

**NRES Committee East Midlands -  
Northampton**

**Annual Report**

**01 April 2011 – 31 March 2012**

## Part 1 – Committee Membership and Training

<b>Name of REC:</b>	NRES Committee East Midlands - Northampton
<b>Type of REC:</b>	Type III
<b>Type of Flag:</b>	N/A
<b>Chair:</b>	Mr Ken Willis
<b>Vice-Chair:</b>	Mr Mike Newman
<b>Alternate Vice-Chair:</b>	None
<b>Co-ordinator:</b>	Miss Jessica Parfremment
<b>PRSC Co-ordinator:</b>	N/A
<b>Assistant Co-ordinator:</b>	Miss Georgia Copeland
<b>Committee Address:</b>	The Old Chapel Royal Standard Place Nottingham NG1 6FS
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### Chair's overview of the past year:

The year has been both interesting and challenging; recently recruited members have developed and are now proving to be support and inspiration to a committee that has undergone changes in coordinator and the loss of valuable members. Due to current restrictions on recruitment, no new members have yet been appointed.

The recruitment of a replacement expert pharmacist member will expand the scope of referrals, which in turn will prove an interest and challenge to our recent recruits.

Given the reduced membership the committee has functioned well, and I would like to thank the members and coordinators for their hard work and commitment

Training events have been reasonably well supported.

Feedback from the majority of researchers has indicated that they have found the ethical review to be a worthwhile and beneficial process.

An expression of thanks is made to the co-opted members who have supported this committee.

The application statistics indicate that whilst there are issues with quite a number of applications the majority have been resolved effectively and promptly.

## NRES Committee East Midlands - Northampton Membership:

Name	Occupation	Expert or Lay	Dates	
			Appointed	Resigned
Mr John Aldridge	Senior Lecturer in Nursing	Expert	24/04/2008	
Dr Timothy Bedford	Consultant Anaesthetist	Expert	05/09/2008	
Ms Elaine Blackshaw	Clinical Trial Manager	Expert	29/02/2008	
Mr Derek Butters	Industrial Pharmacy Consultant and Locum Pharmacist	Expert	01/02/2012	
Mr Alan Caswell	Lay Member	Lay	01/12/2011	
Dr Geoff Dickens	Research Manager	Expert	15/04/2002	30/04/2012
Dr Susan Dyson	Doctor of Education, Head of Nursing & Midwifery Research	Expert	14/04/2008	26/09/2011
Mrs Lorenza Francescut	Research Technician	Lay	15/04/2008	
Ms Elizabeth Gibbons	Senior Research Officer	Expert	13/07/2011	
Mr Mike Newman	Consultant Gynaecologist	Expert	08/04/2005	
Mrs Yael Vinciguerra	Lay Member	Lay	16/08/2011	
Mr Clive Wilkinson	Lay Member	Lay Plus	08/02/2010	
Mr Ken Willis	Medical Devices Manager	Lay	17/01/2005	

### Deputy Members

Name	Occupation	Expert or Lay	Meeting date attended
None			

### Co-opted Members

Name	Occupation	Expert or Lay	Meeting date attended
Mr John Baker	Radiation Protection Advisor and Senior Lecturer (retired)	Lay	16/06/2011
Dr Ian Ross	Consultant Physician	Expert	20/10/2011
Ms Margaret Vince	Translator	Lay Plus	21/07/2011
Mrs Madeleine Wang	Patient Advocate	Lay Plus	21/07/2011
Mr Robert Johnson	Expert Member	Expert	21/04/2011
Dr Carl Edwards	Implementation Fellow	Lay	16/06/2011
Mr Stephen Barrett	Research Coordinator	Lay	16/06/2011 20/10/2011

