

# NRES Committee East of England - Norfolk

## Annual Report

01 April 2011 – 31 March 2012

## Part 1 – Committee Membership and Training

<b>Name of REC:</b>	NRES Committee East of England - Norfolk
<b>Type of REC:</b>	Authorised REC
<b>Type of Flag:</b>	Research involving adults lacking capacity
<b>Chair:</b>	Michael Sheldon MA, PhD
<b>Vice-Chair:</b>	Dr Robert Stone
<b>Alternate Vice-Chair:</b>	Dr Elizabeth Lund
<b>Co-ordinator:</b>	Mrs Lynda McCormack until 11 November 2011 Miss Anna Bradnam from 14 November 2011
<b>PRSC Co-ordinator:</b>	Mrs Lynda McCormack until 11 November 2011 Miss Anna Bradnam from 14 November 2011
<b>Assistant Co-ordinator:</b>	Ms. Har Hari Kaur from 01 December 2011
<b>Committee Address:</b>	Victoria House Capital Park Fulbourn Cambridge CB21 5XB
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## Chair's overview of the past year:

It is a sign of the Committee's general good health that, during a year in which there have been major changes in the organisation of NRES, the essential business of ethical review has proceeded smoothly and in a cooperative and good-humoured atmosphere. We think it is important that researchers should find us constructive. Maintaining membership at a level that reliably meets quorum requirements remains an issue, but at present we have 11 members: one member on a period of extended leave has been able to return but two people recently recruited needed to resign. The requirement to offer proportionate review has been a major addition to the committee's work and as Chair I am particularly grateful that Elizabeth Lund, the Alternate Vice Chair, has taken on oversight of a process with such demanding deadlines. Another extra element in our work has been dealing with amendments to studies initially approved by one of the recently-closed Cambridge committees.

## NRES Committee East of England - Norfolk Membership:

Name	Occupation	Expert or Lay	Dates	
			Appointed	Resigned
Reverend Bill Bazely	Senior Hospital Chaplain	Lay	01/08/2005	31/12/2011
Mrs Sarah Blount	Retired Magistrate	Lay Plus	01/01/2012	
Mr Ron Driver	Lecturer/Statistician	Expert	01/12/2008	
Miss Sheila Ginty	Senior Sister - Surgery	Expert	01/08/2005	
Ms Leanne Groves	Psychological Therapist/Occupational Therapist	Expert	08/10/2010	
Mrs Janette Guymer	NHS Administrator	Lay Plus	01/09/2010	
Dr Linda Harvey	Research Scientist	Expert	01/06/2011	
Dr Gillian Hawkes	Research Associate	Lay Plus	25/05/2011	09/02/2012
Mrs Pamela Keeley	Retired East Anglian Eye Bank Nurse Manager	Expert	01/08/2005	
Dr Peter E Langdon	Clinical Senior Lecturer and Clinical Psychologist	Expert	01/11/2007	
Dr Elizabeth Lund	Independent Consultant, Nutrition and Gastrointestinal Health	Lay	01/08/2005	
Mr George Mak-Pearce	Psychological Therapist	Expert	14/06/2011	
Michael Sheldon MA, PhD	Retired Clinical Psychologist	Lay	01/08/2005	
Dr Robert Stone	General Practitioner	Expert	01/08/2005	

### Deputy Members

Name	Occupation	Expert or Lay	Meeting date attended

### Co-opted Members

Name	Occupation	Expert or Lay	Meeting date attended
Mr Colin Green	Drugs & Therapeutics Pharmaceutical Advisor	Expert	11/07/2011

