

**NRES Committee East of England -
Essex**

Annual Report

01 April 2011 – 31 March 2012

Part 1 – Committee Membership and Training

Name of REC:	NRES Committee East of England - Essex
Type of REC:	Type III
Type of Flag:	Phase 1 Studies in Patients Research Involving Adults Lacking Capacity Research Involving Prisoners or Prisons
Chair:	Dr Alan Lamont
Vice-Chair:	Dr Niki Bannister
Alternate Vice-Chair:	Dr Andy Stevens
Co-ordinator:	Ms Suzanne Emerton
PRSC Co-ordinator:	Ms Suzanne Emerton
Assistant Co-ordinator:	Not Applicable
Committee Address:	East of England Rec Office 1 Victoria House Capital Park Fulbourn Cambridge CB21 5XB
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Chair's overview of the past year:

The Essex REC has had a year of considerable stress, commencing with the reorganisation of the East of England service in which a number of valued members transferred elsewhere, or decided to stand down. The resulting depleted committee, particularly low in expert members, has risen to the challenge of Proportionate Review with the associated short timelines, and has coped with recruitment restrictions. The committee and coordinator are now regularly dealing with amendments and subcommittee work from four now subsumed REC's: Essex 1, 2 and Mid, and Suffolk plus occasional others. This has placed a high workload on a generally willing membership, and will not be sustainable without the recently promised recruitment, to be set alongside the announcement that there is to be a further review and reduction in numbers of REC's. As chair, I am very grateful to the officers, membership and to the coordinator, Suzanne, for their diligence, perseverance and hard work over the past year. We can all look forward to 'interesting times' to come.

Alan Lamont

NRES Committee East of England - Essex Membership:

Name	Occupation	Expert or Lay	Dates	
			Appointed	Resigned
Mr Tony Baker	Retired Consultant Head of Medical Physics	Expert	01/04/2011	
Dr Niki Bannister	Retired Hospital Doctor	Expert	01/04/2011	
Ms Rachel Burrows	Project Commercial Assistant	Lay	01/04/2011	
Dr Alan Calverd	Scientific Consultant	Lay	01/04/2011	
Mr Alan Edwards	Retired Company Director	Lay	01/04/2011	
Mrs Marilyn Jones	retired Nurse Manager	Lay	01/04/2011	02/02/2012
Dr Gerry Kamstra	Solicitor	Lay	01/04/2011	
Dr Alan Lamont	Consultant Oncologist	Expert		
Mr Simon Laurence	Retired Patent Agent	Lay	01/04/2011	
Ms Sarah Jane Lee	University Lecturer in Nursing	Expert	01/04/2011	
Ms Julie Lockhart	PPI Representative	Lay	01/04/2011	
Dr Andy Stevens	Principal Lecturer - Media Consultant	Lay	01/04/2011	
Mrs Caroline Ward	Head of Health & Wellbeing Children's Services	Expert	01/04/2011	
Mrs Helen Watkins	Financial Manager	Lay	01/04/2011	
Mrs Deborah - Anne Whittle	Pharmacist	Expert	01/12/2011	

Deputy Members

Name	Occupation	Expert or Lay	Meeting date attended

Co-opted Members

Name	Occupation	Expert or Lay	Meeting date attended

Member Bank

Name	Occupation	Expert or Lay	Meeting date attended

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

Name	Declaration of Interest	Date
Mrs Caroline Ward	None (as stated on form dated 31.03.11)	27/04/2011
Ms Sarah Jane Lee	Senior Lecturer, School of Health & Human Sciences, University of Essex	31/03/2012
Mrs Marilyn Jones	Volunteer with 'Headway' (Brain Injury Charity).Public Governor of Colchester Hospital University Foundation Trust (as stated on form dated 18.03.11)	27/04/2011
Mr Alan Edwards	None (as stated on form dated 31.03.12)	31/03/2012
Dr Alan Calverd	Director: Radiation Consultancy Services Ltd, United Open MRI Ltd and Medical Physics Cooperative Ltd Proprietor: Quality Associates Shareholder: Exhalation Technologies Ltd(as stated on form dated 31.03.12)	31/03/2012
Mrs Helen Watkins	Lay member of Clinical Ethics Committee at the Princess Alexandra Hospital, Harlow	31/03/2012
Dr Gerry Kamstra	Positions: As a lawyer, advises a number of pharma and medical device companies. Shareholdings: Discretionary pension investments Connection to genetic/voluntary body: - occasional pro bono legal advice given to Genetic Alliance UK- unpaid member of ABPI Intellectual Property Network and of the Bioindustry Association Intellectual Property Committee(as stated on form dated 31.03.12)	31/03/2012
Dr Niki Bannister	None (as stated on form dated 07.04.11)	27/04/2011
Dr Andy Stevens	Principal Lecturer and Sponsor, Anglia Ruskin University (as stated on form dated 07.04.11)	27/04/2011
Mr Tony Baker	None	31/03/2012
Mrs Deborah - Anne Whittle	None	31/03/2012
Dr Alan Lamont	None	31/03/2012
Ms Julie Lockhart	None	31/03/2012
Ms Rachel Burrows	None	31/03/2012

