

**NRES Committee East Midlands -
Nottingham 1**

Annual Report

01 April 2013 – 31 March 2014

Part 1 – Committee Membership and Training

Name of REC:	NRES Committee East Midlands - Nottingham 1
Type of REC:	Authorised REC
Type of Flag:	Research involving adults lacking capacity Research involving Children
Chair:	Mr Robert Johnson
Vice-Chair:	Reverend Keith Lackenby
Alternate Vice-Char:	Dr Ian Ross
Co-ordinator:	Miss Rebecca Morledge/Miss Helen Wakefield
PRSC Co-ordinator:	Miss Rebecca Morledge /Miss Helen Wakefield
Assistant Co-ordinator:	Miss Rebecca Morledge/Miss Rachel Nelson
Committee Address:	The Old Chapel Royal Standard Place Nottingham NG1 6FS
Telephone:	0115 8839695
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Chair's overview of the past year:

The committee functions in a relaxed and friendly atmosphere and has continued to provide high quality ethical review. Members, all of whom are volunteers, give an outstanding level of commitment in processing Proportionate reviews and substantial amendments. We are grateful for the excellent support provided by the the staff of the REC centre.

Keith Lackenby – Vice-Chair

NRES Committee East Midlands - Nottingham 1 Membership:

Name	Occupation	Expert or Lay	Dates	
			Appointed	Resigned
Mr Robert Johnson	Lay member	Lay	01/04/2004	01/04/2014
Dr Glenys Caswell	Research Fellow	Expert	01/12/2010	
Professor Cris Constantinescu	Professor of Clinical Neurology	Expert	19/07/2008	
Dr Madeleine Craze	Research Technician	Expert	09/01/2013	Break in Service 03.02.14 – 30.01.2015
Dr Ursula Holdsworth	Retired Staff Grade Community Paediatrician	Expert	01/10/2011	
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 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	

Co-opted Members

Name	Occupation	Expert or Lay	Meeting date attended
Ms Margret Vince	Translator	Lay Plus	13/08/2013
Miss Catherine Shenton	Lay Member	Lay Plus	13/08/2013

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

Name	Declaration of Interest	Date
Mr Robert Johnson	None	01/12/2013
Mr Robert Oldroyd	Prostate Cancer UK Research Advisory Committee. NB: the committee funds research, it does not conduct it.	01/12/2013
Reverend Keith Lackenby	None	01/12/2013
Dr Glenys Caswell	Research fellow at University of Nottingham.	13/01/2014
Dr Ian Ross	Shareholdings at Astra Zeneca.	01/12/2013
Mr Ian Thompson	None	01/12/2013
Mr Jon Merrills	None	14/01/2014
Dr Madeleine Craze	None	14/01/2014
Mrs Sarah Lennon	None	12/01/2014
Mrs Shirley E White	None	01/12/2013
Dr Ursula Holdsworth	None	01/12/2013
Professor Cris Constantinescu	Advisory Board Member of Biogen/dec, GW, Teva, Morphosys, Merck-Serono (occasional).University of Nottingham MRI Management Committee.Past member of University of Nottingham School of Clinical Sciences Research Committee.Member of Research Council of Norway, Review Panel Committee.	01/12/2013

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

Month	Date	Number of Members Present at Meeting
May	14/05/2013	9
June	11/06/2013	10
July	09/07/2013	9
August	13/08/2013	8
September	10/09/2013	8
October	08/10/2013	10
November	12/11/2013	12
December	10/12/2013	8
January	14/01/2014	11
February	11/02/2014	10
March	11/03/2014	10

11 full committee meetings were held during the reporting period.

Proportionate Review Sub Committee Meetings held during 01 April 2013 - 31 March 2014:

Month	Date	Number of Members Present at Meeting
May	14/05/2013	3
June	11/06/2013	3
July	09/07/2013	3
August	13/08/2013	3
October	08/10/2013	3
November	12/11/2013	3
December	10/12/2013	3
January	14/01/2014	3
February	11/02/2014	3
March	11/03/2014	3

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

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

Name	Number of Meetings Attended
Reverend Keith Lackenby	11
Dr Ian Ross	10
Mr Jon Merrills	10
Mr Robert Johnson	10
Mr Robert Oldroyd	9
Mrs Sarah Lennon	9
Dr Ursula Holdsworth	9
Mr Ian Thompson	9
Professor Cris Constantinescu	8
Dr Glenys Caswell	7
Mrs Shirley E White – Attended 3 PR Meetings	6
Dr Madeleine Craze – Break in Service 03/02/14 – 30/01/15	5