### Member Bank

Name	Occupation	Expert or Lay	Meeting date attended

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

Name	Declaration of Interest	Date
Dr Gillian Hawkes	Research Associate, UEA	21/06/2011
Michael Sheldon MA, PhD	None	27/01/2012
Dr Robert Stone	None	09/01/2012
Dr Elizabeth Lund	<p>Consultant on ethical aspects of food intervention studies on a European Union project 'PlantLIBRA' (EC project number 245199) through a private consultancy company in Rome-Italy named Hylobates Consultancy. Seeking further consultancy work as an independent consultant currently named on one further EU FP7 proposal. Trustee of Asperger East Anglia.</p> <p>Member of the steering group of the People with Asperger Syndrome and anxiety disorders (PAsSA) trial.</p> <p>Reviewer of papers for journals such as Carcinogenesis, Gut, Cancer Research, American Journal of Clinical Nutrition, British Journal of Nutrition etc.</p>	13/02/2012
Miss Sheila Ginty	None	12/12/2011
Mr Ron Driver	Member R&D Committee South Essex Partnership Mental Health NHS Trust. Advisor - Research Design Service (RDS) for East of England	12/12/2011
Mrs Janette Guymer	Subscribes to the ITP Support Association which does commission research into ITP. Currently work for the Norfolk CLRN as a Research Support Officer	12/12/2011
Ms Leanne Groves	None	13/02/2012
Dr Linda Harvey	Currently Chair of the Institute of Food Research Human Research Governance Committee	17/01/2012
Mr George Mak-Pearce	None	12/12/2011
Dr Peter E Langdon	Works collaboratively with Aspergers East Anglia on several research projects. - Member - HTA Psychological and Community Therapies Panel, NIHR Clinical Senior Lecturer - Norwich Medical School NIHR Research Fellow - NIHR	09/01/2012
Mrs Pamela Keeley	None	09/01/2012
Mrs Sarah Blount	Trustee - Norfolk and Norwich Families House Patient Member - East Anglian Cancer Research Network Steering Group. (This membership will come to an end probably during 2012 but could be terminated forthwith if so advised.)	05/01/2012

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

<b>Month</b>	<b>Date</b>	<b>Number of Members Present at Meeting</b>
April	11/04/2011	9
May	09/05/2011	8
June	13/06/2011	9
July	11/07/2011	9
August	08/08/2011	10
September	12/09/2011	9
December	12/12/2011	7
January	09/01/2012	11
February	13/02/2012	8
March	12/03/2012	10

10 full committee meetings were held during the reporting period.

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

<b>Month</b>	<b>Date</b>	<b>Number of Members Present at Meeting</b>
September	02/09/2011	3
September	05/09/2011	4
October	10/10/2011	4
November	07/11/2011	4
December	05/12/2011	4
January	03/01/2012	3
February	06/02/2012	4
March	05/03/2012	4

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

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

<b>Name</b>	<b>Number of Meetings Attended</b>
Michael Sheldon MA, PhD	10
Miss Sheila Ginty	10
Mr Ron Driver	10
Mrs Janette Guymmer	10
Dr Elizabeth Lund	9
Mrs Pamela Keeley	8
Ms Leanne Groves	8
Dr Linda Harvey	6
Dr Robert Stone	6
Reverend Bill Bazely	5
Mr George Mak-Pearce	3
Dr Peter E Langdon	2
Dr Gillian Hawkes	1
Mrs Sarah Blount	1

**Number of inquorate meetings held: 0**

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

<b>Name</b>	<b>Number of Meetings Attended</b>
Dr Elizabeth Lund	7
Mrs Pamela Keeley	7
Ms Leanne Groves	7
Mr Ron Driver	6
Michael Sheldon MA, PhD	1
Dr Robert Stone	1
Mrs Janette Guymmer	1

