

**NRES Committee East Midlands -  
Nottingham 1**

**Annual Report**

**01 April 2011 – 31 March 2012**

## Part 1 – Committee Membership and Training

<b>Name of REC:</b>	NRES Committee East Midlands - Nottingham 1
<b>Type of REC:</b>	Authorised
<b>Type of Flag:</b>	MCA/Paediatric
<b>Chair:</b>	Mr Robert Johnson
<b>Vice-Chair:</b>	Mr Keith Lackenby
<b>Alternate Vice-Chair:</b>	None
<b>Co-ordinator:</b>	Miss Andrea Graham
<b>PRSC Co-ordinator:</b>	Miss Andrea Graham
<b>Assistant Co-ordinator:</b>	Ms Wendy Rees
<b>Committee Address:</b>	The Old Chapel Royal Standard Place Nottingham NG1 6FS
<b>Telephone:</b>	0115 8839436
<b>Fax:</b>	0115 8839924
<b>Email:</b>	Andrea.Graham@nottspct.nhs.uk

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

As is the sign of the times, the last year has proven to be very busy for the committee especially with the added work of the proportionate committee. May I take this opportunity to thank committee members and administrative staff for all their support, enthusiasm and dedication. It is sadness that we say goodbye to Trish Wheat. We wish her well as she supports another committee. I obviously though would like to welcome Andrea Graham as the new administrator for Nottingham 1.

## NRES Committee East Midlands - Nottingham 1 Membership:

Name	Occupation	Expert or Lay	Dates	
			Appointed	Resigned
Dr Walter Bouman	Consultant Psychiatrist	Expert	01/10/2002	
Dr Glenys Caswell	Research Fellow	Expert	01/12/2010	
Professor Cris Constantinescu	Professor of Neurology	Expert	19/07/2008	
Ms Helen Crow	Research Midwife	Expert	01/10/2002	
Dr Ursula Holdsworth	Retired Staff Grade Community Paediatrician	Expert	01/10/2011	
Mr Robert Johnson	Research Coordinator - Professional registration maintained	Expert	01/04/2004	
Reverend Keith Lackenby	Lay member	Lay Plus	10/10/2006	
Mrs Sarah Lennon	Surgical Registrar GMC registration maintained	Expert	01/09/2011	
Mr Jon Merrills	Barrister / Pharmacist	Expert	06/08/2004	
Mr Robert Oldroyd	Lay member	Lay Plus	10/10/2006	
Dr Noble Philips	General Practitioner	Expert	15/10/2002	
Dr Ian Ross	Consultant Physician	Expert	01/10/2008	
Mr Ian Thompson	Lay member	Lay Plus	19/10/2006	
Mrs Shirley E White	Lay member	Lay Plus	10/10/2006	
Ms Fran Willis	Teacher	Lay Plus	01/12/2010	29/02/2012

### Deputy Members

Name	Occupation	Expert or Lay	Meeting date attended
None			

### Co-opted Members

Name	Occupation	Expert or Lay	Meeting date attended
Dr Frances Game (Nottingham2)	Consultant Physician	Expert	12/4/2011

### Member Bank

Name	Occupation	Expert or Lay	Meeting date attended
N/a			

### NRES Committee East Midlands - Nottingham 1: Members' Declarations of Interest:

Name	Declaration of Interest	Date
Dr Glenys Caswell	Researcher employed by University of Nottingham	29/02/2012
Mrs Sarah Lennon	Husband is lead consultant for research at Derby Royal Hospital - Emergency Dept.	13/12/2011
Professor Cris Constantinescu	Scientific/Medical Advisory Board, Teva Pharmaceuticals, Biography.CLRN Lead for Nervous System Disorders for Trent	13/12/2011
Mr Robert Johnson	None	10/01/2012
Dr Walter Bouman	None	10/01/2012
Dr Ian Ross	Shareholdings in Astrazeneca & Glaxosmithkline	13/11/2011
Mr Jon Merrills	Occasional consultancy with pharmacy firms own consultancy involving management of pharmacy companies.	13/12/2011
Mr Robert Oldroyd	None	13/12/2011
Mrs Shirley E White	None	10/01/2012
Ms Helen Crow	None	13/12/2011
Reverend Keith Lackenby	None	13/12/2011
Mr Ian Thompson	None	13/12/2011
Dr Ursula Holdsworth	None	13/12/2011
Dr Noble Philips	None	10/01/2012