Number of inquorate meetings held: 0

**Attendance of Members at proportionate review sub-committee meetings:
01 April 2013 – 31 March 2014:**

Name	Number of Meetings Attended
Mr Robert Johnson	8
Reverend Keith Lackenby	6
Mrs Shirley E White	3
Dr Ian Ross	3
Mr Jon Merrills	2
Mr Robert Oldroyd	2
Mrs Sarah Lennon	2
Dr Glenys Caswell	1
Dr Madeleine Craze	1
Dr Ursula Holdsworth	1
Mr Ian Thompson	1

Training 01 April 2013 – 31 March 2014:

Name of Member	Date	Event(s) attended
Dr Madeleine Craze	23/04/2013 - 23/04/2013	Induction, NRES
Dr Glenys Caswell	07/10/2013 - 07/10/2013	Nottingham REC Centre Local Training Event, HRA
Dr Glenys Caswell	07/10/2013 - 07/10/2013	Equality & Diversity, HRA
Dr Ian Ross	07/10/2013 - 07/10/2013	Nottingham REC Centre Local Training, HRA
Dr Ian Ross	07/10/2013 - 07/10/2013	Equality & Diversity, HRA
Mrs Sarah Lennon	07/10/2013 - 07/10/2013	Nottingham REC Centre Local Training Event, HRA
Mrs Sarah Lennon	07/10/2013 - 07/10/2013	Equality & Diversity, HRA
Mrs Shirley E White	07/10/2013 - 07/10/2013	Nottingham REC Centre Local Training Event, HRA
Mrs Shirley E White	07/10/2013 - 07/10/2013	Equality & Diversity, HRA
Dr Ursula Holdsworth	07/10/2013 - 07/10/2013	Nottingham REC Centre Local Training Event, HRA
Dr Ursula Holdsworth	07/10/2013 - 07/10/2013	Equality & Diversity, HRA
Reverend Keith Lackenby	07/10/2013 - 07/10/2013	Nottingham REC Centre Local Training Event, HRA HRA
Reverend Keith Lackenby	07/10/2013 - 07/10/2013	Equality & Diversity, HRA
Mr Ian Thompson	07/10/2013 - 07/10/2013	Nottingham REC Centre Local Training Event, HRA
Mr Ian Thompson	07/10/2013 - 07/10/2013	Equality & Diversity, HRA
Mrs Shirley E White	23/10/2013 - 23/10/2013	Patient Moving and Handling, Topaz Training Solutions
Mr Robert Johnson	23/10/2013 - 23/10/2013	Equality & Diversity, HRA
Reverend Keith Lackenby	08/11/2013 - 08/11/2013	NREAP/REC Chairs' Network Meeting, NRES
Mr Robert Johnson	08/11/2013 - 08/11/2013	NREAP/REC Chairs' Network Meeting, NRES
Professor Cris Constantinescu	30/04/2013 - 30/04/2013	Daniel Sokol book 'Doing Clinical Ethics', Self Directed Learning
Dr Glenys Caswell	25/03/2014 - 25/03/2014	Research Involving the Disadvantaged and Vulnerable: A Workshop for Researchers and Reviewers, HRA
Mr Robert Oldroyd	25/03/2014 - 25/03/2014	Research Involving the Disadvantaged and Vulnerable: A Workshop for Researchers and Reviewers, HRA

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	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	59	100.00
Total Applications Reviewed	59	100

Table 2: Other REC activity during the reporting period:

Number of applications made invalid by co-ordinator	6
Number of studies withdrawn prior to the meeting	6
Number of student applications reviewed	31
Number of paediatric applications reviewed	6
Number of device applications reviewed	0
Number of prisoner applications reviewed	0
Number of applications involving adults unable consent reviewed	8
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	2	3.39
Favourable Opinion with Additional Conditions	23	38.98
Unfavourable Opinion	7	11.86
Provisional Opinion	27	45.76
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	59	100
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:

Status of applications at date of generation of report	Number	%
Further Information Favourable Opinion with Standard Conditions	26	44.07
Further Information Favourable Opinion with Additional Conditions	0	0.00
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	2	3.39
Favourable Opinion with Additional Conditions	23	38.98
Unfavourable Opinion	7	11.86
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	1	1.69
Total	59	100

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

Total Applications Reviewed	27
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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	11	40.74
Favourable Opinion with Additional Conditions	10	37.04
No Opinion transfer to full committee for review	1	3.70
Provisional Opinion	5	18.52
Unfavourable Opinion	0	0.00
Total	27	100

Table 7: Other Management Information for the reporting period:

Average number of applications reviewed per full meeting	5.36
Number of applications for full ethical review over 60 days	0
Number of applications over 60 days as a % of total	0.00%
Number of days taken to final decision - average	31
Number of days taken to final decision - mode	34
Number of SSAs (non-Phase 1) reviewed	3
Number of applications for SSA review over 25 days	0
Number of applications for SSA review over 25 days as % of all non-Phase 1 (SSAs)	0.0%
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	78
Number of substantial amendments over 35 days	0
Number of substantial amendments over 35 days as a % of total substantial amendments	0.0%
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	4
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	3.8%

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
13/EM/0161	Balance and the Mind Programme Development Grant	35
13/EM/0197	Primary Care Outcomes	15
13/EM/0201	AlleRiC Focus	13
13/EM/0214	Pre-operative Nutrition In Neck of femur Trial (POINT)	23
13/EM/0221	Staff and patient perceptions of prevention of inpatient aggression	25
13/EM/0249	Evaluating Simulation Skills Transfer to Emergency Asthma Management	9
13/EM/0277	Intercycle variability study v1.0	46
13/EM/0290	Acute Exercise & Appetite Regulation in Lean vs. Obese: INTAKE	51
13/EM/0295	Smoking in a CAMHS setting - A qualitative exploration.	34
13/EM/0335	Evaluation of blood brain barrier in MPS IIIB patients	49
13/EM/0341	Interrogative Suggestibility and Change Blindness	39
13/EM/0342	Sweet taste receptor expression and function in the uterus Version 1.0	56
13/EM/0343	Complete v culprit-only revascularisation in PPCI for STEMI -COMPLETE	34
13/EM/0368	Alcohol use in Service Users with Intellectual Disability	49
13/EM/0372	A study of interventions in challenging behaviour	43
13/EM/0378	Inspiring Hope and Self Belief in Early Psychosis: A Pilot Study	34
13/EM/0390	The Epidemiology of foot complaints in systemic lupus erythematosus	11
13/EM/0405	An Evaluation of the Suicide/Self-Harm Formulation	39
13/EM/0413	SSWLI	48
13/EM/0415	EPOCH Trial	30
13/EM/0416	LADA	28
13/EM/0418	Examining the use of Discovery Awareness in UK ID services: version 1	29
14/EM/0003	Smart Inhalers for Asthmatic Adolescents Final Version 1.0	50
14/EM/0004	The Planning Your Future Care Study	27
14/EM/0012	A feasibility RCT of ACT for Spinal Cord Stimulation Surgery Patients	33
14/EM/0056	Epidemiology, management, outcomes and pathophysiology of SCAD	33
14/EM/0057	Physical activity in children with Type 1 diabetes study v1.0 13.01.14	42
14/EM/0061	Parkinson MR Imaging Repository: Part 1 - Multicentre MRI study in PD	34
14/EM/0079	'Black ethnic minority' men and Primary mental health engagement 2	8

14/EM/0083	Leg oedema In Multiple Sclerosis (LIMS) Version 1.0	31
14/EM/0112	Inspiratory muscle training for advanced cancer patients 1	29

Further Information Favourable Opinion with Additional Conditions

REC Reference	Application Short Title	Number of Days on Clock
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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
13/EM/0198	Impact of the Patient Participation Direct Enhanced Service on PPGs v2	12
13/EM/0199	ECHoES Trial	11
13/EM/0286	Qualitative study of a shared care clozapine service Version 1	8
13/EM/0327	Tissue collection framework to improve outcomes in solid tumours	8
13/EM/0388	OSTEOARTHRITIS RESEARCH ON PATIENTS' JOINT TISSUES, BLOOD AND URINE	8
13/EM/0432	Gynae cancer awareness	20
13/EM/0433	Predictive model for av-fistula maturation using ultrasound (V1)	9
13/EM/0472	The Nudge Project	9
14/EM/0040	Metabolomics to characterize diet (The MAIN Study)	8
14/EM/0041	CellSpex	8
14/EM/0081	Long term evaluation of the management of prostate cancer patients.	11
14/EM/0099	Home Administered Pre-surgical Psychological Intervention for Knee OA	30
14/EM/0122	Seeking help for OCD: a study comparing three videos (Version 1)	10