### Member Bank

Name	Occupation	Expert or Lay	Meeting date attended
N/A			

**NRES Committee East Midlands - Northampton: Members' Declarations of Interest:**

<b>Name</b>	<b>Declaration of Interest</b>	<b>Date</b>
Mr Ken Willis	None	15/12/2011
Mr John Aldridge	None	16/12/2011
Mrs Lorenza Francescut	None	15/12/2011
Ms Elaine Blackshaw	None	15/12/2011
Dr Timothy Bedford	None	15/12/2011
Mrs Yael Vinciguerra	None	15/12/2011
Mr Clive Wilkinson	None	15/12/2011
Mr Alan Caswell	None	15/12/2011
Ms Elizabeth Gibbons	None	15/12/2011
Mr Mike Newman	None	01/04/2012
Mr Derek Butters	none	01/02/2012

**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	21/04/2011	7
May	19/05/2011	7
June	16/06/2011	8
July	21/07/2011	8
August	18/08/2011	7
October	20/10/2011	9
November	17/11/2011	9
December	15/12/2011	10
January	19/01/2012	9
February	16/02/2012	8
March	15/03/2012	8

11 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>
March	15/03/2012	3

1 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>
Mr John Aldridge	11
Mr Ken Willis	11
Ms Elaine Blackshaw	10
Mr Clive Wilkinson	8
Dr Geoff Dickens	8
Mr Mike Newman	7
Dr Timothy Bedford	6
Mrs Yael Vinciguerra	6
Mr Alan Caswell	5
Ms Elizabeth Gibbons	5
Mrs Lorenza Francescut	4
Mr Derek Butters	1

**Number of inquorate meetings held: None**

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

<b>Name</b>	<b>Number of Meetings Attended</b>
Mr Clive Wilkinson	1
Mr John Aldridge	1
Mr Ken Willis	1

**Training 01 April 2011 – 31 March 2012:**

<b>Name of Member</b>	<b>Date</b>	<b>Event(s) attended</b>
Dr Susan Dyson	06/07/2011 – 06/07/2011	Online Equality and Diversity Training, NRES
Dr Susan Dyson	06/10/2011 – 06/10/2011	East Midlands REC Centre Training Day- Statistics/Qualitative Data/Personal Identifiable Data/MCA DVD, East Midlands REC Centre Training Day
Ms Elaine Blackshaw	06/10/2011 – 06/10/2011	East Midlands REC Centre Training Day- Statistics/Qualitative Data/Personal Identifiable Data/MCA DVD, East Midlands REC Centre
Ms Elizabeth Gibbons	06/10/2011 – 06/10/2011	East Midlands REC Centre Training Day- Statistics/Qualitative Data/Personal Identifiable Data/MCA DVD, East Midlands REC Centre
Mr Mike Newman	06/10/2011 – 06/10/2011	East Midlands REC Centre Training Day- Statistics/Qualitative Data/Personal Identifiable Data/MCA DVD, East Midlands REC Centre
Ms Elizabeth Gibbons	08/02/2012 – 08/02/2012	Members Induction Training; OP1001, NRES
Mrs Yael Vinciguerra	17/11/2011 – 17/11/2011	MCA DVD Training, NRES
Mr Ken Willis	17/11/2011 – 17/11/2011	MCA DVD, NRES
Dr Geoff Dickens	17/11/2011 – 17/11/2011	MCA DVD, NRES
Mr John Aldridge	17/11/2011 – 17/11/2011	MCA DVD, NRES
Mrs Lorenza Francescut	17/11/2011 – 17/11/2011	MCA DVD, NRES
Dr Timothy Bedford	17/11/2011 – 17/11/2011	MCA DVD, NRES
Mr Alan Caswell	17/11/2011 – 17/11/2011	MCA DVD, NRES
Mr Alan Caswell	29/03/2012 – 29/03/2012	Members Induction Training, NRES
Dr Geoff Dickens	01/01/2012 – 01/01/2012	St Andrews Healthcare annual mandatory training , St Andrews Healthcare
Dr Geoff Dickens	01/09/2011 – 01/09/2011	Presentation of research papers at conference
Mrs Yael Vinciguerra	29/03/2012 – 29/03/2012	Induction, HRA
Ms Elaine Blackshaw	30/11/2011 – 30/11/2011	Information Governance Training, QMC
Mr Clive Wilkinson	17/11/2011-17/11/2011	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:**

