

National Research Ethics  
Service

  
*Health Research Authority*

# NRES Committee East of England - Essex

## Annual Report

**01 April 2013 – 31 March 2014**

## Part 1 – Committee Membership and Training

<b>Name of REC:</b>	NRES Committee East of England - Essex
<b>Type of REC:</b>	Recognised
<b>Type of Flag:</b>	MCA and Prison Research
<b>Chair:</b>	Dr Alan Lamont
<b>Vice-Chair:</b>	Dr Nikki Bannister
<b>Alternate Vice-Chair:</b>	Mr Alan Edwards
<b>REC Manager:</b>	Mrs Alka Bhayani
<b>REC Assistant:</b>	Amy Spruce
<b>Committee Address:</b>	London REC Office Health Research Authority Ground Floor, Skipton House 80 London Road London SE1 6LH
<b>Telephone:</b>	020 7972 2554
<b>Fax:</b>	020 7972 2592
<b>Email:</b>	<a href="mailto:NRESCommittee.EastofEngland-Essex@nhs.net">NRESCommittee.EastofEngland-Essex@nhs.net</a>

### Chair's overview of the past year:

The year since April 2013 has been a period of change, if not instability for the Essex REC. As chair I am most grateful to the members and officers for bearing with the disrupted infrastructure resulting from the relocation of the office, and the resultant loss of our previous coordinator, Suzanne Emerton. After a considerable delay, we now have a new substantive coordinator, Alka and assistant Amy, who have already shown themselves to be assets to the service. Quoracy and workload has been a problem at times through the year, due to depletion of our numbers and delayed recruitment. We hope to improve that with an expected round of new people soon. Sadly for us, and congratulations to her, we have just seen our vice-chair Niki Bannister gain the position of chair of Cambridge East REC, so some further changes will be required to meet the challenges of the next year.

## 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	28/02/2014
Ms Rachel Burrows	Project Commercial Assistant	Lay Plus	01/04/2012	
Dr Alan Calverd	Scientific Consultant	Lay	01/04/2011	
Mr Alan Edwards	Retired Company Director	Lay Plus	01/04/2011	
Dr Gerry Kamstra	Solicitor	Lay Plus	01/04/2011	
Dr Alan Lamont	Consultant Oncologist	Expert	01/04/2011	
Mr Simon Laurence	Retired Patent Agent	Lay Plus	01/04/2011	
Ms Sarah Jane Lee	University Lecturer in Nursing	Expert	01/04/2011	17/12/2013
Ms Julie Lockhart	PPI Representative	Lay Plus	01/04/2011	
Ms Sarah Starr	Senior Nurse	Expert	01/10/2012	
Dr Andy Stevens	Media Consultant & Retired Principal Lecturer	Lay Plus	01/04/2011	

### Co-opted Members

Name	Occupation	Expert or Lay	Meeting date attended	
Ms. Stephanie Ellis	Retired Civil Servant	Lay	04 July 2013	05 September 2013

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

Name	Declaration of Interest	Date
Dr Alan Lamont	Previous member of Colchester Trust R&D steering committee.	18/02/2014
Mr Alan Edwards	None	04/02/2014
Mr Simon Laurence	None	31/03/2014
Mr Tony Baker	None	05/02/2014
Ms Rachel Burrows	None	05/02/2014
Dr Gerry Kamstra	Currently a partner in a firm of solicitors. In that role advises client companies involved in the development and testing of healthcare products. Retiring at end of April 2014, so this connection will end then.	05/02/2014
Ms Julie Lockhart	Voluntary member of East of England Ambulance Service.	05/02/2014
Ms Sarah Starr	No declared interests.	01/03/2014
Dr Niki Bannister	None.	13/01/2014
Dr Andy Stevens	Part time PhD supervisor with Anglia Ruskin University	01/08/2013
Dr Alan Calverd	Technical Director: United Open MRI (and subsidiaries); Scientific Director: Radiation Consultancy Services Ltd Director: Medical Physics Cooperative Ltd; Sole trader: Quality Associates; Shareholder in Exhalation Technology Ltd. Radiation Consultancy Services Ltd, Medical Physics Cooperative Ltd and Quality Associates are occasionally contracted to advise clients and underwrite ARSAC and HRA applications.	31/03/2013

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

<b>Month</b>	<b>Date</b>	<b>Number of Members Present at Meeting</b>
April	04/04/2013	7
May	02/05/2013	7
July	04/07/2013	9
August	01/08/2013	8
September	05/09/2013	8
October	03/10/2013	9
November	07/11/2013	7
December	05/12/2013	8
February	06/02/2014	7

9 full committee meetings were held during the reporting period.