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

Month	Date	Number of Members Present at Meeting
April	12/04/2011	9
May	10/05/2011	8
June	14/06/2011	9
August	09/08/2011	8
September	13/09/2011	8
October	11/10/2011	12
November	08/11/2011	12
December	13/12/2011	10
January	10/01/2012	13
February	14/02/2012	12
March	13/03/2012	10

11 full committee meetings were held during the reporting period.

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

<b>Month</b>	<b>Date</b>	<b>Number of Members Present at Meeting</b>
April	12/04/2011	3
June	14/06/2011	3
August	09/08/2011	3
September	13/09/2011	2
October	11/10/2011	3
November	08/11/2011	3
December	13/12/2011	3
January	10/01/2012	3
February	14/02/2012	3
March	13/03/2012	3

10 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>
Reverend Keith Lackenby	11
Professor Cris Constantinescu	9
Dr Glenys Caswell	9
Dr Noble Philips	9
Mr Ian Thompson	9
Mr Robert Oldroyd	8
Mrs Shirley E White	8
Mrs Sarah Lennon	7
Mr Jon Merrills	7
Mr Robert Johnson	7
Dr Ian Ross	6
Dr Ursula Holdsworth	6
Ms Fran Willis	5
Ms Helen Crow	5
Dr Walter Bouman	4

**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>
Reverend Keith Lackenby	10
Mrs Shirley E White	8
Mr Robert Johnson	5
Dr Ian Ross	2
Mr Ian Thompson	2
Mr Robert Oldroyd	1
Dr Frances Game (co-opted from Nottingham 2)	1

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

<b>Name of Member</b>	<b>Date</b>	<b>Event(s) attended</b>
Mr Robert Oldroyd	26/01/2012 - 26/01/2012	NRES Medical Devices Training, NRES
Reverend Keith Lackenby	07/09/2011 - 07/09/2011	NRES Training Day for New REC Chairs, NRES
Dr Walter Bouman	09/08/2011 - 09/08/2011	MCA, NRES
Ms Helen Crow	09/08/2011 - 09/08/2011	MCA, NRES
Dr Noble Philips	09/08/2011 - 09/08/2011	MCA, NRES
Reverend Keith Lackenby	09/08/2011 - 09/08/2011	MCA, NRES
Mrs Shirley E White	09/08/2011 - 09/08/2011	MCA, NRES
Professor Cris Constantinescu	09/08/2011 - 09/08/2011	MCA, NRES
Dr Glenys Caswell	09/08/2011 - 09/08/2011	MCA, NRES
Mr Ian Thompson	09/08/2011 - 09/08/2011	MCA, NRES
Mr Robert Johnson	01/06/2011 - 01/06/2011	East Midlands Training Day - Statistics, Personal Identifiable Data & MCA, East Midlands REC Centre
Mrs Shirley E White	01/06/2011 - 01/06/2011	East Midlands Training Day - Statistics, Personal Identifiable Data & MCA, East Midlands REC Centre
Mr Jon Merrills	01/06/2011 - 01/06/2011	East Midlands Training Day - Statistics, Personal Identifiable Data & MCA, East Midlands REC Centre
Mrs Sarah Lennon	29/03/2012 - 29/03/2012	Induction, NRES
Dr Ursula Holdsworth	28/03/2012 - 28/03/2012	NRES members National Training Day, NRES
Dr Ian Ross	28/03/2012 - 28/03/2012	NRES Members National Training Day, NRES
Mr Robert Oldroyd	14/03/2012 - 14/03/2012	NRES Members National Training Day, NRES
Dr Ursula Holdsworth	29/03/2012 - 29/03/2012	Induction, 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	56	100.00
<b>Total Applications Reviewed</b>	<b>56</b>	<b>100</b>

