

National Research Ethics
Service


Health Research Authority

**NRES Committee East of England -
Cambridge East**

Annual Report

01 April 2013 – 31 March 2014

Part 1 – Committee Membership and Training

Name of REC:	NRES Committee East of England - Cambridge East
Type of REC:	Recognised to review CTIMPs in Healthy Volunteers – type i Recognised to review CTIMP's in patients type ii
Type of Flag:	Establishing Research Tissue Banks, Establishing Research Databases, Medical Device Study, Phase 1 Studies in Healthy Volunteers, Phase 1 studies in Patients
Chair:	Dr Daryl Rees/Dr Niki Bannister
Vice-Chair:	N/A
Alternate Vice-Chair:	Reverend David Parkes
Co-ordinator:	Liza Selway
PRSC Co-ordinator:	N/A
Assistant Co-ordinator:	Rachel Nelson/Carolyn Halliwell
Committee Address:	The Old Chapel Royal Standard Place Nottingham NG1 6FS
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Chair's overview of the past year:

2013-14 was a year of substantial change for Cambridge East REC and at times it has been a challenge to maintain the service.

Both our long-serving and experienced Chair, Daryl Rees and AVC/ acting VC, Rev David Parkes, together with several members (Simon Bond, Ingrida Robinson, Catherine Hubbard, Alison Wooster) have moved on due to work and other commitments. On behalf of the committee I thank them all for their valued contributions.

After a renewed recruitment drive we have welcomed Patricia Westcott and Jessica Santos as new members and look forward to the appointment of a VC shortly. I joined the committee in January 2014 from the Essex REC and would like to thank all members for making me feel part of the team.

There has been a period of settlement with the change of REC Office from Cambridge to Nottingham, and we are pleased to have our regular Rec Manager, Liza Selway back taking our minutes.

This report cannot omit expressing sincere thanks to Norfolk's Chair Michael Sheldon, who has stepped in more than once to chair. We have also been helped by Norfolk's VC, Liz Lund, and Nottingham 1 VC Rev Keith Lackenby as co-opted members, with Keith also chairing several subcommittees.

NRES Committee East of England - Cambridge East Membership:

Name	Occupation	Expert or Lay	Dates	
			Appointed	Resigned
Mrs Carole Alderton	Lay member	Lay	01/04/2011	
Dr. Niki Bannister	Retired Hospital Doctor	Expert	01/02/2014	
Dr Simon Bond	Statistician	Expert	01/04/2011	17/09/2013
Dr Jacqueline Cornelissen	Clinical Research Manager - Late Stage	Lay	01/12/2011	
Dr Madhu Davies	Consultant in Pharmaceutical Medicine and Devices	Expert	01/10/2012	
Dr Catherine Hubbard	Consultant Radiologist	Expert	01/04/2011	28/02/2014
Mr Iain Martin	Retired RAF Officer	Lay Plus	01/10/2012	
Miss Anna Raphael	Bioethicist	Lay Plus	19/07/2011	
Dr Daryl Rees	Clinical Pharmacologist (Industry)	Expert	01/04/2011	18/10/2013
Reverend David Parkes	Retired Chaplin	Lay Plus	01/09/2012	31/03/2013
Mrs Ingrida Robinson	Quality Governance Manager	Lay	01/04/2011	31/12/2013
Dr Simon Russell	Consultant Oncologist	Expert	01/04/2011	
Mrs Patricia Westcott	Retired Oncology Specialist Nurse & Co-ordinator for a Cancer Charity	Lay	22/10/2013	
Mrs Melanie Whittick	Consultant Pharmacist	Expert	01/04/2011	
Mrs Alison Wooster	Lay member	Lay	01/04/2011	31/03/2014

Co-opted Members

Name	Occupation	Expert or Lay	Meeting date attended
Dr Niki Bannister	Retired Hospital Doctor	Expert	19 th November 2013 21 st January 2014
Reverend Keith Lackenby	Retired Reverend	Lay Plus	21 st January 2014
Dr Elizabeth Lund	Independent Consultant, Nutrition and Gastrointestinal Health	Lay	18 th February & 18 th March 2014
Dr Michael Sheldon	Retired Clinical Psychologist	Expert	18 th March 2014

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

Name	Declaration of Interest	Date
Dr Catherine Hubbard	None	21/01/2014
Dr Madhu Davies	None	17/01/2014
Reverend David Parkes	Member of Patients Participants Participation Group involved in setting up specifications for health services and assessment of tenders.	17/01/2014
Niki Bannister	None	13/01/2014
Jacqueline Cornelissen	None	01/12/2013
Mrs Melanie whittick	Share in GSK received in previous employment in Glaxo Group Research	20/01/2014
Mr Iain Martin	None	01/01/2014
Mrs Patricia Westcott	None	20/01/2014
Dr Simon Russell	None	01/12/2013
Mrs Carole Alderton	None	01/12/2013

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

Month	Date	Number of Members Present at Meeting
April	16/04/2013	11
May	21/05/2013	0
June	18/06/2013	10
July	16/07/2013	9
September	17/09/2013	10
October	15/10/2013	10
November	19/11/2013	7
December	17/12/2013	7
January	21/01/2014	7
February	18/02/2014	8
March	18/03/2014	9

11 full committee meetings were held during the reporting period.

