

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

Annual Report

01 April 2011 – 31 March 2012

Part 1 – Committee Membership and Training

Name of REC:	NRES Committee East of England - Cambridge East
Type of REC:	I and III
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
Vice-Chair:	Mrs Rebekah Ley
Co-ordinator:	Miss Susan Davies
Assistant Co-ordinator:	Miss. April Saunders (From October 2011)
Committee Address:	Victoria House Capital Park Fulbourn Cambridge CB21 5XB
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Chair's overview of the past year:

This is the first year of operation, during which the Committee reviewed a broad range of studies including student research, medical devices, CTIMPs and Phase 1 applications. Attendance by members was high throughout the year and review times for all applications requiring full ethical review were within the 60-day allocated timeframe. Only 1 out of 98 substantial amendment assessments had a review time outside of the allocated 35-day timeframe.

I should like to take this opportunity thank all the committee members for their professionalism, and sound judgement throughout the year and the administration team for their continued support and hard work.

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 Simon Bond	Statistician	Expert	01/04/2011	
Dr Jacqueline Cornelissen	Clinical Research Associate	Expert	01/04/2011	
Dr Catherine Hubbard	Consultant Radiologist	Expert	01/04/2011	
Mrs Rebekah Ley	Assistant Director Medico-Legal and Patient Experience	Lay Plus	01/04/2011	
Revd David Parkes	Retired Chaplain	Lay Plus	01/04/2011	
Miss Anna Raphael	Internship in Bioethics	Lay Plus		
Dr Daryl Rees	Industrial Clinical Pharmacologist (Chair)	Expert	01/04/2011	
Mrs Ingrida Robinson	Quality Governance Manager	Expert	01/04/2011	
Dr Simon Russell	Consultant Oncologist	Expert	01/04/2011	
Mrs Melanie Whittick	Consultant Pharmacist	Expert	01/04/2011	
Mrs Alison Wooster	Lay member	Lay	01/04/2011	

Deputy Members

Name	Occupation	Expert or Lay	Meeting date attended

Co-opted Members

Name	Occupation	Expert or Lay	Meeting date attended
Ian Skidmore	Retired Company Director	Lay	13/03/2012

Member Bank

Name	Occupation	Expert or Lay	Meeting date attended

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

Name	Declaration of Interest	Date
Dr Jacqueline Cornelissen	Is a Senior CRA for Pharmanet 3 a CRO [Maidenhead - UK] since Dec 2006.	11/01/2012
Mrs Ingrida Robinson	Manages the Record and Development department at Peterborough & Stamford Hospitals NHS Foundation Trust, and also attend the R & D meetings of the Trust quarterly. I declare my position at these meetings if the ethics review is due at Cambridge East and I am not if I involved in discussion if I declare an interest.	05/01/2012
Dr Simon Bond	Employed by Cambridge University Hospital NHS Foundation Trust.	05/01/2012
Mrs Rebekah Ley	Assistant Director at Cambridge University Hospitals NHS foundation Trust - No Direct involvement in research.	05/01/2012
Dr Daryl Rees	Director Salupout Consulting, Owner Salupout Consulting. Shareholder Salupout Consulting.	05/01/2012
Dr. Ian Skidmore	Positions: Director of Skidmore Consulting Ltd - this company is about to close but will continue as a sole trader.Connection:Trustee of MRC Technology	27/02/2012
Mrs Carole Alderton	None	10/04/2011
Revd David Parkes	None	31/03/2012
Dr Simon Russell	None	31/03/2012
Mrs Alison Wooster	None	31/03/2012
Dr Catherine Hubbard	Dr Hubbard's place of work, Hinchingsbrooke Hospital, is run by Circle Partnership through an operational franchise.	31/03/2012
Miss Anna Raphael	None	31/03/2012
Mrs Melanie Whittick	Discretionary shares in GSK. Held for over 15 years from previous employment in Glaxo Group research	31/03/2012
Mrs Melanie Whittick	Review of Studies submitted to RMG Cambridgeshire PCT (Panel member) for approval	31/03/2012