<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	61	100.00
<b>Total Applications Reviewed</b>	<b>61</b>	<b>100</b>

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

Number of applications made invalid by co-ordinator	1
Number of studies withdrawn prior to the meeting	4
Number of student applications reviewed	39
Number of paediatric applications reviewed	1
Number of device applications reviewed	0
Number of prisoner applications reviewed	1
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	5	8.20
Unfavourable Opinion	6	9.84
Provisional Opinion	50	81.97
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>61</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	40	65.57
Further Information Favourable Opinion with Additional Conditions	8	13.11
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	0	0.00
Favourable Opinion with Additional Conditions	5	8.20
Unfavourable Opinion	6	9.84
Provisional Opinion	2	3.28
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>61</b>	<b>100</b>

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

<b>Total Applications Reviewed</b>	<b>4</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	0	0.00
Favourable Opinion with Additional Conditions	2	50.00
No Opinion transfer to full committee for review	0	0.00
Provisional Opinion	1	25.00
Unfavourable Opinion	1	25.00
<b>Total</b>	<b>4</b>	<b>100</b>

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

<b>Average number of applications reviewed per full meeting</b>	5.55
<b>Number of applications for full ethical review over 60 days</b>	0
<b>Number of applications over 60 days as a % of total</b>	0.00%
<b>Number of days taken to final decision - average</b>	32
<b>Number of days taken to final decision - mode</b>	28
<b>Number of SSAs (non-Phase 1) reviewed</b>	4
<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>	98
<b>Number of substantial amendments over 35 days</b>	0
<b>Number of substantial amendments over 35 days as a % of total substantial amendments</b>	0.0%
<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>	1
<b>Number of modified amendments over 14 days as a % of total modified amendments</b>	50.0%
<b>Number of proportionate review applications for ethical review over 14 days*</b>	1
<b>Number of proportionate review applications over 14 days as a % of total</b>	25.00%

**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/EM/0112	Correlation between rise in Troponin I and degree of myocardial damage	43
11/EM/0113	Social deprivation and engagement with IAPT therapies	51
11/EM/0117	Continuous non-invasive CO monitoring during Anaesthesia.	43
11/EM/0118	Validating SRS and ORS for a clinical health population (V1)	38
11/EM/0122	Skill mix and staffing in A&E: perceptions of nurses and managers	47
11/EM/0123	The role of anger in offending behaviour version 1	34
11/EM/0127	Exercise in the Dialysis Unit : Opinions of Patients and Staff	34
11/EM/0208	Physical activity research study by Dr Wheeler	18
11/EM/0210	Interscalene nerve block needle positioning - Version 1	18
11/EM/0214	Investigating Music Induced Hearing Loss in an Adult Population.	36
11/EM/0215	Varicella virus epidemiology in Multiple Sclerosis	25
11/EM/0216	Relapse prevention in psychosis	25
11/EM/0224	Breath-holding (auto-CPAP) to optimize preoxygenation	26
11/EM/0232	Mechanisms underlying postoperative insulin resistance&inflammation v1	49
11/EM/0233	The Genetics of Salt Imbalance on Thiazide Diuretic Medication	32
11/EM/0241	Psychopathic individuals' experiences of therapeutic relationships	30
11/EM/0249	Ultrasound imaging of biomechanical properties of blood vessels.v1	31
11/EM/0250	Over the counter analgesia (pain relief) use prior to A&E attendance	35
11/EM/0279	(duplicate) Impact of pharmacist intervention on influenza vaccination	34
11/EM/0289	Antibodies to SOX in patients with cerebral tumours	30
11/EM/0292	Immunonutrition and QOL of cancer patients on neoadjuvant treatment.	34
11/EM/0296	Use and development of clinical judgement during nurse training VER 2	27
11/EM/0297	Effects of Superovulation on Oocyte Development and Embryo Quality	28
11/EM/0361	Exploratory study of patient need for ICU follow up care version 1	28
11/EM/0368	Follow-up Study of Successfully Discharged Cambian Patients	20
11/EM/0376	COgnitive therapy for Pain In the Chest (COPIC)	18
11/EM/0410	Prognostic value of MRI in asymptomatic AS	31
11/EM/0415	The role of peripheral and central vision in postural stability.	30
11/EM/0437	Emotional and Cognitive Outcomes of Walking during Chemotherapy	35
11/EM/0460	Does SPDU improve outcomes for hospitalized Parkinson's patients?	19
11/EM/0462	A Feasibility Study of Coronary OCT Correlation and Strain Mapping	23