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

Number of applications made invalid by co-ordinator	2
Number of studies withdrawn prior to the meeting	5
Number of student applications reviewed	32
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	7
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	2	3.51
Favourable Opinion with Additional Conditions	21	36.84
Unfavourable Opinion	1	1.75
Provisional Opinion	32	56.14
Invalid	0	0.00
No Opinion Pending Consultation with Referee	0	0.00
Provisional Opinion Pending Consultation with Referee	1	1.75
Not Requiring Review by NHS REC	0	0.00
<b>Total</b>	<b>57</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	31	54.39
Further Information Favourable Opinion with Additional Conditions	1	1.75
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	2	3.51
Favourable Opinion with Additional Conditions	21	36.84
Unfavourable Opinion	1	1.75
Provisional Opinion	1	1.75
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>57</b>	<b>100</b>

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

<b>Total Applications Reviewed</b>	<b>37</b>
------------------------------------	-----------

**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	14	37.84
Favourable Opinion with Additional Conditions	13	35.14
No Opinion transfer to full committee for review	2	5.41
Provisional Opinion	8	21.62
Unfavourable Opinion	0	0.00
<b>Total</b>	<b>37</b>	<b>100</b>

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

<b>Average number of applications reviewed per full meeting</b>	5.09
<b>Number of applications for full ethical review over 60 days</b>	1
<b>Number of applications over 60 days as a % of total</b>	1.79%
<b>Number of days taken to final decision - average</b>	39
<b>Number of days taken to final decision - mode</b>	35
<b>Number of SSAs (non-Phase 1) reviewed</b>	0
<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%
<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>	78
<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>	3
<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>	11
<b>Number of proportionate review applications over 14 days as a % of total</b>	31.43%

**\*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/EM/0072	Knowledge Sharing for Safe Discharge	36
11/EM/0075	Management of falls in older adults within an Emergency Department(v1)	41
11/EM/0086	Ischaemic Heart Disease patient views - depression screening(QOF DEP1)	51
11/EM/0100	How and why women seek non-routine ultrasound in low risk pregnancy	35
11/EM/0103	Staying at Work: helping people with IA keep working: a pilot study	44
11/EM/0134	The role of acceptance & stressful life events on OCD in older adults.	51
11/EM/0201	Dyadic Art Therapy Delphi Group / Version 1	30
11/EM/0202	A study of staff attitudes and behaviour towards problem drinkers	21
11/EM/0204	Initial Validation of a New Physical Activity Questionnaire	26
11/EM/0205	Dental care of young people with serious mental illness	56
11/EM/0285	An evaluation project to explore training of faculty for high fidelity	15
11/EM/0324	A mixed methods study to explore the effects of a risk enablement tool	54
11/EM/0328	Assessment and Mechanism of the Refractory Period in Asthma	56
11/EM/0329	DIGEST 1: Gut Function and Endotoxin in CKD, V2	49
11/EM/0330	Prevalence of congenital uterine malformations in high-risk women	54
11/EM/0347	Vicorder Study Version 1	36
11/EM/0349	Does preop patient preparation improve length of stay in hospital	56
11/EM/0392	Regular Attenders in primary care- A case study approach.	46
11/EM/0397	Osseofix study	46
11/EM/0403	Experiences of Bilingual Parents of Children Receiving Speech Therapy	21
11/EM/0405	Validation of non-invasive cardiac output monitor	37
11/EM/0433	Evaluation of a therapy to enhance coping with pain in knee OA	41
11/EM/0442	ENCEPH UK - Prospective Cohort Study	50
12/EM/0009	Substance use disorder in Asperger Syndrome (version 1)	47
12/EM/0011	First time mothers' experience of caesarean section Version 1	58
12/EM/0013	Effects of gastric vs jejunal feeding in diabetic gastroparesis	45
12/EM/0034	Investigating barriers to physical activity in pregnancy	14
12/EM/0035	Tackling alcohol misuse in dental settings v3	14
12/EM/0042	Spread the message, not the germs	39
12/EM/0044	Arthritis Research UK Gout Treatment Trial - Phase 2	54