Meetings for Full Ethical Review 01 April 2011 - 31 March 2012:

Month	Date	Number of Members Present at Meeting
April	19/04/2011	9
May	17/05/2011	9
July	19/07/2011	10
August	16/08/2011	9
September	20/09/2011	8
October	18/10/2011	10
November	15/11/2011	9
December	20/12/2011	10
January	17/01/2012	10
February	14/02/2012	8
March	13/03/2012	9

11 full committee meetings were held during the reporting period.

Attendance of Members: 01 April 2011 – 31 March 2012:

Name	Number of Meetings Attended
Revd David Parkes	11
Dr Simon Bond	10
Dr Simon Russell	9
Dr Daryl Rees	9
Mrs Alison Wooster	9
Mrs Carole Alderton	9
Mrs Melanie Whittick	9
Mrs Ingrida Robinson	8
Dr Catherine Hubbard	8
Mrs Rebekah Ley	7
Dr Jacqueline Cornelissen	6
Miss Anna Raphael	5
Dr. Ian Skidmore (co-opted member)	1

Number of inquorate meetings held: 0

Training 01 April 2011 – 31 March 2012:

Name of Member	Date	Event(s) attended
Dr Jacqueline Cornelissen	26/07/2011 - 26/07/2011	Medical Device Training, NRES
Mrs Carole Alderton	03/06/2011 - 03/06/2011	Equality & Diversity, NRES
Revd David Parkes	29/06/2011 - 29/06/2011	Equality & Diversity, NRES
Mrs Ingrida Robinson	04/07/2011 - 04/07/2011	Equality & Diversity, NRES
Dr Simon Russell	11/05/2011 - 11/05/2011	Equality & Diversity, NRES
Miss Anna Raphael	22/09/2011 - 22/09/2011	Informed Consent and Explaining Risk in Randomised Trials , NRES
Mrs Ingrida Robinson	10/08/2011 - 10/08/2011	Introduction to Good Clinical Practice, NIHR
Mrs Carole Alderton	14/09/2011 - 14/09/2011	Update Session with Janet Wisely, NRES
Mrs Alison Wooster	14/09/2011 - 14/09/2011	Update Session with Janet Wisely, NRES
Miss Anna Raphael	28/09/2011 - 28/09/2011	NRES Training, NRES
Miss Anna Raphael	28/09/2011 - 28/09/2011	NRES Phase 1 training , NRES
Dr Daryl Rees	06/12/2011 - 06/12/2011	NRES Chairs National Training Day, NRES
Miss Anna Raphael	01/11/2011 - 01/11/2011	CTIMP Training, NRES
Mrs Carole Alderton	13/02/2012 - 13/02/2012	Clinical Research Ethics and GCP Forum , The Institute of Clinical Research
Dr Daryl Rees	20/12/2011 - 20/12/2011	Shared Ethical Debate - Phase 1 application , NRES
Mrs Carole Alderton	20/12/2011 - 20/12/2011	Shared Ethical Debate - Phase 1 application , NRES
Dr Simon Bond	20/12/2011 - 20/12/2011	Shared Ethical Debate - Phase 1 application , NRES
Dr Jacqueline Cornelissen	20/12/2011 - 20/12/2011	Shared Ethical Debate - Phase 1 application , NRES
Dr Catherine Hubbard	20/12/2011 - 20/12/2011	Shared Ethical Debate - Phase 1 application , NRES
Revd David Parkes	20/12/2011 - 20/12/2011	Shared Ethical Debate - Phase 1 application , NRES
Miss Anna Raphael	20/12/2011 - 20/12/2011	Shared Ethical Debate - Phase 1 application , NRES
Mrs Ingrida Robinson	20/12/2011 - 20/12/2011	Shared Ethical Debate - Phase 1 application , NRES
Mrs Melanie Whittick	20/12/2011 - 20/12/2011	Shared Ethical Debate - Phase 1 application , NRES
Mrs Melanie Whittick	31/01/2012 - 31/01/2012	Phase 1, NRES