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

Month	Date	Number of Members Present at Meeting
April	07/04/2011	10
May	04/05/2011	9
June	02/06/2011	10
July	07/07/2011	10
August	04/08/2011	7
October	05/10/2011	9
November	03/11/2011	11
December	01/12/2011	9
January	05/01/2012	14
February	02/02/2012	8
March	01/03/2012	10

11 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
August	16/08/2011	3
September	13/09/2011	4
October	18/10/2011	3
November	15/11/2011	4
December	20/12/2011	4
January	17/01/2012	3
February	02/02/2012	3
March	01/03/2012	3

8 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
Ms Julie Lockhart	11
Dr Alan Calverd	10
Dr Alan Lamont	10
Mr Simon Laurence	10
Dr Niki Bannister	9
Mrs Helen Watkins	9
Mr Alan Edwards	8
Dr Andy Stevens	8
Dr Gerry Kamstra	7
Mr Tony Baker	7
Mrs Marilyn Jones	7
Mrs Caroline Ward	4
Ms Rachel Burrows	3
Ms Sarah Jane Lee	2
Mrs Deborah - Anne Whittle	2

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
Ms Julie Lockhart	5
Dr Alan Lamont	4
Dr Andy Stevens	4
Dr Gerry Kamstra	3
Dr Niki Bannister	3
Mr Alan Edwards	3
Mrs Helen Watkins	2
Mrs Marilyn Jones	1
Dr Alan Calverd	1
Mr Tony Baker	1

Training 01 April 2011 – 31 March 2012:

Name of Member	Date	Event(s) attended
Dr Alan Lamont	31/05/2011 - 31/05/2011	Equality & Diversity, NRES
Dr Alan Calverd	31/05/2011 - 31/05/2011	Equality & Diversity, NRES
Mrs Helen Watkins		Equality & Diversity, NRES online
Dr Alan Lamont	02/02/2012 - 02/02/2012	SED "Sharptalk", NRES
Dr Niki Bannister	02/02/2012 - 02/02/2012	SED "Sharptalk", NRES
Dr Andy Stevens	02/02/2012 - 02/02/2012	SED "Sharptalk", NRES
Dr Alan Calverd	02/02/2012 - 02/02/2012	SED "Sharptalk", NRES
Mr Alan Edwards	02/02/2012 - 02/02/2012	SED "Sharptalk", NRES
Mr Simon Laurence	02/02/2012 - 02/02/2012	SED "Sharptalk", NRES
Ms Julie Lockhart	02/02/2012 - 02/02/2012	SED "Sharptalk", NRES
Mr Alan Edwards	13/02/2012 - 13/02/2012	Ethics & GCP Forum
Ms Julie Lockhart	28/03/2012 - 28/03/2012	NRES Members National Training Day, NRES
Dr Alan Lamont	06/12/2011 - 06/12/2011	NRES Chairs National Training Day, NRES
Ms Rachel Burrows	10/01/2012 - 10/01/2012	NRES REC Committee Members Induction, NRES
Dr Alan Lamont	01/12/2011 - 01/12/2011	MCA DVD, NRES
Mr Tony Baker	01/12/2011 - 01/12/2011	MCA DVD, NRES
Dr Gerry Kamstra	01/12/2011 - 01/12/2011	MCA DVD, NRES
Mr Simon Laurence	01/12/2011 - 01/12/2011	MCA DVD, 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	3	5.77
Phase 1	0	0.00
Gene Therapy	0	0.00
Research Tissue Bank	0	0.00
Research Database	0	0.00
Others	49	94.23
Total Applications Reviewed	52	100

Table 2: Other REC activity during the reporting period:

Number of applications made invalid by co-ordinator	13
Number of studies withdrawn prior to the meeting	12
Number of student applications reviewed	29
Number of paediatric applications reviewed	3
Number of device applications reviewed	1
Number of prisoner applications reviewed	12
Number of applications involving adults unable consent reviewed	6
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	1	1.92
Unfavourable Opinion	3	5.77
Provisional Opinion	47	90.38
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	33	63.46
Further Information Favourable Opinion with Additional Conditions	6	11.54
Further Information Unfavourable Opinion	1	1.92
Favourable Opinion with Standard Conditions	1	1.92
Favourable Opinion with Additional Conditions	1	1.92
Unfavourable Opinion	3	5.77
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	1	1.92
Not Requiring Review by NHS REC	0	0.00
No decision entered on RED	0	0.00
Number of studies withdrawn after the meeting	4	7.69
Total	52	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	4	28.57
Favourable Opinion with Additional Conditions	0	0.00
No Opinion transfer to full committee for review	4	28.57
Provisional Opinion	5	35.71
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	4.73
Number of applications for full ethical review over 60 days	7
Number of applications over 60 days as a % of total	13.46%
Number of days taken to final decision - average	46
Number of days taken to final decision - mode	51
Number of SSAs (non-Phase 1) reviewed	1
Number of applications for SSA review over 25 days	1
Number of applications for SSA review over 25 days as % of all non-Phase 1 (SSAs)	100.0%
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	103
Number of substantial amendments over 35 days	8
Number of substantial amendments over 35 days as a % of total substantial amendments	7.8%
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	2
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*	1
Number of proportionate review applications over 14 days as a % of total	10.00%

***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/0116	An IPA study of Craving in a UK Population of recovering gamblers	39
11/EE/0118	Barriers to early diagnosis with breast cancer	37
11/EE/0119	Validation of the Addenbrooke's Cognitive Examination Revised (ACE-R)	45
11/EE/0129	Crohn's Endoscopy Study	38
11/EE/0155	Clonal Architecture of Pre-Malignant and Malignant Tumours	57
11/EE/0156	CORAL study: Proof of concept RCT	54
11/EE/0159	Educating nursing staff to increase awareness of carers needs.Version2	57
11/EE/0164	Optical Functional Properties of the OOKP	55
11/EE/0172	Evaluation of the sensitivity of the HoNOS in ECT	33
11/EE/0173	Readiness for injectable naltrexone in prisoners awaiting release	36
11/EE/0195	Empower women and providers: domestic violence and mental health	32
11/EE/0205	The bioavailability and anti-inflammatory effect of ITCs (BAITCs)	43
11/EE/0209	Dependence in Alzheimers Disease in England (DADE2)	38
11/EE/0231	The lived experiences of adolescents with Cystic Fibrosis, Version 1	63
11/EE/0236	Music therapy and the resettlement of women prisoners	45
11/EE/0238	Midwives' experiences of promoting normal birth in a hospital	69
11/EE/0242	What are district and community nurses perception of integrated working	61
11/EE/0265	Psychologists working with children with life-limiting illnesses V1	61
11/EE/0266	Safety of a selective inhibitor of SirT1 in Huntington's Disease 2.0	48
11/EE/0269	The Impact of an Ageing Workforce on Strategic Management	34
11/EE/0279	An exploration of care following hypertension in pregnancy	58
11/EE/0282	Exploring the impact of gender and offence history on moral reasoning	50
11/EE/0401	Obesity, binge eating and metacognitions	58
11/EE/0409	Assessing platelet function in term and preterm infants	32
11/EE/0433	Improving the Health of People with Court Orders Version 6	50
11/EE/0448	Adjustment to a prison environment	34
11/EE/0453	Evaluation of the Offence Prevention Line	41
11/EE/0494	Diabetes pharmacy drop-in clinic	10
11/EE/0506	Insulin sparing effects of Sitagliptin compared to placebo	51
12/EE/0002	Understanding the Health Visitors experience's	56

12/EE/0003	The CoMPASs:ION Programme Version 1 02/11/2011	51
12/EE/0007	(duplicate) 1. Staff and service user perceptions of aggression and it	48
12/EE/0050	Phase II Proof of Concept Study of GRC17536 in patients with PDN	36
12/EE/0093	Assessing at-risk mental state	58
12/EE/0111	Orthodontic patient satisfaction rates and PAR Scores	11