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

<b>Name</b>	<b>Number of Meetings Attended</b>
Dr Niki Bannister	8
Ms Julie Lockhart	8
Dr Alan Lamont	8
Ms Sarah Starr	7
Mr Alan Edwards	7
Mr Simon Laurence	7
Dr Andy Stevens	6
Dr Gerry Kamstra	6
Dr Alan Calverd	6
Mr Tony Baker	5

**Number of inquorate meetings held: None**

**Training 01 April 2013 – 31 March 2014:**

<b>Name of Member</b>	<b>Date</b>	<b>Event(s) attended</b>
Dr Gerry Kamstra	01/02/2014 - 31/03/2014	SDL Training - legal research into new EU CT regulation & compared its provision to current EU CT
Julie Lockhart	01/09/2013	SDL: Learning to use statistical tests in Psychology by Judith Greene and Manuela D'Oliveira. (2 hours)
Niki Bannister	22/01/2014 - 22/01/2014	New Chairs Training , Health Research Authority
Niki Bannister	03/12/2013 - 03/12/2013	NREAP East of England Chairs Meeting , Health Research Authority
Niki Bannister	11/12/2013 - 11/12/2013	Chairs National Training Day, Health Research Authority
Alan Lamont	03/12/2013 – 03/12/2013	NREAP East of England Chairs Meeting , Health Research Authority

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

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

<b>Applications for full ethical review – Study Type</b>	<b>Number</b>	<b>%</b>
Clinical Trial of Investigational Medicinal Product	4	9.30
Phase 1	0	0.00
Gene Therapy	0	0.00
Research Tissue Bank	0	0.00
Research Database	0	0.00
Others	39	90.70
<b>Total Applications Reviewed</b>	<b>43</b>	<b>100</b>

**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	4
Number of student applications reviewed	18
Number of paediatric applications reviewed	2
Number of device applications reviewed	1
Number of prisoner applications reviewed	8
Number of applications involving adults unable consent reviewed	2
Number of applications reviewed funded by the US DHHS	0

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

<b>Decisions taken at meetings following review of applications</b>	<b>Number</b>	<b>%</b>
Favourable Opinion with Standard Conditions	0	0.00
Favourable Opinion with Additional Conditions	2	4.65
Unfavourable Opinion	2	4.65
Provisional Opinion	39	90.70
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
<b>Total</b>	<b>43</b>	<b>100</b>
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:**

<b>Status of applications at date of generation of report</b>	<b>Number</b>	<b>%</b>
Further Information Favourable Opinion with Standard Conditions	33	76.74
Further Information Favourable Opinion with Additional Conditions	6	13.95
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	0	0.00
Favourable Opinion with Additional Conditions	2	4.65
Unfavourable Opinion	2	4.65
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	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
<b>Total</b>	<b>43</b>	<b>100</b>



**Table 5: Other Management Information for the reporting period:**

<b>Average number of applications reviewed per full meeting</b>	4.78
<b>Number of applications for full ethical review over 60 days</b>	2
<b>Number of applications over 60 days as a % of total</b>	4.65%
<b>Number of days taken to final decision - average</b>	41
<b>Number of days taken to final decision - mode</b>	42
<b>Number of SSAs (non-Phase 1) reviewed</b>	7
<b>Number of applications for SSA review over 25 days</b>	1
<b>Number of applications for SSA review over 25 days as % of all non-Phase 1 (SSAs)</b>	14.3%
<b>Number of SSAs (Phase 1) reviewed</b>	0
<b>Number of applications for SSA review over 14 days</b>	0
<b>Number of applications for SSA review over 14 days as % of all Phase 1 (SSAs)</b>	0%
<b>Number of substantial amendments reviewed</b>	77
<b>Number of substantial amendments over 35 days</b>	7
<b>Number of substantial amendments over 35 days as a % of total substantial amendments</b>	9.1%
<b>Number of Section 30 applications reviewed</b>	0
<b>Number of Section 30 applications over 60 days</b>	0
<b>Number of Section 30 applications over 60 days as a % of total Section 30 applications</b>	0%
<b>Number of modified amendments reviewed</b>	6
<b>Number of modified amendments over 14 days</b>	0
<b>Number of modified amendments over 14 days as a % of total modified amendments</b>	0.0%