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

Name	Number of Meetings Attended
Revd David Parkes	9
Dr Madhu Davies	7
Mr Iain Martin	7
Mrs Alison Wooster	7
Mrs Carole Alderton	7
Dr Simon Russell	7
Mrs Melanie Whittick	7
Dr Jacqueline Cornelissen	6
Dr Catherine Hubbard	5
Dr Daryl Rees	5
Patricia Westcott	4
Dr Niki Bannister	4
Dr Simon Bond	3
Miss Anna Raphael	3
Mrs Ingrida Robinson	3

Number of inquorate meetings held: None

Training 01 April 2013 – 31 March 2014:

Name of Member	Date	Event(s) attended
Mrs Alison Wooster	02/10/2013	Resarcher Training Day , HRA
Mr Iain Martin	24/09/2013	Regional Training Day , HRA
Mrs Melanie Whittick	24/09/2013	Regional Training Day, HRA
Revd David Parkes	24/09/2013	Regional Training Day , HRA
Dr Simon Russell	24/09/2013	Regional Trainng Day , HRA
Dr Catherine Hubbard	24/09/2013	Regional Training Day , HRA
Dr Madhu Davies	24/09/2013	Regional Training Day, HRA
Dr Jacqueline Cornelissen	24/09/2013	Regional Training Day , HRA
Mrs Carole Alderton	24/09/2013	Regional Training Day , HRA
Patricia Westcott	24/03/2014	Induction Training, HRA
Niki Bannister	03/12/2013	NREAP Meeting, HRA

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	16.36
Phase 1	2	3.64
Gene Therapy	0	0.00
Research Tissue Bank	2	3.64
Research Database	0	0.00
Others	42	76.36
Total Applications Reviewed	55	100

Table 2: Other REC activity during the reporting period:

Number of applications made invalid by co-ordinator	2
Number of studies withdrawn prior to the meeting	6
Number of student applications reviewed	13
Number of paediatric applications reviewed	2
Number of device applications reviewed	12
Number of prisoner applications reviewed	0
Number of applications involving adults unable consent reviewed	1
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	1	1.82
Favourable Opinion with Additional Conditions	6	10.91
Unfavourable Opinion	3	5.45
Provisional Opinion	45	81.82
Invalid	0	0.00
No Opinion Pending Consultation with Referee	0	0.00
Provisional Opinion Pending Consultation with Referee	0	0.00
Not Requiring Review by NHS REC	0	0.00
Total	55	100
Number of studies sent back to full committee meeting for final opinion	0	

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

Status of applications at date of generation of report	Number	%
Further Information Favourable Opinion with Standard Conditions	32	58.18
Further Information Favourable Opinion with Additional Conditions	10	18.18
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	1	1.82
Favourable Opinion with Additional Conditions	6	10.91
Unfavourable Opinion	3	5.45
Provisional Opinion	0	0.00
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	2	3.64
Not Requiring Review by NHS REC	0	0.00
No decision entered on RED	1	1.82
Number of studies withdrawn after the meeting	0	0.00
Total	55	100

Table 5: Other Management Information for the reporting period:

Average number of applications reviewed per full meeting	5.00
Number of applications for full ethical review over 60 days	1
Number of applications over 60 days as a % of total	1.82%
Number of days taken to final decision - average	37
Number of days taken to final decision - mode	23
Number of SSAs (non-Phase 1) reviewed	8
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	127
Number of substantial amendments over 35 days	1
Number of substantial amendments over 35 days as a % of total substantial amendments	0.8%
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%