Favourable Opinion with Additional Conditions

REC Reference	Application Short Title	Number of Days on Clock
13/EM/0160	Diagnostic potential of low frequency cardiac & skeletal muscle sound	17
13/EM/0166	An enhanced educational intervention for patients with MRSA	17
13/EM/0168	Short-Term Psychodynamic Psychotherapy: The Evaluation of Ego Capacity	29
13/EM/0218	Investigating the function of the immune system during cancer v1	34
13/EM/0222	Myosteatosis and muscle wasting in pancreatic cancer	35

13/EM/0240	Early markers of heart and kidney damage in Fabry disease	8
13/EM/0255	CLOTHES Trial – Clothing for the relief of Eczema Symptoms	21
13/EM/0258	Development of the SPCR Patient Safety Toolkit for general practices.	20
13/EM/0269	COMBI1	32
13/EM/0288	A study of taste changes during weight loss - v1.0	6
13/EM/0293	ExPreS - Experiences of Pregnancy Version 1	28
13/EM/0310	Campylobacter Enteritis and PI-BD: Role of Antibiotics and Microbiota	34
13/EM/0319	Attention Bias and Adolescents with Intellectual Disabilities v1	30
13/EM/0330	ME-PCI Study v1	13
13/EM/0331	PA for the management of fatigue in RA (FRAPA) Version 1	12
13/EM/0336	Efficacy of a tracer device to measure colon chemistry	28
13/EM/0362	Pilot randomised, controlled trial of hysteroscopic septal resection	46
13/EM/0387	Examining characteristics of the effective practitioner.	6
13/EM/0427	MiQuit trial: tailored text messages for pregnant smokers v1	20
13/EM/0430	The 100 Prescriptions study	20
13/EM/0436	Evaluation of the SOLUS Anterior Lumbar Interbody Fusion System (ALIF)	20
13/EM/0437	Response to neoadjuvant therapy in patients with oesophageal cancer	7
13/EM/0470	Better arthritis care; assessing need for education in the community	7
13/EM/0471	Cognitive function & Outcomes in Pulmonary Rehabilitation	9
14/EM/0013	Nottingham Osteoarthritis Biomarker Follow Up Study	24
14/EM/0020	PREM development - questionnaire item production	24
14/EM/0045	Osteoarthritis Risk in Professional Footballers	24
14/EM/0048	BIOPEX Version 2	24
14/EM/0092	Clinical correlates and outcomes of treatment for trans people (v1)	30
14/EM/0097	Parental experiences of taking a child home on long term ventilation	45
14/EM/0109	The function of aggression in forensic psychiatric patients	24
14/EM/0125	Prognostic Indicators for ASAD Outcome	10
14/EM/0126	Women and their partners' experiences of PPH. Version 1	9

Unfavourable Opinion

REC Reference	Application Short Title	Number of Days on Clock
13/EM/0170	Long-stay patients in high and medium secure forensic-psychiatric care	31
13/EM/0231	Hypertension in Dementia - Feasibility Study	27

13/EM/0256	Staff and patients perceptions of situational risk factors	21
13/EM/0301	Malnutrition in care homes: Food or Oral nutritional supplements? V1.0	30
13/EM/0347	Commissioning IAPT: equity of access	34
13/EM/0412	BIOPEX Version 1	23
14/EM/0014	Imaging Pain Relief in Osteoarthritis version 1.0	24

Provisional Opinion

REC Reference	Application Short Title	Number of Days on Clock
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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
13/EM/0171	Perinatal Research - Unwanted thoughts	28

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	
Proportionate review applications for ethical review over 14 days timeline			
REC Reference	Application Short Title	Number of Days on Clock	
13/EM/0197	Primary Care Outcomes	15	
SSAs (non Phase 1) over 25 days timeline			
REC Reference	Application Short Title	Number of Days on Clock	
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
Modified Amendments over 14 day timeline			
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