12/EM/0059	Small airway cell characterisation	54
12/EM/0060	Unmet needs for spasticity management in care home residents	29
12/EM/0086	Pseudophakic CMO assessment by OCT in diabetics version 1	15
12/EM/0087	Personal and family perspectives on CFS/ME	71
12/EM/0098	Steroid injection for Morton's neuroma with and without USS guidance	48
12/EM/0100	The E.G. Scan Study	39
12/EM/0109	Helius Extended Beta	41

#### Further Information Favourable Opinion with Additional Conditions

REC Reference	Application Short Title	Number of Days on Clock
11/EM/0119	Mindfulness Based Stress Reduction for Irritable Bowel Syndrome v.2.3	46
11/EM/0200	Evaluation of the use of patient experience in medical education	28

#### Further Information Unfavourable Opinion

REC Reference	Application Short Title	Number of Days on Clock
---------------	-------------------------	-------------------------

#### Favourable Opinion with Standard Conditions

REC Reference	Application Short Title	Number of Days on Clock
11/EM/0091	INVESTIGATING HOW MEDICAL PROFESSIONALS USE PROTOCOLS IN LEARNING	35
11/EM/0095	Developing a musculoskeletal Patient Reported Outcome Measure (PROM)	22
11/EM/0188	Evaluation of the Dysphagia Evaluation Screening Questionnaire (DESQ)	26
11/EM/0290	Cardiopulmonary exercise testing	15
11/EM/0291	The relationship between IgG, detected by DAT and eluate, on red cells	14
11/EM/0293	HIV Pre-exposure prophylaxis acceptability and risk compensation	6
11/EM/0336	HSV/VZV Encephalitis	13
11/EM/0338	Respiratory viral multiplex and flu resistance genotyping evaluation	6
11/EM/0357	Being a man	28
11/EM/0367	Smoking behaviour and experiences among the homeless	11
11/EM/0408	Medium term outcome post percutaneous coronary angioplasty at a DGH.	7
11/EM/0409	Analysis of norovirus and C. difficile co-carriage and co-infection	7
12/EM/0037	Aortic wall specimens	13
12/EM/0038	The role of ZEB-1 and ZEB-2 in EMT in Oral SCC Progression	7
12/EM/0117	Factors contributing to hospital admission.	13

12/EM/0118	Oxidative DNA Damage and Transcriptional Impairment in Brain Ageing	13
------------	---	----