Further Information Favourable Opinion with Additional Conditions

REC Reference	Application Short Title	Number of Days on Clock
11/EE/0217	Nurse's perceptions of the mental health of new fathers.Version 1	64
11/EE/0321	The Choice study.	29
11/EE/0341	Sepsis biomarkers (ABEL - Proof of Concept)	9
11/EE/0399	OSA and AF	51
11/EE/0489	The effect of post-stroke sleep on daytime function.	60
11/EE/0507	Female Perpetrators of Intimate Partner Violence version 1	39
12/EE/0005	AHE01 Swallowing Treatment using EPS (STEPS Study)	53
12/EE/0038	Dizziness and falls after cataract surgery	11
12/EE/0074	Prison treatment outcomes and processes research study (PTORS) v1.0	68

Further Information Unfavourable Opinion

REC Reference	Application Short Title	Number of Days on Clock
11/EE/0207	Evaluation of pharmacists' role in medicines related problems	89

Favourable Opinion with Standard Conditions

REC Reference	Application Short Title	Number of Days on Clock
11/EE/0131	Understanding Recovery in Psychosis using a Compassion Framework	23
11/EE/0390	Retrospective Analysis of Various Sampling Techniques	11
11/EE/0446	FXIII levels in haemophilia	10
11/EE/0492	Agluna-Treated Stanmore Custom Megaprosthesis Study	7
11/EE/0544	Genetic Predictors Of RA Severity- GENRAS (Version 1)	10

Favourable Opinion with Additional Conditions

REC Reference	Application Short Title	Number of Days on Clock
11/EE/0373	Implementation of a sexual abuse intervention for drug dependent men	27

Unfavourable Opinion

REC Reference	Application Short Title	Number of Days on Clock
11/EE/0126	National Evaluation of the Older People's Pilot	22
11/EE/0235	Implementation of a sexual abuse intervention for drug dependent men	43
12/EE/0049	The role of luminal microorganisms in intestinal diseases - version 1	20
12/EE/0107	INR self & clinic-based tester perceptions of an anticoag. service	11

Provisional Opinion

REC Reference	Application Short Title	Number of Days on Clock
11/EE/0402	Respiratory muscle function in adult cystic fibrosis patients	N/A
12/EE/0099	Fracture Prevention In Primary Hyperparathyroidism (FRIP)	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
11/EE/0444	Genomic Analysis of Mesothelioma	N/A

Withdrawn after the meeting

REC Reference	Application Short Title	Number of Days on Clock
11/EE/0170	Experience of clients with BPD of DBT. Version 1	35
11/EE/0283	Perceived Need For Treatment Within North West Prison's	28
11/EE/0366	Attitudes to Prisoners with Personality Disorder	47
11/EE/0400	The Vascular Effects of B Cell Modulating Treatment in ANCA Vasculitis	40

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
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Not Requiring Review by NHS REC

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/0207	Evaluation of pharmacists' role in medicines related problems	89
11/EE/0217	Nurse's perceptions of the mental health of new fathers.Version 1	64
11/EE/0231	The lived experiences of adolescents with Cystic Fibrosis, Version 1	63
11/EE/0238	Midwives' experiences of promoting normal birth in a hospital	69
11/EE/0242	What are district and community nurses perception of integrated working	61
11/EE/0265	Psychologists working with children with life-limiting illnesses V1	61
12/EE/0074	Prison treatment outcomes and processes research study (PTORS) v1.0	68

Proportionate review applications for ethical review over 14 days timeline		
REC Reference	Application Short Title	Number of Days on Clock
11/EE/0321	The Choice study.	29

SSAs (non Phase 1) over 25 days timeline		
REC Reference	Application Short Title	Number of Days on Clock
11/EE/0225	The bioavailability and anti-inflammatory effect of ITCs (BAITCs)	42

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
11/H0302/1/AM01	discrimination and addiction	AM 1 12 May 2011	39
10/H0301/55/AM30	Norfolk DPS	NOSA 17 01/08/2011	48
10/H0301/55/AM31	Norfolk DPS	NOSA 18 dated 09.08.11	48
10/H0302/15/AM01	PEBL - community input to NHS Commissioning using internet blogs	Amendment No 1 August 12th 2011	43
10/H0301/55/AM34	Norfolk DPS	NOSA 19 12 August 2011	43

10/H0302/7/AM02	Integrated Drug Treatment System Evaluation	Amendment # 2	42
04/Q0102/26/AM06	Neuroimaging autism	AM 11 16 Dec 2011	41
05/Q0102/44/AM07	The National Eden Project	AM 08 January 2012	39

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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