## Training 01 April 2011 – 31 March 2012:

Name of Member	Date	Event(s) attended
Mrs Janette Guymer	22/06/2011 - 22/06/2011	Induction, NRES
Mrs Pamela Keeley	28/04/2011 - 28/04/2011	Introduction to Information Governance, NHS E-learning
Dr Peter E Langdon	06/05/2011 - 06/05/2011	Equality & Diversity, NRES
Mrs Janette Guymer	15/07/2011 - 15/07/2011	Introduction to Good Clinical Practice (GPC), NIHR
Dr Elizabeth Lund	30/06/2011 - 30/06/2011	Equality & Diversity
Mr Ron Driver		Mental Capacity Act - DVD
Mrs Janette Guymer	11/07/2011 - 11/07/2011	NRES MCA DVD, NRES
Michael Sheldon MA, PhD	14/09/2011 - 14/09/2011	NRES Update Session - Janet Wisely, NRES
Dr Linda Harvey		Equality & Diversity, NRES
Michael Sheldon MA, PhD	06/12/2011 - 06/12/2011	NRES Chairs National Training Day; CO2001, NRES
Dr Elizabeth Lund	22/11/2011 - 22/11/2011	NRES Adults Lacking Capacity training , NRES
Michael Sheldon MA, PhD	11/07/2011 - 11/07/2011	MCA DVD for NRES Committee members, NRES
Dr Robert Stone	11/07/2011 - 11/07/2011	MCA DVD for NRES Committee members, NRES
Mrs Pamela Keeley	11/07/2011 - 11/07/2011	MCA DVD for NRES Committee members
Dr Linda Harvey	11/07/2011 - 11/07/2011	MCA DVD for NRES Committee members, NRES
Miss Sheila Ginty	11/07/2011 - 11/07/2011	MCA DVD for NRES Committee members, NRES
Dr Linda Harvey	10/01/2012 - 10/01/2012	Induction, NRES
Mrs Janette Guymer	29/02/2012 - 29/02/2012	Personal Data in Research - A workshop for members of RECs, NRES
Michael Sheldon MA, PhD	14/03/2012 - 14/03/2012	NRES Members National Training Day , NRES
Mr Ron Driver	13/02/2012 - 13/02/2012	Shared Ethical Debate, NRES
Miss Sheila Ginty	13/02/2012 - 13/02/2012	Shared Ethical Debate, NRES
Mrs Janette Guymer	13/02/2012 - 13/02/2012	Shared Ethical Debate, NRES
Ms Leanne Groves	13/02/2012 - 13/02/2012	Shared Ethical Debate, NRES
Dr Linda Harvey	13/02/2012 - 13/02/2012	Shared ethical debate, NRES
Mrs Pamela Keeley	13/02/2012 - 13/02/2012	Shared ethical debate, NRES
Dr Elizabeth Lund	13/02/2012 - 13/02/2012	Shared Ethical Debate, NRES
Michael Sheldon MA, PhD	13/02/2012 - 13/02/2012	Shared Ethical Debate, 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:**

<b>Applications for full ethical review – Study Type</b>	<b>Number</b>	<b>%</b>
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	50	100.00
<b>Total Applications Reviewed</b>	<b>50</b>	<b>100</b>

**Table 2: Other REC activity during the reporting period:**

Number of applications made invalid by co-ordinator	9
Number of studies withdrawn prior to the meeting	6
Number of student applications reviewed	25
Number of paediatric applications reviewed	5
Number of device applications reviewed	1
Number of prisoner applications reviewed	0
Number of applications involving adults unable consent reviewed	5
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	1	2.00
Favourable Opinion with Additional Conditions	7	14.00
Unfavourable Opinion	2	4.00
Provisional Opinion	40	80.00
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>50</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	29	58.00
Further Information Favourable Opinion with Additional Conditions	8	16.00
Further Information Unfavourable Opinion	1	2.00
Favourable Opinion with Standard Conditions	1	2.00
Favourable Opinion with Additional Conditions	7	14.00
Unfavourable Opinion	2	4.00
Provisional Opinion	2	4.00
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>50</b>	<b>100</b>

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

<b>Total Applications Reviewed</b>	<b>19</b>
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**Table 6: Decisions given at proportionate review sub-committee meetings held within the reporting period:**

<b>Decisions taken at proportionate review sub-committee meetings</b>	<b>Number</b>	<b>%</b>
Favourable Opinion with Standard Conditions	9	47.37
Favourable Opinion with Additional Conditions	1	5.26
No Opinion transfer to full committee for review	2	10.53
Provisional Opinion	6	31.58
Unfavourable Opinion	1	5.26
<b>Total</b>	<b>19</b>	<b>100</b>