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
08/h0304/85+5	Norwich Biorepository (formerly the Partners in Cancer Research Human	32
13/EE/0077	Tivozanib Hydrochloride Rollover Protocol(Continued Access)	26
13/EE/0090	Pre-birth care planning meetings for perinatal mental health, v1	23
13/EE/0093	A Randomised Controlled Trial for Primary Spontaneous Pneumothorax	29
13/EE/0100	Preliminary Assessment of Advanced Re-biopsy Targeting (PA-ART)	38
13/EE/0158	Protein Turnover in Renal Failure	22
13/EE/0164	Handling Inhalers - Technique Error Comparison	21
13/EE/0177	Multiple Ascending Dose study of AZD7624	28
13/EE/0186	PIRS Version 1	29
13/EE/0197	TSL research biobank	60
13/EE/0198	ADC as a Prognostic Biomarker in Cervical Cancer	63
13/EE/0204	Glaucoma Initial Treatment Study (GITS)	37
13/EE/0213	Parental bonding in infant primary cleft repair	41
13/EE/0291	Share my Care - data sharing in end of life care	38
13/EE/0294	STEFFI	59
13/EE/0297	TIVUS II Study	55
13/EE/0299	A research study of nerve pathology in CTS v.1	58
13/EE/0331	Mechanisms of right ventricular adaptation to pressure overload v1	39
13/EE/0364	A Phase 2 Study with Denosumab in Non-Small Cell Lung Cancer	42
13/EE/0373	MRI study of neural endophenotypes in Prader-Willi Syndrome.	43
13/EE/0376	Norwich DNA Extraction and Sequencing (NODES)	46
13/EE/0390	PANDA: Pregnancy And chronic hypertension: NifeDipine or IAbetalol	45
13/EE/0433	The Leadless Observational Study	34
13/EE/0436	A safety study of pazopanib and MK-3475 in Renal Cell Carcinoma	58
13/EE/0438	PHYSICA KR Clinical Trial	51
14/EE/0015	Assessment of Cytosponge II collection system	38
14/EE/0017	The effect of GLP-1 on PVR in patients with heart failure	35
14/EE/0024	Real time tissue characterisation using mass spectrometry	31
14/EE/0056	Cardioprotective effects of GLP-1 assessed by conductance catheter	32

14/EE/0062	Laminate External Support Protocol, Rev 01	34
14/EE/0101	High and low dose of IgPro20 for the maintenance treatment of CIDP	28
14/EE/0102	ENSURE in AF (atrial fibrillation) study	26

Further Information Favourable Opinion with Additional Conditions

REC Reference	Application Short Title	Number of Days on Clock
13/EE/0092	Rectal Cell Sampler and Biomarkers for Colorectal Cancer: version 1.0	25
13/EE/0111	Rectal Catheter Evaluation	25
13/EE/0157	The Centre for Attention, Learning and Memory (CALM)	48
13/EE/0173	Portico ALT EU Version 01	23
13/EE/0201	Evaluation of the Latella Device	50
13/EE/0318	Vitamin D and Lifestyle Intervention for Gestational Diabetes Mellitus	52
13/EE/0335	COOL-AMI EU case series clinical study	51
13/EE/0337	Lower Limb Ischaemia, Inflammation and Calcification (LIC) Study	45
14/EE/0008	Use of Carers' Diaries in Dementia	41
14/EE/0014	Brain Network Analysis and Cognition in Small Vessel Disease	33

Further Information Unfavourable Opinion

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

REC Reference	Application Short Title	Number of Days on Clock
14/EE/0023	Dose escalating PK study of PH46A	45

Favourable Opinion with Additional Conditions

REC Reference	Application Short Title	Number of Days on Clock
13/EE/0200	Dose escalating PK study of CHR-5154 and CHR-5426	35
13/EE/0365	Coloplast.CP232	28
13/EE/0402	Phase 2a Multiple Doses of Orally Administered ALS-008176 against RSV	24
13/EE/0430	Rapid Prototyping for Custom Made Cranioplasty Plates	42
13/EE/0449	RCT Evaluating Novel Sensing Technology in Type 2 Diabetes Rev 1.0	36
14/EE/0079	Testing an alternative X-ray technique to detect wrist fractures.	23

Unfavourable Opinion		
REC Reference	Application Short Title	Number of Days on Clock
13/EE/0404	Dose escalating PK study of PH46A	25
14/EE/0002	DREAM GLP-1 Study	24
14/EE/0095	Effects of Modafinil on Cognition in Remitted Depressed Patients	23

Provisional Opinion		
REC Reference	Application Short Title	Number of Days on Clock

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

Further information response not complete		
REC Reference	Application Short Title	Number of Days on Clock
14/EE/0018	Human vasodilatory response of GLP-1	N/A
14/EE/0050	An endothermic cooling system to induce mild hypothermia. V1.0	N/A

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

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

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	
13/EE/0198	ADC as a Prognostic Biomarker in Cervical Cancer	63	

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
13/EE/0017/AM02	Project Nico Pharmacokinetic Study	Substantial Amendment Final Version 1.0, 2013/02/2	36

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