC Reference	Application Short Title	Number of Days on Clock	
SSAs (Phase 1) over 14 days timeline			
REC Reference	Application Short Title	Number of Days on Clock	
Substantial Amendments over 35 day timeline			
Amendment Reference	Application Short Title	Amendment Title	Number of Days on Clock
09/H0308/137/AM11	RCT of treatments in moderate-severe adolescent depression	Substantial Amendment 10	37
Modified Amendments over 14 day timeline			
Amendment Reference	Application Short Title	Amendment Title	Number of Days on Clock
Section 30 application over 60 day timeline			
Amendment Reference	Application Short Title	Amendment Title	Number of Days on Clock