**Table 7: Other Management Information for the reporting period:**

<b>Average number of applications reviewed per full meeting</b>	5.00
<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>	4.00%
<b>Number of days taken to final decision - average</b>	35
<b>Number of days taken to final decision - mode</b>	44
<b>Number of SSAs (non-Phase 1) reviewed</b>	2
<b>Number of applications for SSA review over 25 days</b>	0
<b>Number of applications for SSA review over 25 days as % of all non-Phase 1 (SSAs)</b>	0.0%
<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>	73
<b>Number of substantial amendments over 35 days</b>	2
<b>Number of substantial amendments over 35 days as a % of total substantial amendments</b>	2.7%
<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>	2
<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%
<b>Number of proportionate review applications for ethical review over 14 days*</b>	6
<b>Number of proportionate review applications over 14 days as a % of total</b>	35.29%

**\*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:**

<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>
11/EE/0108	Well-Being and Self-Rated Health in Stroke: A Qualitative Study	25
11/EE/0113	Challenges faced by health professionals working in a diverse society.	42
11/EE/0114	Aetiology of preoperative anaemia	44
11/EE/0127	PREPARE for radical cystectomy study	38
11/EE/0128	An Estimate of the Incidence of Persistent Median Artery Variant	37
11/EE/0130	Why do women stop breastfeeding?	44
11/EE/0146	miRNA Analysis in Multiple Sclerosis	29
11/EE/0147	TEST-BP VERSION: 1.0	47
11/EE/0153	Physical activity of couples in retirement-the EPIC Norfolk Cohort	28
11/EE/0157	How do Specialist Palliative Care Nurses Manage Breakthrough Pain?	42
11/EE/0180	Physical and psychological stress in critically ill patients	26
11/EE/0201	Anti-CCP antibodies as a marker of lung disease in RA version 1	37
11/EE/0204	End of life palliative care in Fenland: are we meeting the needs? v2	28
11/EE/0233	Flavonoids, blood pressure control and blood vessel function	27
11/EE/0268	An exploratory study of body image concerns in youth obesity	51
11/EE/0274	Factors affecting the speech of people with Parkinson's disease (V1)	24
11/EE/0295	An Evaluation of Nurse's empathetic response to Patients with Pain.	30
11/EE/0310	International study to develop a Quality of Life module for melanoma	19
11/EE/0335	Falls Study	45
11/EE/0363	Mild Head Injuries in Children [V.1]	69
11/EE/0364	An exploration of living with motor neurone disease, receiving health	20
11/EE/0472	Insulin-like peptide 3 and osteoporosis in adult males	18
11/EE/0508	Deep Brain Stimulation for Thinking & Memory problems in Parkinson's	31
11/EE/0511	Perceptions of service user involvement in palliative care	85
11/EE/0520	How involved are HIV+ patients in their own care?	27
11/EE/0524	Functional Strength Training for upper limb recovery after stroke	23
11/EE/0525	Functional and balance outcomes in vestibular rehabilitation	16
12/EE/0058	Diagnostic urine biomarker for prostate cancer	23
12/EE/0060	Gait Analysis of Burns Patients	54
12/EE/0067	Validation of CORE-OM in people with MS Version 1.0	14

12/EE/0088	Neoadjuvant endocrine therapy & sentinel node biopsy in breast cancer	48
12/EE/0106	Exercise in patients at risk of developing colon cancer Version 1	44
12/EE/0109	NU-AGE: Dietary strategies for healthy ageing in Europe	38
12/EE/0113	Young Person's Heat Response (LDI Flare) Study	27
12/EE/0117	Views and experiences of acute non-invasive ventilation	36

#### Further Information Favourable Opinion with Additional Conditions

REC Reference	Application Short Title	Number of Days on Clock
11/EE/0245	Prevalence of SpA in Norfolk	28
11/EE/0246	Posttraumatic Cultural Variations: Identity & Self consistency	45
11/EE/0285	Interventions for Anxiety for Adolescents with Autism	34
11/EE/0294	Does pre-clinic texting improve attendance in type 1 diabetes.	32
11/EE/0340	Post-Operative Monitoring of Free Flaps using the Pulsatility Index	44
11/EE/0348	Imaging brain amyloid in adults with Down's syndrome	33
11/EE/0541	Hormonal basis of decision making in financial markets	42
12/EE/0011	F.O.F.A study	49