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	8	13.11
Phase 1	2	3.28
Gene Therapy	0	0.00
Research Tissue Bank	2	3.28
Research Database	0	0.00
Others	49	80.33
Total Applications Reviewed	61	100

Table 2: Other REC activity during the reporting period:

Number of applications made invalid by co-ordinator	3
Number of studies withdrawn prior to the meeting	8
Number of student applications reviewed	19
Number of paediatric applications reviewed	1
Number of device applications reviewed	13
Number of prisoner applications reviewed	0
Number of applications involving adults unable consent reviewed	0
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	1.64
Favourable Opinion with Additional Conditions	3	4.92
Unfavourable Opinion	3	4.92
Provisional Opinion	54	88.52
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	61	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	43	70.49
Further Information Favourable Opinion with Additional Conditions	8	13.11
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	1	1.64
Favourable Opinion with Additional Conditions	3	4.92
Unfavourable Opinion	3	4.92
Provisional Opinion	3	4.92
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	0	0.00
Number of studies withdrawn after the meeting	0	0.00
Total	61	100

Table 5: Other Management Information for the reporting period:

Average number of applications reviewed per full meeting	5.55
Number of applications for full ethical review over 60 days	2
Number of applications over 60 days as a % of total	3.28%
Number of days taken to final decision - average	40
Number of days taken to final decision - mode	60

Number of SSAs (non-Phase 1) reviewed	6
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	98
Number of substantial amendments over 35 days	1

Number of substantial amendments over 35 days as a % of total substantial amendments	1.0%
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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	7
Number of modified amendments over 14 days	0
Number of modified amendments over 14 days as a % of total modified amendments	0.0%

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Table 6: 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
11/EE/0135	BOTOX Prophylaxis in Chronic Migraine Version 1	58
11/EE/0136	Reasons for loss to follow-up after CHD surgery.	58
11/EE/0137	The use of CK markers in defining Basal Like Breast Carcinomas	60
11/EE/0140	Leucocyte filter in obstetric autotransfusion in low resource settings	60
11/EE/0141	Modelling of MMD trial	47
11/EE/0181	Views of non prescribing nurses on non-medical prescribing	22
11/EE/0183	Comparison of urethral insert and tampons for SUI	27
11/EE/0187	The neurocognitive basis of goal-directed behaviour	30
11/EE/0241	V1: An Understanding of Self Stigma and Help Seeking in Depression	28
11/EE/0252	Balloon Assisted Hip Arthroscopy, PR01662 Rev A	57
11/EE/0253	Stem cells in human normal oesophagus	51
11/EE/0257	Z7291090 - Efficacy of a Dentifrice in Dentinal Hypersensitivity	28
11/EE/0258	Digital sensory nerve study	46
11/EE/0281	PMVr	30
11/EE/0290	Study of Rectal Cell Sampler and eDNA test: version 1.0	24
11/EE/0297	Isolation of blood-derived progenitor cells	53
11/EE/0350	Investigation of the cause of encapsulating peritoneal sclerosis	60
11/EE/0351	ECLIPSE Extension Study	51
11/EE/0356	The impact of introducing extracts from films into group therapy.	60
11/EE/0379	Multifaceted podiatry intervention for fall prevention - REFORM study	59
11/EE/0380	VIBE study	23
11/EE/0411	Everyday fluctuations in attention in Alzheimer's disease.Version 1	55
11/EE/0413	Predictors of outcome in obstructive airways disease	48
11/EE/0415	Vismodegib safety study in basal cell carcinoma v1	32
11/EE/0418	KBT012 (QBR110530)	38
11/EE/0431	Compeed Total Care Cold Sore Patch Efficacy and Safety Study	34