<b>Favourable Opinion with Additional Conditions</b>		
<b>REC Reference</b>	<b>Application Short Title</b>	<b>Number of Days on Clock</b>
11/EM/0096	Fear of falling after fracture in adults.	27
11/EM/0102	Stroke prevention after transient ischaemic attack (TIA)	34
11/EM/0145	Asking the question: Exploring barriers and opportunities Version 1	35
11/EM/0147	Father's influence on their partner's choice regarding place of birth	33
11/EM/0148	Early vocabulary intervention in young children with ASD	27
11/EM/0192	VDR-ageing and vitamin D deficiency	33
11/EM/0199	Mechanical Engineering Characterisation of Grasper Injuries	19
11/EM/0209	Attitude towards and Knowledge of Breastfeeding	32
11/EM/0273	INTUITIVE	25
11/EM/0275	Prognostic Value of Upper Limb SSEPs in Hypoxic Brain Injury	22
11/EM/0281	MEDAL: MRI to Establish Diagnosis Against Laparoscopy	25
11/EM/0282	Assessing Fitness to Drive in People with Multiple Sclerosis(MS)	22
11/EM/0322	The use of Coercive Measures within Forensic Psychiatry (Version 1)	35
11/EM/0325	Views about the Mental Health Recovery Star	33
11/EM/0332	RAPPORT study: research with patient & public involvement	18
11/EM/0337	Diabetes, diabetes treatment and cancer V1	14
11/EM/0359	Optimising dialysate sodium to reduce inter-dialytic weight gain	24
11/EM/0364	Porosity and Permeability of the Human Vertebral Endplates (Version 1)	7
11/EM/0365	Health Literacy in Acute Medicine (HeLAM) Study Version 1	12
11/EM/0366	Sexual Self-Concept, Shame & Stigma after a Chlamydia Diagnosis	11
11/EM/0407	Allograft Information Exchange (ALLINEX): Phase three	11
11/EM/0432	Designing a community pharmacy-led intervention for 1st-year students	35
11/EM/0435	Fathers views on supporting their partner in labour-v1 ref:11/em/0435	35
11/EM/0443	Postgraduate MSc in Drug and Alcohol Treatment Thesis 2011	30
11/EM/0445	Ana and the web	37
11/EM/0467	Assessing Quality of Life in Patients with mCRC	6
11/EM/0468	Enteral tube feeding for Motor Neuron disease	5
12/EM/0016	Functional neuroimaging of cross-modal processing in the human brain	41
12/EM/0025	RESET2	33
12/EM/0052	Label-free screening for early detection of Alzheimer dementia	32

12/EM/0084	An evaluation of the reasons why service users choose to attend MIU	6
12/EM/0085	CT texture analysis and mismatch repair in Duke's B colorectal cancer	6
12/EM/0120	Experiences of Trauma injured patients - vs 1.4	13
12/EM/0121	Contacting parents of twins on a large scale: a pilot study	7

#### Unfavourable Opinion

REC Reference	Application Short Title	Number of Days on Clock
12/EM/0047	Personality, Offending Behaviour & Callous and Unemotional Traits.	34

#### Provisional Opinion

REC Reference	Application Short Title	Number of Days on Clock
11/EM/0340	Statistically Proving Shaken Baby Syndrome Study	N/A

#### Provisional Opinion Pending Consultation with Referee

REC Reference	Application Short Title	Number of Days on Clock
---------------	-------------------------	-------------------------

#### Further information response not complete

REC Reference	Application Short Title	Number of Days on Clock
---------------	-------------------------	-------------------------

#### Withdrawn after the meeting

REC Reference	Application Short Title	Number of Days on Clock
---------------	-------------------------	-------------------------

#### Invalid Application

REC Reference	Application Short Title	Number of Days on Clock
---------------	-------------------------	-------------------------

#### No Opinion Pending Consultation with Referee

REC Reference	Application Short Title	Number of Days on Clock
---------------	-------------------------	-------------------------

#### Not Requiring Review by NHS REC

REC Reference	Application Short Title	Number of Days on Clock
---------------	-------------------------	-------------------------

**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>
12/EM/0087	Personal and family perspectives on CFS/ME	71

<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/EM/0091	INVESTIGATING HOW MEDICAL PROFESSIONALS USE PROTOCOLS IN LEARNING	35
11/EM/0095	Developing a musculoskeletal Patient Reported Outcome Measure (PROM)	22
11/EM/0199	Mechanical Engineering Characterisation of Grasper Injuries	19
11/EM/0200	Evaluation of the use of patient experience in medical education	28
11/EM/0201	Dyadic Art Therapy Delphi Group / Version 1	30
11/EM/0202	A study of staff attitudes and behaviour towards problem drinkers	21
11/EM/0290	Cardiopulmonary exercise testing	15
11/EM/0285	An evaluation project to explore training of faculty for high fidelity	15
11/EM/0332	RAPPORT study: research with patient & public involvement	18
11/EM/0403	Experiences of Bilingual Parents of Children Receiving Speech Therapy	21
12/EM/0086	Pseudophakic CMO assessment by OCT in diabetics version 1	15

<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>			
---	--	--	--



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

**Section 30 application over 60 day timeline**

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