

**NRES Committee East of England -
Hertfordshire**

Annual Report

01 April 2011 – 31 March 2012

Part 1 – Committee Membership and Training

Name of REC:	NRES Committee East of England - Hertfordshire
Type of REC:	Authorised REC
Type of Flag:	None
Chair:	Dr Steve Eckersall
Vice-Chair:	Dr Sunda Uthayakumar
Alternate Vice-Chair:	Mr David Grayson
Co-ordinator:	Miss Anna Bradnam
PRSC Co-ordinator:	Miss Anna Bradnam
Assistant Co-ordinator:	Ms Har Hari Kaur (from 01 December 2011)
Committee Address:	Victoria House Capital Park Fulbourn Cambridge CB21 5XB
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Chair's overview of the past year:

At present, this committee faces an uncertain future with the proposed merger with Welywn REC. This has been proposed for a number of reasons, not least because of a reduction in the number of applications coming to the REC which has resulted in two meetings being cancelled in 2012 already.

Since Sept 2011, the committee has been meeting at the Letchworth Centre for Healthy Living, This accommodation has proved to be an acceptable and more economic replacement to the Novotel.

There has been no new recruitments to the REC but the committee had to accept the resignations of two of its valuable and hardworking members, Dr.Patricia Wilson and Mrs.Linda Bose.

NRES Committee East of England - Hertfordshire Membership:

Name	Occupation	Expert or Lay	Dates	
			Appointed	Resigned
Mrs Linda Bose	Voluntary Sector - Retired Manager - Dacorum Relate	Lay	01/04/2007	27/10/2011
Reverend Elizabeth Bradley	Hospital Chaplain	Lay Plus	01/10/2008	
Mr Michael Buck	Retired Solicitor & Chartered Arbitrator	Lay Plus	01/04/2007	
Mrs Heidi Ebrahim	Retired Local Government Officer	Lay Plus	01/04/2007	
Dr Steve Eckersall	Consultant Anaesthetist	Expert	01/04/2007	
Mr David Grayson	Retired Local Government Administrator	Lay Plus	01/04/2007	
Dr Wassim Matta	General Practitioner	Expert	01/10/2008	
Dr Gordon Nichols	Business Manager	Lay Plus	01/07/2007	
Dr Mark Slater	Consultant Psychiatrist	Expert	01/04/2007	
Dr Mark Tanner	Consultant Psychiatrist	Expert	27/06/2007	
Dr Sunda Uthayakumar	Consultant Physician HIV & GUM	Expert	01/04/2007	
Ms Melanie Whittick	Pharmacist	Expert	01/04/2007	
Dr Patricia Wilson	Senior Nurse Lecturer	Expert	01/04/2007	24/11/2011

Deputy Members

Name	Occupation	Expert or Lay	Meeting date attended

Co-opted Members

Name	Occupation	Expert or Lay	Meeting date attended
Mr Stuart Kent	Retired Consultant Surgeon	Expert	11/01/2012

Member Bank

Name	Occupation	Expert or Lay	Meeting date attended

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

Name	Declaration of Interest	Date
Dr Steve Eckersall	None	31/03/2012
Dr Sunda Uthayakumar	None	09/01/2012
Mr David Grayson	Rank and file only member of Viewpoint (Mental Health Service User Charity set up by MIND)	24/01/2012
Mr Michael Buck	None	30/12/2011
Mrs Heidi Ebrahim	None	29/12/2011
Reverend Elizabeth Bradley	None	26/01/2012
Dr Wassim Matta	None	23/12/2011
Dr Mark Tanner	Consultant in NHS - Hertfordshire Partnership NHS Foundation Trust	09/02/2012
Dr Gordon Nichols	Shareholdings in Antisoma PLC	03/01/2012
Dr Mark Slater	Consultant Psychiatrist - Hertfordshire Partnership NHS Foundation Trust	09/03/2012
Ms Melanie Whittick	Discretionary shares in GSK from previous employment in Glaxo Group Research.	31/03/2012
Ms Melanie Whittick	Reviewer 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
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April	27/04/2011	10
May	25/05/2011	12
June	22/06/2011	9
July	27/07/2011	10
September	28/09/2011	8
October	26/10/2011	9
November	23/11/2011	8
January	25/01/2012	9
March	28/03/2012	11

9 full committee meetings were held during the reporting period.