11/EE/0455	Assessing the impact of the UFTO	35
11/EE/0466	Safety & Efficacy of CNV1014802 in patients with Trigeminal Neuralgia	41
11/EE/0471	ARRIVE - Aripiprazole or Antipsychotics as treatment in Schizophrenia	24
11/EE/0515	Primary IGF-1 deficiency (PIGFD) tissue bank	51
11/EE/0538	Interval: study of optimum frequency of blood donations in England, V1	48
12/EE/0001	The Barts Lung Tissue Bank	33
12/EE/0013	Support needs of patients with metastatic breast cancer (version 1.0)	55
12/EE/0023	Mechanisms of restricted and repetitive behaviours in autism	38
12/EE/0029	Fesoterodine and sexual function, Version 1.7	64
12/EE/0035	HeartCycle: Novel Non-Invasive Sensors Study	37
12/EE/0066	Decision-making about risk reducing gastrectomy	39
12/EE/0071	2012-AAR-005 ALFAPump vs standard care in ascites treatment V.01	29
12/EE/0072	2012 AAR 005 ALFAPump RFH Sub Study	29
12/EE/0097	Bioequivalence Study of a Gel Swallowing Aid	49
12/EE/0098	A Postmarketing Study of the Sigma HP® Partial Knee System	47
12/EE/0104	The lived experience of coping with rehabilitating a partner	41
12/EE/0119	Cost effectiveness of two types of slide sheets: a pilot study	44

Further Information Favourable Opinion with Additional Conditions

REC Reference	Application Short Title	Number of Days on Clock
11/EE/0167	Phase II PoC study of APD515 v1.0	27
11/EE/0393	functional outcome following knee arthroplasty	44
11/EE/0436	Anatomical Variation in Adipose Tissue Depots	33
11/EE/0480	Dopamine, antipsychotics and food related reward	23
11/EE/0488	Immunology of failing metal-on-metal hip replacement	22
11/EE/0532	The CAPE Study: Community care pathways at the end of life Version 1.0	56
12/EE/0075	Safety of ScopeGuide in patients with Implantable Cardiac Devices	33
12/EE/0127	Single Administration of KBSA301 in Patients with Severe Pneumonia.	63

Further Information Unfavourable Opinion		
REC Reference	Application Short Title	Number of Days on Clock

Favourable Opinion with Standard Conditions		
REC Reference	Application Short Title	Number of Days on Clock
11/EE/0355	Paired Lymphocyte Analysis	17

Favourable Opinion with Additional Conditions		
REC Reference	Application Short Title	Number of Days on Clock
11/EE/0249	Evaluation of venous thromboembolism using non-contrast MR venography	28
11/EE/0288	CT evaluation of liver perfusion following liver transplantation	42
11/EE/0289	Oticon Ponto Pro Power Study	22

Unfavourable Opinion		
REC Reference	Application Short Title	Number of Days on Clock
11/EE/0171	RETILASE TRIAL	21
11/EE/0287	Effect of cognitive fluctuations in neurocognitive performance	44
11/EE/0536	The IMAGINE 4 Study	32

Provisional Opinion		
REC Reference	Application Short Title	Number of Days on Clock
11/EE/0403	Investigating the links between Burnout, Stress and PTSD in nurses.	N/A
11/EE/0410	To determine the effect of posture on Respiratory Muscle Strength	N/A
12/EE/0095	A study of belimumab in the prevention of kidney transplant rejection	N/A

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

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 7: Items exceeding timelines:

Full applications for ethical review over 60 day timeline		
REC Reference	Application Short Title	Number of Days on Clock
12/EE/0029	Fesoterodine and sexual function, Version 1.7	64
12/EE/0127	Single Administration of KBSA301 in Patients with Severe Pneumonia.	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
09/H0304/77/AM02	Generation of Donor Induced Pluripotent Stem (IPS) Cells for Research	Amendment #2	40

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