**Table 6: Breakdown of current status of all applications reviewed within the reporting period:**

<b>Further Information Favourable Opinion with Standard Conditions</b>		
<b>REC Reference</b>	<b>Application Short Title</b>	<b>Number of Days on Clock</b>
13/EE/0095	Fruit and vegetable extracts supplementation and vascular function	41
13/EE/0101	A pilot study of imagery rescripting therapy in OCD	53
13/EE/0103	Therapy engagement in secure services: service user perspective	43
13/EE/0107	Energy Balance and Sleep in Obesity	48
13/EE/0118	Evaluation of Drug Recovery Wings (DRWs)	49
13/EE/0123	RHYTHM-I	51
13/EE/0124	Flintstone Foods 1 version 1	52
13/EE/0125	Exploring the impact of Hospice Neighbors on patients experiences.V:1	34
13/EE/0174	MAPP: imagery-focused therapy (imCT) for Bipolar Disorder	30
13/EE/0175	CHALK Study. Version 1.	56
13/EE/0187	Donepezil in Aneurysmal Subarachnoid Haemorrhage (DASH) Trial	56
13/EE/0189	Mindful traits among individuals with an eating disorder	26
13/EE/0193	Stowhealth UCS McLaren (SUM) Weight Management - Version 1	31
13/EE/0216	GDC-0068 in Subjects with locally advanced / metastatic adenocarcinoma	62
13/EE/0220	Study into incidence, prevalence and cause of obesity in prison	33
13/EE/0234	Exposure to arsenic in residents with private drinking water supplies	62
13/EE/0235	valuating the impact of a CBT-based intervention supporting uptake and	32
13/EE/0296	The neural basis of gambling cognitions: the role of the opioid system	50
13/EE/0298	A prison Therapeutic Community's (TC) view about prisoner autonomy	40
13/EE/0300	AA-induced platelet aggregation in vascular surgery	36
13/EE/0301	CFS/ME Case series: anxiety	40
13/EE/0338	Mepilex Transfer Ag on Diabetic Foot Ulcer	51
13/EE/0344	BRAIN: Behaviour and Resting state Activity In Newborns	38
13/EE/0345	FGF117360 Clinical study using drug GSK3052230 in Subjects with Cancer	41
13/EE/0346	The Peak PlasmaBlade in DIEP free flap dissection	42
13/EE/0382	The "CATch" Study: Computerised Aphasia Therapy in Chronic Aphasia	52
13/EE/0400	Music Therapy for Stroke Rehabilitation	30
13/EE/0406	Violence and forensic mental health therapeutic relationships	33
13/EE/0422	DanceFit Prime: A dance based activity intervention for primary care.	59

14/EE/0029	Experiences of personal recovery in Personality Disorder	38
14/EE/0045	Vitamin D supplementation study	45
14/EE/0046	RCT of Groups for Alcohol-misusing Short-term Prisoners (GASP)	35
14/EE/0053	Treatment options for depression Version 1	35

#### Further Information Favourable Opinion with Additional Conditions

REC Reference	Application Short Title	Number of Days on Clock
13/EE/0182	A prevalence study of Mental Disorders in Foreign Nationals	42
13/EE/0243	Dual Diagnosis for young adult offenders: Prevalence and need profile	36
13/EE/0249	Engager 2: Developing & evaluating a collaborative care intervention	36
13/EE/0289	Understanding how brain injury affects development. Version 1.	45
13/EE/0385	Parkinson's Disease and Impulsivity: biological and behavioural markers	42
13/EE/0386	Understanding the role of Dopamine in Reality Monitoring	42

#### 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
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#### Favourable Opinion with Additional Conditions

REC Reference	Application Short Title	Number of Days on Clock
13/EE/0328	Learning from hospital admissions by reviewing patient's records	42
13/EE/0343	CAPITAL	22

#### Unfavourable Opinion

REC Reference	Application Short Title	Number of Days on Clock
13/EE/0237	Music Therapy for Stroke Rehabilitation	14
13/EE/0394	Gas-LLAMP	26

#### Provisional Opinion

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

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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
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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 7: Items exceeding timelines:**

<b>Full applications for ethical review over 60 day timeline</b>			
<b>REC Reference</b>	<b>Application Short Title</b>	<b>Number of Days on Clock</b>	
13/EE/0216	GDC-0068 in Subjects with locally advanced / metastatic adenocarcinoma	62	
13/EE/0234	Exposure to arsenic in residents with private drinking water supplies	62	

  

<b>Proportionate review applications for ethical review over 14 days timeline</b>		
<b>REC Reference</b>	<b>Application Short Title</b>	<b>Number of Days on Clock</b>

  

<b>SSAs (non Phase 1) over 25 days timeline</b>		
<b>REC Reference</b>	<b>Application Short Title</b>	<b>Number of Days on Clock</b>
14/EE/0058	Engager 2: Developing & evaluating a collaborative care intervention	28

  

<b>SSAs (Phase 1) over 14 days timeline</b>		
<b>REC Reference</b>	<b>Application Short Title</b>	<b>Number of Days on Clock</b>

  

<b>Substantial Amendments over 35 day timeline</b>			
<b>Amendment Reference</b>	<b>Application Short Title</b>	<b>Amendment Title</b>	<b>Number of Days on Clock</b>
10/H0301/55/AM53	Norfolk DPS	NOSA29 (Additional interview)	36
12/EE/0533/AM01	Odyssey Options II	Amendment #1	36
05/Q0102/44/AM12	The National Eden Project	05/Q0102/44Am12	36
12/EE/0531/AM01	The neural basis of gambling cognitions	Substantial Amendment 1- Additional Routes for Rec	37
08/H0301/71/AM01	Influence of endothelial function on carotid intima-media thickness	SA01 30th July 2013	37
MH363/AM06	A study on the proteins CTCF and BORIS in breast and prostate samples	Amendment 2 9th August 2013	36
13/EE/0235/AM01	Evaluating the impact of a CBT-based intervention supporting uptake and	Substantial Amendment 1 dated 21/1/14	39

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

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