Proportionate Review Sub Committee Meetings held during 01 April 2011 - 31 March 2012:

Month	Date	Number of Members Present at Meeting
September	02/09/2011	3
September	30/09/2011	3
October	28/10/2011	3
November	25/11/2011	3
December	14/12/2011	3
December	30/12/2011	3
January	11/01/2012	3
February	08/02/2012	3
March	14/03/2012	3

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

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

Name	Number of Meetings Attended
Mr David Grayson	9
Mr Michael Buck	8
Mrs Heidi Ebrahim	8
Dr Steve Eckersall	8
Ms Melanie Whittick	8
Reverend Elizabeth Bradley	7
Dr Wassim Matta	7
Dr Gordon Nichols	7
Dr Mark Slater	6
Dr Mark Tanner	6
Dr Patricia Wilson	5
Dr Sunda Uthayakumar	4
Mrs Linda Bose	3

Number of inquorate meetings held: 0

**Attendance of Members at proportionate review sub-committee meetings:
01 April 2011 – 31 March 2012:**

Name	Number of Meetings Attended
Mr David Grayson	9
Mrs Heidi Ebrahim	4
Dr Mark Tanner	4
Dr Sunda Uthayakumar	4
Dr Gordon Nichols	1
Dr Patricia Wilson	1
Mrs Linda Bose	1
Reverend Elizabeth Bradley	1
Mr Michael Buck	1
Mr Stuart Kent	1

Training 01 April 2011 – 31 March 2012:

Name of Member	Date	Event(s) attended
Dr Mark Tanner	26/04/2011 - 26/04/2011	Equality & Diversity, NHS Core Learning Unit
Dr Mark Tanner	12/04/2011 - 12/04/2011	Introduction to Information Governance - Introductory Level, NHS - Connecting for Health
Reverend Elizabeth Bradley	11/06/2011 - 11/06/2011	Equality & Diversity, Luton and Dunstable Hospital NHS Trust
Dr Sunda Uthayakumar	17/06/2011 - 17/06/2011	Equality & Diversity, NRES
Dr Gordon Nichols	16/06/2011 - 16/06/2011	Equality & Diversity, NRES
Mr David Grayson	26/09/2011 - 26/09/2011	NRES Update - Janet Wisely (1/2 day), NRES
Reverend Elizabeth Bradley	26/10/2011 - 26/10/2011	NRES MCA Training video and discussion, NRES
Mrs Linda Bose	26/10/2011 - 26/10/2011	MCA DVD for NRES Committee members, NRES
Dr Patricia Wilson	26/10/2011 - 26/10/2011	MCA DVD for NRES Committee members, NRES
Dr Mark Tanner	26/10/2011 - 26/10/2011	MCA DVD for NRES Committee members, NRES
Mr David Grayson	26/10/2011 - 26/10/2011	MCA DVD for NRES Committee members, NRES
Dr Wassim Matta	26/10/2011 - 26/10/2011	MCA DVD for NRES Committee members, NRES
Mr Michael Buck	26/10/2011 - 26/10/2011	MCA DVD for NRES Committee members, NRES
Ms Melanie Whittick	13/02/2012 - 13/02/2012	Ethics and GCP Forum, NRES
Dr Mark Tanner	07/12/2011 - 07/12/2011	NRES Statistics Training, NRES
Reverend Elizabeth Bradley	14/03/2012 - 14/03/2012	NRES Members National Training Day - booking confirmed 07/03/2012 , NRES
Mr David Grayson	26/10/2011 - 26/10/2011	NRES MCA DVD Training, NRES
Reverend Elizabeth Bradley	26/10/2011 - 26/10/2011	NRES MCA DVD Training, NRES
Mr Michael Buck	26/11/2011 - 26/11/2011	NRES MCA DVD Training, NRES
Mrs Heidi Ebrahim	26/11/2011 - 26/11/2011	NRES MCA DVD Training, NRES
Dr Mark Slater	26/11/2011 - 26/11/2011	NRES MCA DVD Training, NRES
Dr Mark Tanner	26/11/2011 - 26/11/2011	NRES MCA DVD Training, NRES
Ms Melanie Whittick	31/01/2012 - 31/01/2012	Phase 1 Studies, 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	0	0.00
Phase 1	0	0.00
Gene Therapy	0	0.00
Research Tissue Bank	0	0.00
Research Database	0	0.00
Others	52	100.00
Total Applications Reviewed	52	100

Table 2: Other REC activity during the reporting period:

Number of applications made invalid by co-ordinator	5
Number of studies withdrawn prior to the meeting	7
Number of student applications reviewed	20
Number of paediatric applications reviewed	5
Number of device applications reviewed	0
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	1.92
Favourable Opinion with Additional Conditions	6	11.54
Unfavourable Opinion	4	7.69
Provisional Opinion	41	78.85
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	52	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	31	59.62
Further Information Favourable Opinion with Additional Conditions	7	13.46
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	1	1.92
Favourable Opinion with Additional Conditions	6	11.54
Unfavourable Opinion	4	7.69
Provisional Opinion	2	3.85
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	1	1.92
Total	52	100