#### Further Information Unfavourable Opinion

REC Reference	Application Short Title	Number of Days on Clock
11/EE/0216	Cellular mechanisms in the pathogenesis of postop atrial fibrillation	32

#### Favourable Opinion with Standard Conditions

REC Reference	Application Short Title	Number of Days on Clock
11/EE/0165	T-lymphocyte ratios in seminoma. Version 4	22
11/EE/0359	Exploring Consanguinity - Version 1	19
11/EE/0372	Autistic features in children with a history of abuse and neglect	12
11/EE/0378	Cellular mechanisms in the pathogenesis of postop atrial fibrillation	10
11/EE/0429	Factors influencing the uptake of bereavement services	8
11/EE/0430	Posterior impingement of the ankle joint and subtalar movement	8
12/EE/0068	Non-coding RNAs in myositis v 1.0	8
12/EE/0069	Genetic Diversity and Virulence of Parainfluenza Viruses	10
12/EE/0070	Hull Airway Reflux Questionnaire scores following cough treatment	10
12/EE/0118	Pelvic floor dysfunction symptoms in women with low back pain.	12

**Favourable Opinion with Additional Conditions**

REC Reference	Application Short Title	Number of Days on Clock
11/EE/0212	Shoulder pain: Predicting response to physiotherapy treatment v1	17
11/EE/0221	DALI Vitamin D Dosing and Process Pilot Study	25
11/EE/0237	Influence of Migration Related Experiences on Afghan Refugees in UK	24
11/EE/0332	Comparing Social Anxiety in Individuals with and without Psychosis v.1	45
12/EE/0010	An action evaluation of the Namaste Care Programme in care homes	32
12/EE/0016	GENESIS - A Genetic Study of Stillbirth	25
12/EE/0027	Prometheus proPSA/marker study	11
12/EE/0054	Does colposcopy affect sexual function?	18

**Unfavourable Opinion**

REC Reference	Application Short Title	Number of Days on Clock
11/EE/0501	Prognostic significance of incidental troponin I rise in the elderly	27
11/EE/0523	Monitoring exercise therapy for fallers using accelerometry	10
12/EE/0064	Effect of encapsulated nutrients on gut peptide secretion	18

**Provisional Opinion**

REC Reference	Application Short Title	Number of Days on Clock
12/EE/0065	Baby behaviour study	N/A
12/EE/0112	RCT of Early vs Late Removal of Ureteric Stents Post Kidney Transplant	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
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**Invalid Application**

REC Reference	Application Short Title	Number of Days on Clock
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<b>No Opinion Pending Consultation with Referee</b>		
<b>REC Reference</b>	<b>Application Short Title</b>	<b>Number of Days on Clock</b>

<b>Not Requiring Review by NHS REC</b>		
<b>REC Reference</b>	<b>Application Short Title</b>	<b>Number of Days on Clock</b>



**Table 9: 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>
11/EE/0363	Mild Head Injuries in Children [V.1]	69
11/EE/0511	Perceptions of service user involvement in palliative care	85

<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>
11/EE/0359	Exploring Consanguinity - Version 1	19
11/EE/0364	An exploration of living with motor neurone disease, receiving health	20
11/EE/0472	Insulin-like peptide 3 and osteoporosis in adult males	18
11/EE/0525	Functional and balance outcomes in vestibular rehabilitation	16
11/EE/0520	How involved are HIV+ patients in their own care?	27
12/EE/0117	Views and experiences of acute non-invasive ventilation	36

<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>

<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>
09/H0310/78/AM03	Alveolar nitric oxide and VEGF in idiopathic interstitial pneumonia	Amendment #3	36
09/H0306/72/AM03	Regional perfusion in deceased organ donors. Version 1.0	Amendment 1.5 (14/09/2011)	36

<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</b>

			<b>Clock</b>
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<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>