12/EM/0021	Genetic testing in the diagnosis of Coeliac Disease	43
12/EM/0022	Users' views of the quality of emergency ambulance services	44
12/EM/0027	V1: A Phenomenological Study: Women's Experience of Birthplans	29
12/EM/0033	Women's Experiences of Vaginismus and its Treatment	38
12/EM/0067	Talking about hearing voices: a narrative analysis of experience	29
12/EM/0072	Exploring close relationships after traumatic brain injury. Version 1.	32
12/EM/0074	Exploring athlete experiences of eating disorders.	40
12/EM/0075	Secondary lung cancer screening in COPD patients	29
12/EM/0078	Parent and HCP use of language to describe acutely sick children	43
12/EM/0125	Understanding recovery- a delphi study with service users v1	23

#### Further Information Favourable Opinion with Additional Conditions

REC Reference	Application Short Title	Number of Days on Clock
11/EM/0121	A Study of Early Pregnancy Experiences	41
11/EM/0153	Exploring Young Peoples' School Experiences - Version 1	42
11/EM/0162	Evaluation of new hearing tests for speech understanding	31
11/EM/0301	Motor neurone disease and decisions about gastrostomy feeding (v 1.0)	28
11/EM/0304	Does the presence of violent fantasy impact on the judgement of risk?	21
11/EM/0306	Survey to Assess Current Occupational Lead Exposures	36
11/EM/0369	Cerebral Autoregulation in Parkinson's Disease	24
11/EM/0375	The accuracy of clinical tests for Morton's Neuroma, V.1 17th Aug 2011	21

#### 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
11/EM/0124	Monolithic Adsorbent Columns for Extracorporeal Medical Devices	34
11/EM/0149	Effects of Regular Exercise During Dialysis	28
11/EM/0252	TIA Training Needs	25
11/EM/0419	Body composition, nutrition & outcomes after neoadjuvant chemotherapy	24

11/EM/0476	The Y chromosome and Cardiovascular risk factors	57
12/EM/0124	Azzalure® drug utilisation study	11
12/EM/0126	Reliability of the Cervical Vertebrae Maturation (CVM) Method.	7

#### Unfavourable Opinion

REC Reference	Application Short Title	Number of Days on Clock
11/EM/0152	Parents' perceptions of support needs in the transition to parenthood	43
11/EM/0260	Does the Assertive Outreach approach improve quality of life?	24
11/EM/0411	Relationship between hydration and outcome in older patients	21
12/EM/0023	Survey of Psychiatric Inpatients' Experiences of Physical Examination	37
12/EM/0097	Impact of depth of anaesthesia on post operative pain	40
12/EM/0112	Low Back Pain and chiropractic awareness in opioid dependent clients	28
12/SC/0245	Dietary evaluation in kidney disease patients receiving dialysis	11

#### Provisional Opinion

REC Reference	Application Short Title	Number of Days on Clock
12/EM/0094	Body shame and disgust-sensitivity in adult dialysis patients (V1)	N/A
12/EM/0110	INVESTIGATION OF PSYCHOLOGICAL FACTORS AFFECTING INSULIN ADHERENCE 1	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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#### No Opinion Pending Consultation with Referee

REC Reference	Application Short Title	Number of Days on Clock
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<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>	
<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>	
12/EM/0125	Understanding recovery- a delphi study with service users v1	23	
<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>
<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>
10/H0402/63/AM01/1	CLAHRC LNR social science research programme	Substantial Amendment 1 Modified	17
<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>