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

Total Applications Reviewed	19
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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	3	15.79
Favourable Opinion with Additional Conditions	11	57.89
No Opinion transfer to full committee for review	0	0.00
Provisional Opinion	5	26.32
Unfavourable Opinion	0	0.00
Total	19	100

Table 7: Other Management Information for the reporting period:

Average number of applications reviewed per full meeting	5.78
Number of applications for full ethical review over 60 days	4
Number of applications over 60 days as a % of total	7.69%
Number of days taken to final decision - average	42
Number of days taken to final decision - mode	45

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	59
Number of substantial amendments over 35 days	0
Number of substantial amendments over 35 days as a % of total substantial amendments	0.0%

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	0
Number of modified amendments over 14 days	0
Number of modified amendments over 14 days as a % of total modified amendments	0%

Number of proportionate review applications for ethical review over 14 days*	13
Number of proportionate review applications over 14 days as a % of total	68.42%

***NB – Proportionate Review Service was in pilot phase until September 2011 and was an aim not a target**

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
11/EE/0111	Dopaminergic modulation of human social decision making	63
11/EE/0124	The Dairy Milk Mucus Study	38
11/EE/0139	Evaluation of patients' experience of using 'Move-on-up' video	22
11/EE/0142	Psychometric functions for displacement and static perimetry	45
11/EE/0143	Vitreous macrophages in diabetic retinopathy.	48
11/EE/0144	Patient-reported outcomes in patients with psychosis	45
11/EE/0145	Use and non-use of Home-Start Services.	37
11/EE/0189	Aesthetic Outcome in Maxillary Implant Restorations	55
11/EE/0196	Early life and environmental determinants of bone microarchitecture	31
11/EE/0223	Piloting a novel intervention for improving phosphate control	41
11/EE/0227	PROMPT Platelet Responsiveness and Outcome from Platelet Transfusion	45
11/EE/0228	Experiences of Multi-Family Groups	46
11/EE/0239	Reward Image Response - V1	37
11/EE/0247	Suitability of patients with severe burns for facial transplant V1	44
11/EE/0255	Super-athletes for Health (Version 1)	37
11/EE/0273	The Expert as Leader	33
11/EE/0277	IL-1 and the microcirculation: Observational phase	35
11/EE/0345	PH-QLQ v1 Pulmonary Hypertension QoL Questionnaire	25
11/EE/0374	Utility of echocardiography to guide CRT in heart failure	55
11/EE/0377	Novel urinary markers for detecting prostate cancer	51
11/EE/0383	Posttraumatic stress and growth in parents of preterm infants	63
11/EE/0387	Comparison of urinary PABA excretion in children and adults	54
11/EE/0395	Effect of preoperative anabolic strategies on carbohydrate metabolism	49
11/EE/0449	Faecal Excretion of Vitamin K and its Metabolites in Infants	31
11/EE/0487	Experiences of Help-Seeking for Dissociative Identity Disorder 2	58
11/EE/0490	Feasibility study of Spectral Mammography imaging	42
11/EE/0491	Understanding Hospital Admissions Close to the End of Life (ACE Study)	53
11/EE/0497	Acceptance and commitment therapy for chronic pain	55
11/EE/0502	Investigating sound therapy for tinnitus in Cochlear Implantees	29
11/EE/0503	Depression and physical activity in people with multiple sclerosis	32

12/EE/0028	Impulse oscillometry and abdominal volume	99
12/EE/0039	Reality monitoring in schizophrenia	38
12/EE/0040	Blueprint	45
12/EE/0042	Personality & Treatment Outcomes in Offenders with Learning Disability	47
12/EE/0079	A non-interventional, observational study of the use of Zonisamide	22
12/EE/0141	Patients' perspectives of living with a long-term condition.	51

Further Information Favourable Opinion with Additional Conditions

REC Reference	Application Short Title	Number of Days on Clock
11/EE/0192	emulsion layering study version 1	43
11/EE/0224	What is it like to engage veterans in psychotherapy?	45
11/EE/0232	Use of Face mask spirometry as a prognostic indicator in MND	58
11/EE/0240	Multiparametric MRI to assess treatment response in mesothelioma	43
11/EE/0263	Measuring symptoms of trauma in adults with an Intellectual Disability	53
11/EE/0271	Evaluating the Efficacy of Metacognitive Training for Schizophrenia	37
11/EE/0299	Experiences of newly qualified nurses	24

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
11/EE/0193	Pathological analysis of Neuronopathic Gaucher Disease	29
11/EE/0343	Geographical breakdown of MMR1 uptake (version 1)	26
11/EE/0346	Meiosis in unfertilised human oocytes 1	25
11/EE/0456	UKOSS: Pregnancy in women with Chronic Kidney Disease Stage 5	15

Favourable Opinion with Additional Conditions

REC Reference	Application Short Title	Number of Days on Clock
11/EE/0353	Im-Con: Improving Consultations in General Practice (Version 1)	27
11/EE/0361	Procalcitonin in Atopic Dermatitis	63
11/EE/0369	Assessing the impact of Crohn's disease genes on gut immune function	49
11/EE/0388	Measurements of fatigue in persons with a neuromuscular disease.	20
11/EE/0426	Blood Gas Sampling: A Randomised Controlled Trial of Local Anaesthesia	21

11/EE/0440	Sharing news study	29
11/EE/0504	Mindfulness Based Cognitive Therapy Training in Primary Care	19
11/EE/0505	Uptake and Use of Assistive Technology for Older People	20
11/EE/0548	"PLAY ME"	16
11/EE/0550	The acute effect of Pneumatic Compression in critical limb ischemia.	9
11/EE/0551	James Lind Alliance Pressure Ulcer Priority Setting Process	15
12/EE/0031	Patient perceptions and motivations for inclusion on a database	8
12/EE/0076	Clinical usefulness of a new questionnaire in physiotherapy v1	8
12/EE/0078	4888-O Evaluation of New Ostomy Barriers and Drainable Pouches	8
12/EE/0136	Bone Marrow Cells for Cartilage Repair	14
12/EE/0140	A Randomised control trial to compare performance on two hearing aids	14
12/EE/0148	fMRI studies of visual object processing with ventral stream lesions	30

Unfavourable Opinion

REC Reference	Application Short Title	Number of Days on Clock
11/EE/0190	ICTASOPP001 Patients and Carers	22
11/EE/0261	Experiences of Help-Seeking for Dissociative Identity Disorder	44
11/EE/0486	Experiences of Children and Adolescents with an Acquired Brain Injury	26
12/EE/0145	Experience of memorial change in EMDR: A qualitative study	30

Provisional Opinion

REC Reference	Application Short Title	Number of Days on Clock
12/EE/0131	Does London's Low Emission Zone improve children's respiratory health?	N/A
12/EE/0142	Relationship between childhood experiences and psychotic symptoms.	N/A

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
11/EE/0125	Analysis of Nasal Batten Grafts	23

Invalid Application		
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REC Reference	Application Short Title	Number of Days on Clock
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No Opinion Pending Consultation with Referee		
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REC Reference	Application Short Title	Number of Days on Clock
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Not Requiring Review by NHS REC		
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REC Reference	Application Short Title	Number of Days on Clock
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Table 9: Items exceeding timelines:

Full applications for ethical review over 60 day timeline		
REC Reference	Application Short Title	Number of Days on Clock
11/EE/0111	Dopaminergic modulation of human social decision making	63
11/EE/0361	Procalcitonin in Atopic Dermatitis	63
11/EE/0383	Posttraumatic stress and growth in parents of preterm infants	63
12/EE/0028	Impulse oscillometry and abdominal volume	99

Proportionate review applications for ethical review over 14 days timeline		
REC Reference	Application Short Title	Number of Days on Clock
11/EE/0343	Geographical breakdown of MMR1 uptake (version 1)	26
11/EE/0346	Meiosis in unfertilised human oocytes 1	25
11/EE/0345	PH-QLQ v1 Pulmonary Hypertension QoL Questionnaire	25
11/EE/0388	Measurements of fatigue in persons with a neuromuscular disease.	20
11/EE/0456	UKOSS: Pregnancy in women with Chronic Kidney Disease Stage 5	15
11/EE/0502	Investigating sound therapy for tinnitus in Cochlear Implantees	29
11/EE/0503	Depression and physical activity in people with multiple sclerosis	32
11/EE/0504	Mindfulness Based Cognitive Therapy Training in Primary Care	19
11/EE/0505	Uptake and Use of Assistive Technology for Older People	20
11/EE/0548	"PLAY ME"	16
11/EE/0551	James Lind Alliance Pressure Ulcer Priority Setting Process	15
12/EE/0079	A non-interventional, observational study of the use of Zonisamide	22
12/EE/0141	Patients' perspectives of living with a long-term condition.	51

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		
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Amendment Reference	Application Short Title	Amendment Title	Number of Days on Clock
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Modified Amendments over 14 day timeline

Amendment Reference	Application Short Title	Amendment Title	Number of Days on Clock
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Section 30 application over 60 day timeline

Amendment Reference	Application Short Title	Amendment Title	Number of Days on Clock
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